

**State of Board of Health
Agenda
June 23, 2022 – 8:30 a.m.
Perimeter Center, Boardroom 2**

Call to Order and Welcome	Maribel Ramos Nominating Committee Chair
Nomination of Officers	Nominating Committee Members
Adjourn	

**State of Board of Health
Agenda
June 23, 2022 – 9:00 a.m.
Perimeter Center, Boardroom 2**

Call to Order and Welcome	Faye Prichard, Chair
Introductions	Ms. Prichard
Review of Agenda	Alexandra Jansson, MPP
Approval of March 31, 2022 Minutes	Ms. Prichard
Commissioner's Report	Colin Greene, MD, MPH State Health Commissioner
Regulatory Action Update	Michael Capps, MPH Legislative and Regulatory Coordinator
Break	
Public Comment Period	
<u>Lunch Presentation</u> Public Health History in Virginia	Jeff Stover Chief of Staff Virginia Department of Health
Budget Update	Stephanie Gilliam Deputy Director for Budget Office of Financial Management
<u>Regulatory Action Items</u> Rainwater Harvesting Regulations 12VAC5-635 (Proposed Amendments)	Julie Henderson Director Office of Environmental Health Services

Food Regulations
12VAC5-421
(Fast Track Amendments)

Ms. Henderson

Break

Regulations for the Licensure of Hospitals
12VAC5-410
(Fast Track Amendments)

Rebekah Allen, JD
Senior Policy Analyst
Office of Licensure and Certification

Virginia Medical Care Facilities Certificate
of Public Need Rules and Regulations
12VAC5-220
(Fast Track Amendments)

Ms. Allen

Regulations for the Licensure of Nursing Facilities
12VAC5-371
(Fast Track Amendments)

Ms. Allen

Public Participation Guidelines
12VAC5-11
(Fast Track Amendments)

Mr. Capps

Non-Regulatory Action Item
Regional EMS Council Designation

Gary R. Brown
Director
Office of Emergency Medical Services

Report from Nominating Committee

Ms. Ramos

Other Business

Adjourn

**State Board of Health
March 31, 2022 - 9:00am
Perimeter Center, Boardroom 2, 9960 Mayland Drive, Henrico VA 23233**

Members Present: Faye Prichard, Chair; Jim Edmondson; Melissa Green; Anna Jeng; Gary Critzer; Stacey Swartz; Wendy Klein, MD, Vice Chair; Benita Miller, DDS; Holly Puritz, MD; Maribel Ramos; Elizabeth Harrison; and Mary Margaret Whipple.

Members Absent: Jim Shuler, Linda Hines, and Patricia Kinser, PhD.

VDH Staff Present: Kathryn Crosby, Chief Diversity, Equity, and Inclusion Officer; Tiffany Ford, Deputy Commissioner for Administration; Bob Hicks, Deputy Commissioner for Public Health and Preparedness; Joe Hilbert, Deputy Commissioner for Governmental and Regulatory Affairs; Alexandra Jansson, Senior Policy Analyst; Dr. Colin Greene, Acting State Health Commissioner; Dr. Lilian Peake, State Epidemiologist; Maria Reppas, Director, Office of Communications.

Other Staff Present: Robin Kurz, JD, Senior Assistant Attorney General; Vanessa MacLeod, JD, Office of the Attorney General.

Call to Order

Ms. Prichard called the meeting to order at 9:02am.

Introductions

Ms. Prichard welcomed those in attendance to the meeting. Ms. Prichard then started the introductions of the Board members and VDH staff present.

Review of Agenda

Ms. Jansson reviewed the agenda and the items contained in the Board's binder.

Approval of December 10, 2021 Minutes

Dr. Swartz made the motion to approve the minutes from the December 10, 2021 meeting with Dr. Klein seconding the motion. The minutes were approved unanimously by voice vote.

Commissioner's Report

Dr. Greene provided the Commissioner's Report to the Board. He updated the Board on key issues and projects VDH is engaged in including:

- VDH Strategic Objectives
- COVID-19 Update
- Sexually Transmitted Infections
- Comprehensive Harm Reduction
 - There was a discussion about the safety of naloxone.
- Social Determinants of Health
 - There was discussion of multiple projects and surveys from the Office of Family Health Services that collect information on SDOH

- Projects Funded by American Rescue Plan Act (ARPA)
 - There was brief discussion about what projects were being considered for broadband and oral health.

There was additional discussion about several topics in the presentation. Around sexually transmitted infections, discussion included diagnosis and treatment of syphilis by community providers outside of the Health Department, insurance coverage for treatment of syphilis and increased funding for free clinics to increase availability of treatment. There was also a brief discussion about the younger ages of new cases and if cases were required to be reported to the health department. For COVID-19 updates and transition to an endemic state, discussion included the value of multiple sources of information in creating guidelines and how best to use the lessons learned to advocate for resources for public health. There was also discussion about pediatric vaccination efforts and natural immunity.

Regulatory Action Update

Ms. Jansson reviewed the summary of all pending VDH regulatory actions.

Since the December 2021 meeting, the Commissioner had taken one regulatory action on behalf of the Board while the Board was not in session - approved NOIRA for Regulations for the Immunization of School Children. This regulatory action conformed the regulations to statutory changes (Chapter 1223) enacted by the 2020 General Assembly. This action will add certain vaccines to the list of minimum immunization requirements for entry into school and day care.

Since the December 2021 meeting the Commissioner has taken one non-regulatory action on behalf of the Board while the Board was not in session - Public Health Order of Public Health Emergency One - Masks in K-12 Schools. This was issued on January 15, 2022, in conjunction with Governor Youngkin's Executive Order 2, which ordered the State Health Commissioner to terminate Order of Public Health Emergency Ten (2021). EO 2 also allowed parents to elect for their children not to be subject to any mask mandate in effect at the child's school or educational program.

Ms. Jansson advised the Board that there are 19 periodic reviews in progress:

- 12 VAC 5-20 Regulations for the Conduct of Human Research
- 12 VAC 5-66 Regulations Governing Durable Do Not Resuscitate Orders
- 12 VAC 5-195 Virginia Women Infants and Children Program Regulations
- 12 VAC 5-200 Regulations Governing Eligibility Standards and Charges for Health Care Services to Individuals
- 12 VAC 5-215 Rules and Regulations Governing Health Data Reporting
- 12 VAC 5-216 Methodology to Measure Efficiency and Productivity of Health Care Institutions
- 12 VAC 5-217 Regulations of the Patient Level Data System
- 12 VAC 5-218 Rules and Regulations Governing Outpatient Data Reporting
- 12 VAC 5-220 Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations

- 12 VAC 5-407 Regulations for the Submission of Health Maintenance Organization Quality of Care Performance Information
- 12 VAC 5-408 Regulation for the Certificate of Quality Assurance of Managed Care Health Insurance Plan (MCHIP) Licensees
- 12 VAC 5-410 Regulations for the Licensure of Hospitals in Virginia
- 12 VAC 5-431 Sanitary Regulations for Hotels
- 12 VAC 5-460 Regulations Governing Tourist Establishment Swimming Pools and Other Public Pools
- 12 VAC 5-462 Swimming Pool Regulations Governing the Posting of Water Quality Results
- 12 VAC 5-501 Rules and Regulations Governing the Construction of Migrant Labor Camps
- 12 VAC 5-508 Regulations Governing the Virginia Physician Loan Repayment Program
- 12 VAC 5-510 Guidelines for General Assembly Nursing Scholarships
- 12 VAC 5-540 Rules and Regulations for the Identification of Medically Underserved Areas in Virginia

Public Comment Period

There were five persons who signed up for public comment. Rachel Becker spoke in support of the regulations that were on the agenda. Nancy DiFranco provided comment on her opposition to including COVID-19 in any vaccine requirements for school children. Doris Knick provided comment regarding radio frequency radiation; see additional comments at the end of the minutes document. Jennifer Gruber provided comment related to public access to meetings and the level of detail in the minutes documents, specifically related to the reporting of December's regulatory action update. Anne Taydus provided comment regarding her opposition the HPV vaccine mandate and concerns about the vaccine's safety.

Fast Track Amendments for the Licensure of Hospices Regulations

Ms. Allen presented fast track amendments to the Regulations for Licensure of Hospices. Chapter 525 of the 2021 Acts of Assembly, Special Session I amended Code of Virginia 32.1-162.5, requiring the State Board of Health to promulgate regulations that "require each hospice facility to establish a protocol to allow patients to receive visits from a rabbi, priest, minister, or clergy of any religious denomination or sect consistent with guidance from the Centers for Disease Control and Prevention and the Centers for Medicare and Medicaid Services and subject to compliance with any executive order, order of public health, Department guidance, or any other applicable federal and state guidance having the effect of limiting visitation" when there is "a declared public health emergency related to a communicable disease of public health threat."

Mr. Critzer made the motion to adopt the fast track amendments and Dr. Klein seconded the motion. There was discussion about examples of access issues in hospices. The amendments were approved unanimously by voice vote.

Fast Track Amendments to the Licensure of Hospitals in Virginia Regulations

Ms. Allen presented fast track amendments to the Regulations for Licensure of Hospitals in Virginia. These amendments are due to the changes to Code of Virginia § 32.1-127 to conform to Chapters 219, 233, and 525 of the 2021 Acts of Assembly, Special Session I. The Board is

required by Code of Virginia § 32.1-127 to promulgate regulations for the licensure of hospitals in order to protect the health, safety, and welfare of citizens receiving care in hospitals.

Chapter 219 requires “each hospital...to establish and implement policies to ensure the permissible access to and use of an intelligent personal assistant provided by a patient, in accordance with such regulations, while receiving inpatient services.” Chapter 233 requires “each hospital with an emergency department to establish a protocol for the treatment and discharge of individuals experiencing a substance use-related emergency.” Chapter 525 requires “each hospital...to establish a protocol to allow patients to receive visits from a rabbi, priest, minister, or clergy of any religious denomination or sect consistent with guidance from the Centers for Disease Control and Prevention and the Centers for Medicare and Medicaid Services and subject to compliance with any executive order, order of public health, Department guidance, or any other applicable federal or state guidance having the effect of limiting visitation” when there is “a declared public health emergency related to a communicable disease of public health threat.”

Dr. Swartz made the motion to adopt the fast track amendments and Ms. Whipple seconded the motion. There was discussion around the use of phones in hospitals. The fast track amendments were approved unanimously by voice vote.

Legislative Update - 2022 General Assembly

Ms. Jansson presented the legislative update from the 2020 General Assembly Session. She highlighted bills that would have an impact on VDH’s work. Subject areas included the following:

- Health Workforce
- Medical Care Facilities Regulation
- Environmental Health
- Data Reporting
- Other
- Freedom of Information Act (FOIA)/Public Meetings

There was discussion around the process for establishing maximum contaminant levels, the potential motivation behind several bills, if there was any current reporting from emergency departments to VDH to build upon for increased data reporting requirements, and the impact of FOIA changes on meetings and requests.

Budget Update- 2022 General Assembly

Ms. Gilliam presented an update on the status of the budget from the 2022 General Assembly Session. She described the Governor’s introduced budget and amendments from the House and Senate related to VDH programs. She noted that there will be a Special Session upcoming to complete the budget work, and additional details will be provided.

There was discussion around what projects may be included in expansion of disease interventions, details about health equity funding, how laboratory funding is allocated through federal grants to the Division of Consolidated Laboratory Services and increases for funds

related to nurse education and the trauma fund. Ms. Gilliam noted that full details are not available since the budget had not passed by the adjournment sine die of the regular Session.

There was a request to have Ms. Gilliam provide an update at the June meeting.

Appointment of Nominating Committee

Ms. Prichard proposed the following persons to be on the nominating committee: Ms. Ramos as Chair, and Dr. Swartz and Mr. Edmondson as members. Dr. Klein made the motion and Ms. Whipple seconded. The motion was approved by unanimous voice vote.

Other Business

Members also discussed the role and availability of monoclonal antibody treatments. Dr. Greene noted that the treatments are largely available, though not being used in high numbers. If the treatments became scarce, VDH would have a role in helping to determine areas of need for distribution. Dr. Swartz noted that low reimbursement is a barrier for pharmacies to provide antivirals. Ms. Green shared that nursing homes are providing these treatments to their patients. Ms. Ramos asked if there was a plan for funding coverage for uninsured Virginians with the Health Resources and Services Administration funding ending.

Adjourn

Mr. Critzer motioned to adjourn the meeting. Mr. Edmondson seconded the motion. The motion passed by unanimous voice vote. The meeting adjourned at 1:07pm.

Speak at VDH BOH meeting tomorrow

Doris Knick <healersporch@yahoo.com>

Wed, Mar 30, 2022 at 4:58 PM

Reply-To: Doris Knick <healersporch@yahoo.com>

To: "Jansson, Alexandra" <alexandra.jansson@vdh.virginia.gov>

Ms. Jansson,

I would like this document attached added to the public record for tomorrow. I plan on speaking in regard to the 11,000 pages of evidence.

Is it possible for you to print the 27 volumes of evidence from the link below?

[11,000 Pages of Evidence Filed in Landmark 5G Case Against the FCC, Hearing Set for Jan. 25 • Children's Health Defense \(childrenshealthdefense.org\)](https://www.childrenshealthdefense.org/)

Sincerely,

Doris Knick

Your Advocate for Wellness,

"May your path to healing be natural, safe, pure and JOYfilled."

[Quoted text hidden]

**Aug 13 CHD_EHT vs FCC Case & Evidence (1).pdf**

80K

On Aug 13, 2021, the US Courts of Appeals, DC Circuit ruled in Case 20-1025, Environmental Health Trust, et al. v FCC — a lawsuit that challenged the legality of the FCC’s attempted de facto rule-making, a sneaky maneuver that tried to extend its current RF microwave radiation exposure guidelines to frequencies above 6,000 MHz, without any reasoned decision-making. **The judges caught the FCC and remanded FCC Order 19-126 back to the FCC, invalidating the Order.**

The DC Circuit judges ruled the following in Case 20-1025:

“ . . . we grant the petitions in part and remand to the Commission to provide a reasoned explanation for its determination that its guidelines adequately protect against harmful effects of exposure to radio-frequency [microwave] radiation. It must, in particular,

- *(i) provide a reasoned explanation for its decision to retain its testing procedures for determining whether cell phones and **other portable electronic devices comply with its guidelines,***
- *(ii) **address the impacts of RF radiation on children, the health implications of long-term exposure to RF radiation, the ubiquity of wireless devices, and other technological developments that have occurred since the Commission last updated its guidelines, and***
- *(iii) address the impacts of RF radiation on the environment.”*

Wireless radio frequency microwave radiation is bioactive and is currently being insufficiently regulated. Therefore, each state or locality can regulate the maximum power output of microwave radiation from wireless infrastructure antennas that reaches any areas that are accessible to human beings and other living organisms, consistent with the **11,000+ pages of peer-reviewed, scientific evidence** that Environmental Health Trust and Children’s Health Defense and others plaintiffs placed in the FCC’s public record: **Link to all 27 volumes of evidence can be found here:**
<https://childrenshealthdefense.org/defender/landmark-5g-case-against-fcc-hearing-set-jan-25/>



COMMONWEALTH of VIRGINIA

Department of Health
P O BOX 2448
RICHMOND, VA 23218

Colin M. Greene, MD, MPH
State Health Commissioner

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

MEMORANDUM

DATE: May 6, 2022

TO: Virginia State Board of Health

FROM: Julie Henderson, Director, Office of Environmental Health Services

SUBJECT: Draft Rainwater Harvesting Regulations, 12VAC5-635

The Rainwater Harvesting System Regulations (Regulations) are new regulations to promote the use of rainwater as means to reduce fresh water consumption, ease demands on public treatment works and water supply systems, and promote conservation. Chapter 817 of the 2018 Reconvened Session Virginia Acts of Assembly (House Bill 192) amended § 32.1-248.2 of the Code of Virginia (Code) to require the Board of Health (Board) to adopt regulations regarding the use of rainwater. Regulations regarding use of rainwater are required to (i) describe the conditions under which rainwater may appropriately be used and for what purposes; and (ii) provide standards for the use of rainwater harvesting systems, including systems that collect rainwater for use by commercial enterprises but do not provide water for human consumption, as defined in §32.1-167.

Water used for human consumption in Virginia is currently provided from permitted waterworks and from private wells; both programs are regulated by the Virginia Department of Health (VDH). However, a demand for another source of water supply exists where public source and groundwater availability is limited. For example, groundwater limitations may occur as (i) a result of natural scarcity or contamination, or (ii) in coastal areas under threat of inundation or salt water intrusion. In addition, rainwater harvesting is an emerging technology with early adopters having interest in natural resource protection. The Uniform Statewide Building Code relies upon VDH to provide water quality standards, including treatment standards for non-potable applications. The proposed Regulations will allow VDH to provide certification to building officials that rainwater harvesting systems applicable to both potable and non-potable use are protective of public health.

Upon approval by the Board, the proposed draft regulations will be submitted for executive branch review and, upon approval by the Governor, will be published in the Virginia Register of Regulations with provision for a 60-day public comment period.



townhall.virginia.gov

Proposed Regulation Agency Background Document

Agency name	Virginia Department of Health (VDH)
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-635
VAC Chapter title(s)	Rainwater Harvesting System Regulations
Action title	Rainwater Harvesting Regulations
Date this document prepared	May 2, 2022

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

Brief Summary

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

The Rainwater Harvesting System Regulations (Regulations) are new regulations to provide standards for the use of rainwater harvesting systems, including systems that collect rainwater for human consumption. The Regulations will promote the use of rainwater as means to reduce fresh water consumption, ease demands on public treatment works and water supply systems, and promote conservation.

The Regulations establish the relationship with the statutes and regulations applicable to other agencies, and seeks to avoid duplication of regulatory oversight for both non-potable uses of harvested rainwater and potable use for users below the threshold qualifying as a waterworks. The Regulations also establish administrative processes for permitting, inspecting, and issuing construction and operation permits for intended potable rainwater harvesting systems, along with appropriate exemptions from the regulations (e.g. rain barrels are exempt).

In order to ensure systems installed pursuant to the Regulations are protective of human health, and that the Regulations are not unduly burdensome, rainwater harvesting systems are divided into four end-tier uses. The

highest end-tier use – potable water – requires the greatest level of treatment and oversight. The specified end-use will determine the minimum design, construction, and ongoing operation and maintenance standards for each system. VDH will require permits to construct and operate a rainwater harvesting system for potable use. Non-potable systems will be documented in a registry but will not be subject to permitting by VDH.

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the “Definitions” section of the regulation.

ARCSA	American Rainwater Catchment Systems Association
DHCD	Department of Housing and Community Development
DPOR	Department of Professional and Occupational Regulation
EPA	United States Environmental Protection Agency
GMP	Guidance Memorandum and Policies
ICC	International Codes Council
VDH	Virginia Department of Health
USBC	Virginia Uniform Statewide Building Code

Mandate and Impetus

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

Chapter 817 of the 2018 Reconvened Session Virginia Acts of Assembly (House Bill 192) amended § 32.1-248.2 of the Code of Virginia (Code) to require the Board of Health (Board) to adopt regulations regarding the use of gray water and rainwater. VDH intends to address regulation of gray water in pending revision of the Sewage Handling and Disposal Regulations (12VAC5-610). Regulations regarding use of rainwater are required to (i) describe the conditions under which rainwater may appropriately be used and for what purposes; and (ii) provide standards for the use of rainwater harvesting systems, including systems that collect rainwater for use by commercial enterprises but do not provide water for human consumption, as defined in §32.1-167. House Bill 192 further instructs the Department to promote the use of rainwater as means to reduce fresh water consumption, ease demands on public treatment works and water supply systems, and promote conservation; and to consider recognizing rainwater as an independent source of fresh water available for use by the residents of the Commonwealth.

Legal Basis

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

Section 32.1-12 of the Code permits the Board to make, adopt, promulgate, and provide for reasonable variances and exemptions therefrom as may be necessary to carry out the provisions of §32.1 of the Code. Section 32.1-248.2 of the Code requires the Board to adopt regulations regarding the use of rainwater and rainwater harvesting systems, including the conditions under which rainwater may be appropriately used and for what purpose.

Purpose

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

Rainwater has been harvested and used for centuries in the Commonwealth in the absence of guidance or regulation addressing the protection of human health. In recent years, the harvesting and use of rainwater for non-potable purposes has occurred under VDH's March 31, 2011, Virginia Rainwater Harvesting & Use Guidelines (GMP-2011-01), and in accordance with the requirements of the Uniform Statewide Building Code (USBC), and the International Plumbing Code. VDH's current Rainwater Harvesting & Use Guidelines recommend against the use of harvest rainwater for potable use given the lack of a robust regulatory program to ensure the safety of harvested rainwater for potable use. The goal of this proposed Regulations is to provide a mechanism for VDH to approve rainwater harvesting systems as protective of public health.

Over the past decade, rainwater harvesting systems have become more common across North America. Officials responsible for inspecting these systems have voiced their need for more detailed design parameters to ensure safe implementation of these systems to protect public health. New information and research has improved understanding of risk to public health associated with rainwater harvesting, which is addressed in the proposed Regulations. Examples of recent advancements in considerations for public health impacts include the development of standards for use of harvested rainwater developed by the American Rainwater Catchment Systems Association (ARCSA) and the International Code Council (ICC).

Water used for human consumption in Virginia is currently provided from permitted waterworks and from private wells; both programs are regulated by VDH. However, a demand for another source of water supply exists where public source and groundwater availability is limited. For example, groundwater limitations may occur as (i) a result of natural scarcity or contamination, or (ii) in coastal areas under threat of inundation or salt water intrusion. In addition, rainwater harvesting is an emerging technology with early adopters having interest in natural resource protection. The USBC relies upon VDH to provide water quality standards, including treatment standards for non-potable applications. The Regulations will allow VDH to provide certification to building officials that rainwater harvesting systems applicable to both potable and non-potable use are protective of public health.

Substance

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

The following substantive provisions are being considered for inclusion in the Regulations:

- Definitions as necessary for consistency with the Code of Virginia, other regulations and code documents related to rainwater harvesting and water reuse, storm water, the USBC, and current industry standards;
- Reference to administrative processes to reflect current law and to provide consistency with other VDH regulations;
- Identification of reasonable exemptions from the Regulations (e.g., rain barrels, waterworks);
- Criteria to acknowledge nationally recognized standards and certifications – including but not limited to, the American Society of Plumbing Engineers, National Sanitation Foundation, ARCSA, ICC, and American Society of Sanitary Engineering – for approval of rainwater harvesting components and certification of persons involved in the design, installation, inspection, repair, and maintenance of rainwater harvesting systems;
- Standards for rainwater harvesting performance objectives;
- Requirement that rainwater system components meet national lead-free standards;
- Standards for rainwater harvesting collection parameters;
- Standards for drought response;
- Standards for rainwater harvesting conveyance system requirements;
- Standards for rainwater pre-filtration;
- Standards for harvested rainwater storage;
- Pump and filtration parameters;
- Disinfection and other treatment parameters;
- Water quality parameters for systems used for human consumption;
- Inspection, operation, and maintenance requirements for rainwater harvesting systems;
- Cross connection prevention and backflow prevention standards;
- System permit requirements; and
- Alternate compliance pathways for rainwater to be used both for human consumption and not for human consumption applications.

Issues

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

Primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions

Advantages include provision of an additional source of water supply for beneficial use to all persons in the Commonwealth. The Regulations will also provide clarity to designers and builders regarding water quality standards applicable to rainwater harvesting systems as described in the USBC. It is possible that some, but not all, members of the public may consider the need to obtain a permit for a rainwater harvesting system intended for potable use to be a disadvantage. VDH had not identified other disadvantages to the public in the Regulations.

Primary advantages and disadvantages to the agency or Commonwealth

The Regulations will assist the Commonwealth by enhancing protection of public health and the environment and provide an additional avenue to address current disparities throughout the Commonwealth by providing an

additional source of water to persons with limited access. Disadvantages are that the Regulation and the Code do not provide VDH with authority to recover any cost for implementation of this new regulatory program.

Other pertinent matters to the regulated community, government officials, and the public

The Regulations provide opportunity to the regulated community, government officials, and the public to investigate and develop novel means to preserve and protect existing water supplies and other natural resources throughout the Commonwealth.

Requirements More Restrictive than Federal

Identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements, or no requirements that exceed applicable federal requirements, include a specific statement to that effect.

The federal government does not regulate the harvesting of rainwater for reuse. However, the United States Environmental Protection Agency (EPA) Office of Research and Development has developed log-reduction targets applicable to the treatment of various forms of reuse water, including rainwater. This program does not carry the force of federal regulation, but is nonetheless recognized nationally as an appropriate reference standard. EPA does not intend to develop a federal regulatory program with respect to reuse water, and intends instead that the log-reduction targets serve as reference standards for states' use. Because Virginia will base water quality standards in the Regulations on these standards, which are not federally enforceable, the use of these log-reduction targets will be more restrictive than federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

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

Other State Agencies Particularly Affected

Virginia Department of Environmental Quality
Virginia Department of Housing and Community Development
Virginia Department of Professional and Occupational Regulation

Localities Particularly Affected

VDH does not anticipate any locality to be particularly affected.

Other Entities Particularly Affected

VDH anticipates that the Regulation will affect realtors; builders; homeowners; plumbing, electrical, and engineering trades/professions; and manufacturers and sellers of materials and equipment subject to use in the design and installation of rainwater harvesting systems.

Economic Impact

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

Impact on State Agencies

<p><i>For your agency:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including:</p> <ul style="list-style-type: none"> a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources 	<p>VDH anticipates that there will be five cost items for which funding is not currently provided.</p> <ol style="list-style-type: none"> 1. There will be an estimated one-time cost of \$68,000 for VDH’s database vendor to modify the internal Environmental Health Database (EHD) to incorporate a permitting program for Rainwater Harvesting Systems for Potable Use to track program permits, operation, and maintenance. There will also be an annual ongoing cost of \$54,000 to VDH’s database vendor to maintain this system. 2. There will be a one-time cost of \$34,000 to VDH’s database vendor to develop an online tool for registering rainwater harvesting systems with VDH. There will also be an on-going annual cost of \$24,000 to VDH’s database vendor to maintain this tool. 3. There will be an estimated staff resource cost of \$134,000 to provide development, support, and review of the operation and maintenance of both systems described in 1 and 2 above. VDH anticipates that the development costs will decrease over time as the operation and maintenance effort increases. The annual staff resource cost will be revised as appropriate as the program becomes established. 4. Because these are new regulations, there will be personnel costs for developing training and outreach
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	<p>programs and materials to familiarize VDH staff and the regulated community with the regulations. There will be an ongoing cost associated with the engineering review of permit applications, and there will be an ongoing cost for enforcement of the regulations. VDH estimates an annual staff resource cost of \$200,000 to provide the training, outreach, engineering review, and enforcement processes. VDH anticipates that the training and outreach costs will decrease over time as the engineering review and enforcement costs increase. As the program becomes established, the annual staff resource cost will be revised as appropriate.</p> <p>5. There will be a staff resource cost at local health departments to process applications for potable rainwater harvesting system permits. Costs of this nature are generally supported by permit fees; however, the Code provides no authority for VDH to charge a fee. VDH anticipates the cost to process each application will vary based on the size and complexity of the systems with a range of \$300 to \$1500 in staff resources per application.</p> <p>These costs must be supported by additional VDH general funds and cannot be absorbed by existing resources. VDH will require additional funding and authority for permit fees in order to implement the Regulations.</p>
<p><i>For other state agencies:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.</p>	<p>VDH has reached out to the Department of Housing and Community Development (DHCD) in order to ensure consistency between the Regulations and the USCB, and whether this would impose financial impact on that agency. DHCD confirmed that any impacts would be minimal and can be absorbed without additional funding.</p>

	<p>The Department of Environmental Quality (DEQ) did not identify a financial impact based on the regulations as proposed. The Department of Professional and Occupational Regulation did not identify a financial impact based on the regulations as proposed.</p>
<p><i>For all agencies:</i> Benefits the regulatory change is designed to produce.</p>	<p>The Regulations are designed to improve public health by establishing water quality standards for all uses of harvested rainwater.</p>

Impact on Localities

<p>Projected costs, savings, fees or revenues resulting from the regulatory change.</p>	<p>There are no anticipated economic costs or savings to localities from the development of these Regulations. As rainwater harvesting becomes common, the regulated community may petition local governments to eliminate mandatory connection to public water supplies or reduce fees for public water for users who rely primarily on harvested rainwater. However, the economic impact of this potential action is unknown at this time.</p>
<p>Benefits the regulatory change is designed to produce.</p>	<p>There is some potential for economic benefit to localities based on a possible increase in the ability for taxable property to be developed. However, the amount of economic benefit is unknown at this time.</p>

Impact on Other Entities

<p>Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.</p>	<p>The Regulations will affect homeowners, builders, realtors, and property developers by clarifying potential additional sources of water supply for intended beneficial use. This will have a positive impact, allowing for additional development where existing water sources are insufficient. There are currently an estimated several hundred homeowners relying on cisterns throughout Virginia who regularly pay for hauled water to maintain their water supply (costs range from \$110 to \$150.00/1000 gallons). The Regulations will allow these individuals to reduce or discontinue reliance on that service.</p> <p>The Regulations will also positively affect manufacturers and sellers of rainwater</p>
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	<p>harvesting system components and designers, installers, and inspectors of rainwater harvesting systems by establishing clear criteria for these systems, thus encouraging their use.</p>
<p>Agency's best estimate of the number of such entities that will be affected. Include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that:</p> <ul style="list-style-type: none"> a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million. 	<p>VDH anticipates that rainwater harvesting systems represent a potential resource applicable to both new construction and renovation of virtually any structure in the Commonwealth. The Regulations would apply to small businesses that manufacture or market equipment or materials that can be used in the installation of a rainwater harvesting system, as well as those that employ plumbers, electricians, engineers, or other workers who may participate in system design, installation, operation, and maintenance, or abandonment. It is difficult to provide an accurate estimate of affected entities given this broad scope as this is a new regulatory program. There is at least one primary provider of rainwater harvesting equipment currently in operation in Virginia. VDH does not anticipate more than a small number of applicants for potable rainwater harvesting systems during the first five years of the Regulations, with increasing rates of application over time as acceptance of rainwater as a potable source of drinking water increases.</p>
<p>All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to:</p> <ul style="list-style-type: none"> a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements. 	<p>VDH anticipates the Regulations can provide a distinct avenue for water supply for both non-potable and potable use to individuals and businesses. The cost of systems will vary depending on the proposed end-use of the water; however, the Regulations are based on current industry standards and are not anticipated to increase construction costs beyond those applicable today. VDH requested a water treatment system provider to estimate the construction/installation cost of a system to provide a potable system for a single-family home based on the provisions of the draft Regulations. The estimated cost is \$10,550.00 (2021), which VDH considers comparable to the cost of a private well or connection fee to a public drinking water</p>

	<p>supply. As this represents a novel form of water supply, particularly for residential applications, VDH anticipates that system costs may experience a cycle of cost ranges until the supply and demand pattern becomes established (i.e., may be relatively high for first adopters and decrease as systems become more common). Components of rainwater harvesting systems are generally available for other water management and treatment processes, and unit costs should remain consistent with existing water conditioning and treatment systems. VDH anticipates permitting timeframes to be consistent with those for private wells. Ongoing sampling and reporting costs are included for potable uses in the Regulations, and are anticipated to cost from \$300 to \$1,200 annually, determined by the size of the system.</p> <p>The Regulations require design professionals, installers, and inspectors to undertake training and testing for certification under the American Society of Sanitary Engineering’s Rainwater Catchment Systems standards. There are a variety of training providers, and the cost is typically \$400 to \$600 for online training.</p>
<p>Benefits the regulatory change is designed to produce.</p>	<p>The Regulations will provide an additional source of water supply to the people of Virginia. Further, the Regulations are designed to improve public health by establishing water quality standards for all uses of harvested rainwater.</p>

Alternatives to Regulation

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

Section 32.1-248.2 of the Code requires the Board to adopt regulations regarding the use of rainwater and provide standards for the use of rainwater harvesting systems, including systems that collect rainwater for use by commercial enterprises but do not provide water for human consumption, as defined in § 32.1-167. As an alternative, VDH considered the adaptation of VDH’s Virginia Rainwater Harvesting & Use Guidelines (GMP-

2011-01) from guidance to Regulations. VDH concluded that although a straightforward adaptation of the existing guidelines would comply with § 32.1-248.2 of the Code, it would not fully address the goals implied in the statute. In addition, it would not represent an avenue to address the demand for potable water supply where no other water source is feasible. Further, it would not be consistent with mandates elsewhere in the Code relative to resource protection and management (for example, groundwater management areas).

This proposed action includes potential benefits for small businesses, primarily, but not limited to, manufacturers and sellers of rainwater harvesting systems and system components, plumbers, electricians, and water quality laboratories, as it will clarify requirements for system design, installation, operation and maintenance and water quality standards.

Regulatory Flexibility Analysis

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

The harvesting and use of rainwater for non-potable use currently occurs in Virginia following VDH guidelines and the USBC. The VDH guidelines were developed pursuant to Code of Virginia § 32.1-248.2 as enacted by Ch. 155 of the 1998 Acts of the Assembly, which required the Department to develop guidelines.

Chapter 817 of the 2018 Acts of Assembly amended § 32.1-248.2 to mandate VDH to adopt regulations regarding the use of rainwater. VDH assembled a group of stakeholders comprised of participants from the agency, other state agencies, environmental groups, manufacturers and designers, private citizens, and university representatives. Pursuant to the efforts of this group, the following alternative regulatory methods were adopted in the writing of the regulations:

1. The requirement for an owner to obtain a permit for a rainwater harvesting system is limited to Tier 4 systems used for potable water supply. Rainwater harvesting systems used for Tiers 1-3 non-potable purposes require registration only.
2. Performance requirements apply to the design and construction of rainwater harvesting systems in place of prescriptive design and operational standards.
3. Reporting deadlines allow flexibility for verification sampling and testing.
4. Rainwater harvesting system inspection schedules are limited to the minimum frequency needed to confirm the system is functioning in accordance with design and therefore protective of public health.
5. Compliance and reporting requirements for system performance are limited to the minimum required information to confirm the system is functioning in accordance with design and therefore protective of public health.
6. Section 12VAC5-635-20 provides exemptions for rainwater harvesting systems reliant on rain barrels, and for Tier 1-3 (nonpotable) rainwater harvesting systems used by an agricultural operation.
7. Public health considerations prevent the exemption of small businesses from all or any part of the requirements; however, there is no distinction between requirements for small businesses and those for homeowners or other users of rainwater harvesting systems.

Periodic Review and Small Business Impact Review Report of Findings

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

In addition, as required by § 2.2-4007.1 E and F of the Code of Virginia, discuss the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation; (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, discuss why the agency's decision, consistent with applicable law, will minimize the economic impact of regulations on small businesses.

The Regulations are not being used to announce a periodic review or small business impact review.

Public Comment

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

A Notice of Intended Regulatory Action (NOIRA) was published for the Regulations in the Virginia Register on March 1, 2021. No comments were received during the advertised 30 day public comment period.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below.

VDH is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal, (ii) any alternative approaches, (iii) the potential impacts of the Regulations, and (iv) the agency's regulatory flexibility analysis stated in that section of this background document.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall website at: <https://townhall.virginia.gov>. Comments may also be submitted by mail, email or fax to Lance Gregory, Director, Division of Onsite Sewage and Water Services, Environmental Engineering, and Marina Programs, Office of Environmental Health Services, Virginia Department of Health, 109 Governor Street, Richmond, VA 23219, lance.gregory@vdh.virginia.gov, (804) 864-7491 (office), (804) 864-7475 (fax). In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will not be held following the publication of this stage of this regulatory action.

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

Table 2: Promulgating New VAC Chapter(s) without Repeal and Replace

New chapter-section number	New requirements to be added to VAC	Other regulations and laws that apply	Change, intent, rationale, and likely impact of new requirements
Part I General Framework of Regulations			
635-10	Definitions for: Agent, ANSI, ASSE, Board, Cistern, Commissioner, Contaminant, Conveyance system, Debris excluder, Department, Disinfection, Distribution System, End use, End use tier, Filtration, First flush, harvested rainwater, Human consumption, Installer, Local health department, log reduction, log reduction target, maintenance, non-potable water, NSF, Operator, Owner, Point of use, Potable water, Precipitation, Rainwater harvesting system, Screen, Secondary Water Supply, Service Connection, Stormwater, Treatment, Treatment system, USBC, Water storage unit, and Waterworks.	None	<p>INTENT: The intent of the definitions is to ensure clarity.</p> <p>RATIONALE: The definitions will provide consistency with federal guidelines, the USBC, other VDH regulations, and industry terminology.</p> <p>LIKELY IMPACT: The likely impact of the definitions is clarity for the regulated community regarding terms used in the chapter.</p>
635-20	Applicability of regulations	Code of Virginia §§ 32.1-12 and 32.1-248.2 and § 32.1-167.	<p>INTENT: The intent of the section is to clarify that the regulations do not apply to existing rainwater harvesting systems unless they are altered or rehabilitated, and to identify exclusions from the regulations.</p> <p>RATIONALE: Section 32.1-12 of the Code of Virginia grants authority to the Board for the</p>

New chapter-section number	New requirements to be added to VAC	Other regulations and laws that apply	Change, intent, rationale, and likely impact of new requirements
			<p>provision of reasonable exemptions from regulations. A further rationale for this section is to clarify to the owner of a rainwater harvesting system in existence prior to the promulgation of the Regulations that alteration or rehabilitation to the system must comply with the Regulations.</p> <p>LIKELY IMPACT: The likely impact of the section is clarity for the regulated community about which rainwater harvesting systems are regulated pursuant to 12VAC5-635.</p>
635-30	Relationship to Sewage Handling and Disposal Regulations	§ 32.1-164 12VAC5-610	<p>INTENT: The intent of the section is to clarify that the regulations supersede 12VAC5-610-1170, which addresses cisterns.</p> <p>RATIONALE: This clarifies that the regulations adopted pursuant to Code of Virginia § 32.1-164 do not provide comprehensive regulatory standards for rainwater harvesting systems, only for installation of cisterns. VDH intends to repeal 12VAC5-610-1170 during the next revision of the Sewage Handling and Disposal Regulations, and until that occurs, this section will reduce confusion for the regulated community about the use of cisterns.</p> <p>LIKELY IMPACT: The likely impact of the section is that cisterns used in rainwater harvesting systems will be installed, rehabilitated, and maintained pursuant to 12VAC5-635 instead of 12VAC5-610.</p>
635-40	Relation to State Water Control Board	9VAC25-31, 9VAC25-32, 9VAC25-151, 9VAC25-840, 9VAC25-870, 9VAC25-880, and 9VAC25-890	<p>INTENT: The intent of the section is to clarify that this chapter addresses the standards for the collection and use of that portion of stormwater not regulated pursuant to DEQ’s stormwater regulations.</p>

New chapter-section number	New requirements to be added to VAC	Other regulations and laws that apply	Change, intent, rationale, and likely impact of new requirements
			<p>RATIONALE: The rationale of the section is that Code of Virginia § 62.1-44.15 and § 402 of the federal Clean Water Act address the regulation of most forms of stormwater</p> <p>LIKELY IMPACT: The likely impact of the section is clarity for the regulated community and personnel of VDH and DEQ about stormwater and rainwater related regulations.</p>
635-50	Relation to Uniform Statewide Building Code	Code of Virginia § 36-98	<p>INTENT: The intent of the section is to clarify that the chapter is independent of and in addition to the requirements of the USBC, and to present the requirements for the owner to provide rainwater harvesting system construction permits and operation permits to local building officials when harvested rainwater will supply potable water systems.</p> <p>RATIONALE: The rationale of the section is that Code of Virginia § 36-98 addresses construction standards.</p> <p>LIKELY IMPACT: The likely impact of the section clarity regarding the relationship between VDH permitting authority and the USBC.</p>
60	Right of entry and inspections	Code of Virginia § 32.1-25	<p>INTENT: The intent of the section is to specify VDH right of inspection.</p> <p>RATIONALE: The rationale of the section is that Code of Virginia § 32.1-25 provides the commissioner the right to enter at any reasonable time onto any property to inspect, investigate, evaluate, conduct tests, or collect samples for testing as he reasonably deems necessary in order to determine compliance with laws or regulations or conditions in a permit, license, or certificate.</p> <p>LIKELY IMPACT: The likely impact of the section is awareness of VDH’s rights of entry and inspection. The likely impact is also that the commissioner or his</p>

New chapter-section number	New requirements to be added to VAC	Other regulations and laws that apply	Change, intent, rationale, and likely impact of new requirements
			designee may exercise the right to inspect a rainwater harvesting system for compliance with 12VAC5-635.
Part II Procedural Regulations			
70	End-use tiers for rainwater harvesting systems		<p>INTENT: The intent of the section is to identify four end-use tiers classifying the way rainwater harvesting systems are regulated. These are:</p> <p>Tier 1. Low exposure end-use: Non-potable water use where humans will rarely come into contact with the treated rainwater due to the nature of the installation that limits direct or indirect contact under normal operation. Examples include trap primers, restricted access spray irrigation, surface and subsurface irrigation, and ice rinks. In this context, restricted access spray irrigation means spray irrigation in fenced or remote locations where human visitation is controlled or prevented;</p> <p>Tier 2. Medium exposure end-use: Non-potable water use where human contact with treated rainwater is indirect or limited. Examples include toilet and urinal flushing, clothes washing, HVAC evaporative cooling, and rooftop thermal cooling;</p> <p>Tier 3. High exposure end-use: Non-potable water use where human contact with treated rainwater is direct. Examples include hose bibs, pressure washing, fire fighting or protection and fire suppression, decorative fountains, vehicle washing, and non-restricted spray irrigation; and</p> <p>Tier 4. Potable water end-use: intended for human consumption.</p> <p>RATIONALE: The rationale of the section is that Code of Virginia § 32.1-248.2 requires the board to provide standards for the use of rainwater harvesting systems. The Department</p>

New chapter-section number	New requirements to be added to VAC	Other regulations and laws that apply	Change, intent, rationale, and likely impact of new requirements
			<p>selected the end-use tiers based on the International Code Council end-use tiers to help categorize the various types of uses for harvested rainwater and to provide clear distinctions for public protections for the various uses.</p> <p>LIKELY IMPACT: The likely impact of the section is clarity for the regulated community about the end-use of harvested rainwater and whether permitting or registration is required for a rainwater harvesting system.</p>
80	Reserved		.
90	Permits for rainwater harvesting systems; general		<p>INTENT: The intent of the section is to provide registration and permitting requirements for rainwater harvesting systems. Permits are required for Tier 4 end-use. Registration is required for Tier 1, 2, or 3 end-use.</p> <p>RATIONALE: The rationale of the section is to ensure that public health is protected by means of a permitting program by the Department for rainwater harvesting systems for Tier 4 (potable) end-use, and to provide means of tracking total rainwater harvesting throughout the Commonwealth by means of a registry of rainwater harvesting systems for Tier 1, 2, and 3 (non-potable) end-use.</p> <p>LIKELY IMPACT: The likely impact of the section is to reduce the risk of adverse public health outcomes for users, including future users, of permitted rainwater harvesting systems. Owners of rainwater harvesting systems for Tier 4 end-use will begin to obtain permits for the systems and owners of rainwater harvesting systems for other tier end-use will register the systems with VDH.</p>
100	Application procedures for a construction permit for a rainwater harvesting system for Tier 4 end-use		<p>INTENT: The intent of the section is to outline the minimum requirements to apply for a construction permit for a</p>

New chapter-section number	New requirements to be added to VAC	Other regulations and laws that apply	Change, intent, rationale, and likely impact of new requirements
			<p>rainwater harvesting system for Tier 4 end-use.</p> <p>RATIONALE: The rationale is to protect public health by ensuring that construction applications address ownership, contact information, location, separation distances, materials and equipment specifications, operation and maintenance requirements, and site specific information as warranted so that VDH can properly process requests for permits.</p> <p>LIKELY IMPACT: The likely impact of the section is that owners of Tier 4 end-use systems will follow the application procedures for construction permits.</p>
110	Issuance of the construction permit		<p>INTENT: The intent of the section is establish the conditions under which the Commissioner will issue a construction permit for a Tier 4 end-use rainwater harvesting system.</p> <p>RATIONALE: The rationale of the section is Code of Virginia § 32.1-12 grants authority to the Board, the Commissioner, or the Department to carry out provisions of regulations. This also establishes a timeframe in which the agency will act upon request for permits.</p> <p>LIKELY IMPACT: The likely impact of the section is that the commissioner will approve construction permits for owners who follow the application procedures and meet the appropriate qualifications for a permit.</p>
120	Denial of a construction permit		<p>INTENT: The intent of the section is to establish the conditions under which the commissioner will deny a construction permit for a Tier 4 end-use rainwater harvesting system.</p> <p>RATIONALE: The rationale of the section is Code of Virginia § 32.1-12 grants authority to the</p>

New chapter-section number	New requirements to be added to VAC	Other regulations and laws that apply	Change, intent, rationale, and likely impact of new requirements
			<p>Board, the Commissioner, or the Department to carry out provisions of regulations. This section also clarifies an owner's right to appeal a case decision of the Department.</p> <p>LIKELY IMPACT: The likely impact of the section is that the commissioner will deny permits to applicants that do not meet the qualifications for a permit or if approval would pose a public health threat.</p>
130	Revisions of approved plans		<p>INTENT: The intent of the section is to outline the conditions under which a designer, with the consent of the owner, may make design changes following issuance of a valid construction permit for a Tier 4 end-use rainwater harvesting system without prior approval of the department. Further, the section states that the commissioner may suspend or revoke a construction permit if a design change does not comply with the chapter.</p> <p>RATIONALE: The rationale of the section is to simplify the process of minor design changes to a rainwater harvesting system intended for Tier 4 end-use when such changes do not alter the conditions established in the construction permit. This section also clarifies that the Commissioner may suspend or revoke a permit when the design is changed in such a way that it no longer complies with the public health protections outlined in the Regulations.</p> <p>LIKELY IMPACT: The likely impact of the section is that designers will make minor changes to rainwater harvesting system designs without having to go through an approval process with VDH.</p>
140	Installation, inspection, and correction		<p>INTENT: The intent of the section is to describe the responsibilities of the installer and designer of a Tier 4 end-use</p>

New chapter-section number	New requirements to be added to VAC	Other regulations and laws that apply	Change, intent, rationale, and likely impact of new requirements
			<p>rainwater harvesting system to submit statements that certify the work performed, including procedures related to correction of deficiencies, and actions that the department will take if deficiencies are not corrected.</p> <p>RATIONALE: The rationale of the section is to obtain documentation of the actions of the installers and designers of rainwater harvesting systems for Tier 4 end-use for use by the Commissioner in determining the issuance of an operation permit for the system. This allows the Department to verify the system was installed in accordance with the Regulations prior to placing the system into operation, which will reduce the risk of adverse public health outcomes for users, including future users, of permitted rainwater harvesting systems.</p> <p>LIKELY IMPACT: The likely impact of the section is that owners will perform any required inspections and repairs to VDH after installation of the rainwater harvesting system is complete.</p>
150	Requirement for easement		<p>INTENT: The intent of the section is to describe necessary actions in the event that a rainwater harvesting system for Tier 4 end-use, or part thereof, is proposed to be installed on a property other than the owner's.</p> <p>RATIONALE: The rationale of the section is to document, for the benefit of owners of properties on which all or part of a rainwater harvesting system for Tier 4 end-use serving another property is installed, and of owners of such systems, and of future owners, that an easement exists and conditions associated with the easement apply. The rationale is also that the requirement to obtain an easement ensures that rainwater harvesting systems are</p>

New chapter-section number	New requirements to be added to VAC	Other regulations and laws that apply	Change, intent, rationale, and likely impact of new requirements
			<p>not installed on someone else’s property without their permission. LIKELY IMPACT: The likely impact of the section is owners will seek an easement when it is required and follow the procedures for obtaining and recording the easement. This requirement will also minimize the risk of future disputes when rainwater harvesting systems are placed on adjoining properties.</p>
160	Land records		<p>INTENT: The intent of the section is to require recordation and documentation of an instrument describing annual water quality testing and system maintenance requirements of a rainwater harvesting system for Tier 4 end-use in the land records of circuit court, and that the instrument be transferred with the title to the property upon sale or other transfer. RATIONALE: The rationale of the section is to provide future owners of a property served by a rainwater harvesting system for Tier 4 end-use the documentation necessary to operate and maintain the system in accordance with its operation permit. LIKELY IMPACT: The likely impact of the section is increased awareness of operation and maintenance requirements for those purchasing homes with Tier 4 rainwater harvesting systems. The impact is also that owners will begin to record the instruments with their local circuit court.</p>
170	Issuance of operation permit		<p>INTENT: The intent of the section is to establish the conditions under which the commissioner will issue an operation permit for a Tier 4 end-use rainwater harvesting system. RATIONALE: The rationale of the section is that the commissioner will only issue an operating permit for a system</p>

New chapter-section number	New requirements to be added to VAC	Other regulations and laws that apply	Change, intent, rationale, and likely impact of new requirements
			<p>meeting the criteria established in Regulations. LIKELY IMPACT: The likely impact of the section is to reduce the risk of adverse public health outcomes for users, including future users, of permitted rainwater harvesting systems.</p>
180	Variances	Code of Virginia § 2.2-4000 et seq.	<p>INTENT: The intent of the section is to establish the process for the owner of a rainwater harvesting system for Tier 4 end-use to request a variance, the commissioner's ability to approve or deny the request for a variance, and disposition of an approved variance under certain conditions. RATIONALE: The rationale of the section is that Code of Virginia § 32.1-12 grants authority to the Board to provide for reasonable variances to regulations. LIKELY IMPACT: The likely impact of the section is owners will request reasonable variances from the Regulations when the hardship imposed by the Regulations outweighs the benefit that might be received by public health.</p>

New chapter-section number	New requirements to be added to VAC	Other regulations and laws that apply	Change, intent, rationale, and likely impact of new requirements
190	Enforcements, notices, informal conferences, appeals	Code of Virginia § 2.2-4000 et seq.	<p>INTENT: The intent of the section is to establish conditions under which the commissioner may suspend or revoke a permit for a Tier 4 end-use rainwater harvesting system, and the owner’s responsibilities and rights in response to the suspension or revocation of a permit.</p> <p>RATIONALE: The rationale of the section is that Code of Virginia § 2.2-4000 et seq. supplements present and future basis laws conferring authority on agencies to make regulations or decide cases as well as to standardize court review thereof. This section also clarifies the conditions under which the Commissioner can suspend or revoke a permit to ensure public health is protected.</p> <p>LIKELY IMPACT: The likely impact of the section is that owners will be aware of and will exercise their rights and responsibilities with regard to enforcement, notices, informal conferences, and appeals.</p>
Part III Design and Installation			
200	Cross connection abatement	USBC	<p>INTENT: The intent of the section is to provide standards for rainwater harvesting systems intended to ensure that cross-connection abatement equipment and methods conform to the USBC.</p> <p>RATIONALE: The rationale of the section is that cross connection abatement protects public health by providing appropriate means to prevent flow from two otherwise separate piping systems where a physical connection or arrangement is present.</p> <p>LIKELY IMPACT: The likely impact of the section is that designers and installers of rainwater harvesting systems will adhere to cross connection abatement requirements.</p>

New chapter-section number	New requirements to be added to VAC	Other regulations and laws that apply	Change, intent, rationale, and likely impact of new requirements
210	Backflow prevention	USBC	<p>INTENT: The intent of the section is to provide standards for rainwater harvesting systems intended to ensure that backflow prevention equipment and methods conform to the USBC.</p> <p>RATIONALE: The rationale of the section is that backflow prevention protects public health by restricting reversal of the normal direction of flow in piping systems.</p> <p>LIKELY IMPACT: The likely impact of the section is that designers and installers of rainwater harvesting systems will adhere to backflow prevention requirements.</p>
220	Water storage unit location	USBC	<p>INTENT: The intent of the section is to provide standards for the construction and location of rainwater harvesting systems to establish separation distance from potential sources of risk and to ensure that equipment and methods of water storage conform to the USBC.</p> <p>RATIONALE: The rationale of the section is that safe location and construction of water storage units protects public health.</p> <p>LIKELY IMPACT: The likely impact of the section is that designers and installers of rainwater harvesting systems will adhere to water storage unit construction and location requirements.</p>
230	Materials and equipment	USBC	<p>INTENT: The intent of the section is to provide standards for materials and equipment used to construct rainwater harvesting systems and to ensure that materials, equipment, and methods conform to the USBC.</p> <p>RATIONALE: The rationale of the section is to protect public health by ensuring that materials used for the collection, storage, and treatment of harvested rainwater meet appropriate standards relative to the end-use.</p>

New chapter-section number	New requirements to be added to VAC	Other regulations and laws that apply	Change, intent, rationale, and likely impact of new requirements
			<p>LIKELY IMPACT: The likely impact of the section is reduced risk of adverse public health outcomes for users of permitted rainwater harvesting systems because materials and equipment will be appropriate for the end use of the harvested rainwater.</p>
240	Design and installation	USBC	<p>INTENT: The intent of the section is to provide standards for the design and installation of rainwater harvesting systems intended to ensure conformance to the USBC.</p> <p>RATIONALE: The rationale of the section is to protect public health by the establishment of criteria for design and installation of rainwater harvesting systems relative to the end-use.</p> <p>LIKELY IMPACT: The likely impact of the section is reduced risk of adverse public health outcomes for users of permitted rainwater harvesting systems because the design and installation of rainwater harvesting systems will be appropriate to the end use of the harvested rainwater.</p>
250	Filtration	USBC	<p>INTENT: The intent of the section is to provide standards for materials and equipment used for filtration as part of rainwater harvesting systems and to ensure conformance to the USBC.</p> <p>RATIONALE: The rationale of the section is that filtration is a necessary step to removing particulate matter from harvested rainwater for purposes of contaminant removal and protection of the integrity of additional treatment processes and equipment.</p> <p>LIKELY IMPACT: The likely impact of the section is reduced risk of adverse public health outcomes for users of permitted rainwater harvesting systems because filtration materials and equipment used in rainwater harvesting systems will be</p>

New chapter-section number	New requirements to be added to VAC	Other regulations and laws that apply	Change, intent, rationale, and likely impact of new requirements
			appropriate to the end use of the harvested rainwater.
260	Disinfection	USBC	<p>INTENT: The intent of the section is to provide standards for materials and equipment used for disinfection as part of rainwater harvesting systems and to ensure conformance to the USBC.</p> <p>RATIONALE: The rationale of the section is that disinfection is a necessary step to protect public health by inactivating or destroying pathogenic organisms to a level consistent with the end-use of the water from a rainwater harvesting system.</p> <p>LIKELY IMPACT: The likely impact of the section is reduced risk of adverse public health outcomes for users of permitted rainwater harvesting systems because disinfection materials and equipment used in rainwater harvesting systems will be appropriate to the end use of the harvested rainwater.</p>
270	General certification		<p>INTENT: The intent of the section is to provide standards for the labeling of materials and equipment used as part of rainwater harvesting systems and certification standards for designers, installers, and inspectors of rainwater harvesting systems.</p> <p>RATIONALE: The rationale of the section is that public health is protected by certification to recognized industry standards of materials, equipment, and training associated with the design, installation, and operation and maintenance of a rainwater harvesting system.</p> <p>LIKELY IMPACT: The likely impact of the section is that owners will ensure the general certification of materials, equipment, designers, installers, and inspectors pursuant to the Regulations.</p>
280	Temporary removal from service		<p>INTENT: The intent of the section is to provide standards for</p>

New chapter-section number	New requirements to be added to VAC	Other regulations and laws that apply	Change, intent, rationale, and likely impact of new requirements
			<p>temporary removal from service of rainwater harvesting systems when structures are not occupied.</p> <p>RATIONALE: The rationale of the section is to protect public health and property by establishing criteria to secure a rainwater harvesting system not in current use.</p> <p>LIKELY IMPACT: The likely impact of the section is that rainwater harvesting systems will be protected when not in service.</p>
Part IV Performance Requirements			
290	Performance requirements; general		<p>INTENT: The intent of the section is to identify overall performance requirements applicable to rainwater harvesting systems.</p> <p>RATIONALE: The rationale of the section is to protect public health by the establishment of performance requirements that set out the technical criteria in accordance with which rainwater harvesting systems are to be designed, installed, operated, and maintained.</p> <p>LIKELY IMPACT: The likely impact of the section is that owners will ensure operation of their permitted rainwater harvesting systems operate in compliance with these performance requirements, reducing the risk of adverse public health outcomes for users of the systems.</p>
300	Performance requirements; continuity of water supply		<p>INTENT: The intent of the section is to provide performance requirements for the continuity of water supply such that rainwater harvesting systems are not compromised by lack of sufficient precipitation.</p> <p>RATIONALE: The rationale of the section is that natural precipitation patterns cannot be relied upon for a permanent water supply source, and therefore a secondary means of water supply is necessary to ensure a continuous supply is available as a</p>

New chapter-section number	New requirements to be added to VAC	Other regulations and laws that apply	Change, intent, rationale, and likely impact of new requirements
			<p>basic need and to protect public health. LIKELY IMPACT: The likely impact of the section is that rainwater harvesting systems will have a reliable source of water when precipitation levels are insufficient to meet demand.</p>
310	Performance requirements; water quality standards	42 U.S.C. § 300f	<p>INTENT: The intent of the section is to provide standards for water quality rainwater harvesting systems, based on both the Safe Drinking Water Act (potable systems) and end-use Tier. RATIONALE: The rationale of the section is that water quality standards, categorized by end-use, are necessary to protect public health. LIKELY IMPACT: The likely impact of the section is reduced risk of adverse public health outcomes for users of rainwater harvesting systems because all rainwater harvesting systems will meet water quality standards appropriate to the end use of the harvested rainwater.</p>
Part V Operation and Maintenance Requirements			
320	Operator requirements; minimum frequency of visits.		<p>INTENT: The intent of the section is to identify the frequency of inspection of rainwater harvesting systems. RATIONALE: The rationale of the section is to ensure that operators maintain a schedule of inspection of rainwater harvesting systems, based on the end-use of the water, sufficient to protect the health of the system users. LIKELY IMPACT: The likely impact of the section is that operators will visit inspect permitted rainwater harvesting systems pursuant to this section, increasing the likelihood of identifying and completing needed repairs or alterations, reducing the risk of adverse public health outcomes for users of the systems.</p>
330	Operation and maintenance; Operator responsibilities		<p>INTENT: The intent of the section is to identify the</p>

New chapter-section number	New requirements to be added to VAC	Other regulations and laws that apply	Change, intent, rationale, and likely impact of new requirements
			<p>responsibilities for operators of rainwater harvesting systems. RATIONALE: The rationale of the section is to protect the health of the users of the system by clarifying the minimum operation and maintenance responsibilities of the operator responsible for the system. If not properly maintained, the rainwater harvesting system may produce water that is not safe for the intended end-use. LIKELY IMPACT: The likely impact of the section is that operators will know and comply with requirements necessary to ensure rainwater harvesting systems operate in accordance with the Regulations.</p>
340	Operation and maintenance; owner’s responsibilities		<p>INTENT: The intent of the section is to identify the responsibilities for owners of rainwater harvesting systems. RATIONALE: The rationale of the section is to protect the health of the users of a rainwater harvesting system by listing the responsibilities that the owner must meet. If not properly maintained, the rainwater harvesting system may produce water that is not safe for the intended end-use. LIKELY IMPACT: The likely impact of the section is that owners will understand and comply with their responsibilities for operation and maintenance of rainwater harvesting systems.</p>
350	Operation and maintenance manual		<p>INTENT: The intent of the section is to identify the minimum necessary contents of operation and maintenance manuals for rainwater harvesting systems. RATIONALE: The rationale of the section is to protect public health by providing the owners, operators, and users of rainwater harvesting systems a document that describes essential details about the system and its upkeep. If not properly maintained, the</p>

New chapter-section number	New requirements to be added to VAC	Other regulations and laws that apply	Change, intent, rationale, and likely impact of new requirements
			<p>rainwater harvesting system may produce water that is not safe for the intended end-use. LIKELY IMPACT: The likely impact of the section is that owners will include all required information in the operation and maintenance manuals for their rainwater harvesting systems, which will ensure the systems are operated and maintained in such a way that complies with this chapter and protects the health of those who rely on the system for potable water.</p>
360	Mandatory visits; inspection requirements		<p>INTENT: The intent of the section is to identify the minimum inspection requirements for rainwater harvesting systems. RATIONALE: The rationale of the section is to protect public health by establishing minimum standards, based on end-use, for actions to be taken during the inspection of a rainwater harvesting system. LIKELY IMPACT: The likely impact of the section is operators who inspect rainwater harvesting systems will adhere to a consistent standard.</p>
370	Reports		<p>INTENT: The intent of the section is to identify the information to be documented following inspection of rainwater harvesting systems. RATIONALE: The rationale of the section is that documentation of required inspections of rainwater harvesting systems protects public health and establishes baseline data in the event that the system is later determined to be out of compliance LIKELY IMPACT: The likely impact of the section is that inspection reports will be consistently prepared and provided to the required recipients, including VDH.</p>

1 **Project 6687 - Proposed**

2 **Department of Health**

3 **Rainwater Harvesting Regulations**

4 Chapter 635

5 Rainwater Harvesting Regulations

6 Part I

7 General Framework of Regulations

8 **12VAC5-635-10. Definitions.**

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

11 "Agent" means a legally authorized representative of the owner.

12 "ANSI" means the American National Standards Institute.

13 "ASSE" means the American Society of Sanitary Engineering.

14 "Board" means the State Board of Health.

15 "Cistern" means a water storage tank connected to a plumbing system or irrigation system.

16 "Commissioner" means the State Health Commissioner or his designee.

17 "Contaminant" means an objectionable or hazardous physical, chemical, biological, or
18 radiological substance or matter in water.

19 "Conveyance system" means the portion of a rainwater harvesting system that directs
20 collected rainwater to the point of untreated rainwater storage, including gutters, downspouts, roof
21 drains, and connectors. Also called a roof drainage system.

22 "Debris excluder" means a screen or other device installed in the gutter or downspout system
23 to prevent the accumulation of leaves, needles, or other debris in the rainwater harvesting system.

24 "Department" means the Virginia Department of Health.

25 "Disinfection" means a process that inactivates or destroys pathogenic organisms in water by
26 use of a disinfectant. A disinfectant is any chemical and physical agent, including chlorine,
27 chlorine dioxide, chloramines, ozone, and ultraviolet light, added to water in any part of the
28 treatment or distribution process for the purpose of killing or inactivating pathogenic organisms.

29 "Distribution system" means piping and other components carrying water from a rainwater
30 harvesting system to the point of use.

31 "End use" means the use of water from a rainwater harvesting system.

32 "End Use Tier" means a categorization applied to a rainwater harvesting system based on
33 potable or non-potable water quality; end use; and potential for human contact, including
34 ingestion, inhalation, and skin contact.

35 "Filtration" means a process for removing particulate matter from water by passage through
36 porous media.

37 "First flush" means a method for the removal of sediment and debris from the collection
38 surface by diverting initial rainfall from entry into the storage unit.

39 “Harvested rainwater” means water from precipitation, including snowmelt, which falls on an
40 elevated roof not subject to pedestrian access and is directed through gutters and downspouts to
41 a storage tank prior to contact with the ground.

42 “Human consumption” means drinking, food preparation, dishwashing, bathing, showering,
43 hand washing, teeth brushing, and maintaining oral hygiene.

44 “Installer” means the service provider responsible for installation of a rainwater harvesting
45 system in accordance with the construction permit.

46 “Local health department” means the department established in each city and county in
47 accordance with § 32.1-30 of the Code of Virginia.

48 “Log reduction” means the removal of organisms expressed on a logarithmic scale. For
49 example, a 99.9% is a 3-log removal; whereas a 99.99% is a 4-log removal.

50 “Log reduction target” means a level of log removal assigned to an End Use Tier.

51 “Maintenance” means performing adjustments to equipment and controls and in-kind
52 replacement of normal wear and tear parts such as light bulbs, fuses, filters, pumps, motors,
53 conveyance subsystem components, or other like components. Maintenance includes pumping
54 the tanks or cleaning the system components, including tanks, on a periodic basis. Maintenance
55 shall not include replacement of water storage units or work requiring a construction permit and
56 an installer.

57 “Non-potable water” means water not classified as pure water.

58 “NSF” means NSF International, formerly known as the National Sanitation Foundation. NSF
59 collaborates with ANSI and Canadian authorities on drinking water standards development
60 (NSF/ANSI/CAN).

61 “Operator” means a person employed or contracted by an owner to operate and maintain a
62 rainwater harvesting system and holding certification as a designer, installer, or inspector as
63 described in 12VAC5-635-270.B. Owners may be certified to become operators.

64 “Owner” means any person, individual, corporation, partnership, association, cooperative,
65 limited liability company, trust, joint venture, government, political subdivision, or any other legal
66 or commercial entity and any successor, representative, agent, or instrumentality thereof, who
67 owns, leases, or proposes to own or lease a rainwater harvesting system.

68 “Point of use” means a point in a domestic water system nearest to a water-consuming
69 plumbing fixture where water is used.

70 “Potable Water” or “pure water” means water fit for human consumption that (i) is sanitary and
71 normally free of minerals, organic substances, and toxic agents in excess of reasonable amounts;
72 (ii) is adequate in quantity and quality for the minimum health requirements of the persons served;
73 and (iii) conforms to potable water standards defined in the Virginia Uniform Statewide Building
74 Code (§ 36-97 et seq. of the Code of Virginia).

75 “Precipitation” means water that has precipitated from the atmosphere, including rain, snow,
76 sleet, hail, mist, fog, and dew.

77 “Rainwater harvesting system” means a water system for collecting, storing, potentially
78 treating, and distributing rainwater for an end use.

79 “Screen” means a filtration device constructed of corrosion-resistant wire or other approved
80 mesh, having openings in determined sizes.

81 “Secondary water supply” means an alternate source of water that serves a rainwater
82 harvesting system for the purpose of continuity of water supply.

83 “Service Connection” means the point of delivery of water from a rainwater harvesting system
84 to the distribution system of a user. In the case of a building having multiple independent tenants,
85 each independent tenant is considered a service connection for the purpose of this regulation.

86 regardless of distribution system configuration. In general, a service connection is a single
87 residential unit or commercial space.

88 “Stormwater” means precipitation that is discharged across the land surface or through
89 conveyances to one or more waterways and that may include stormwater runoff, snow melt runoff,
90 and surface runoff and drainage.

91 “Treatment” means the use of physical, biological, or chemical means to make water suitable
92 for the intended use.

93 “Treatment system” or “Water treatment system” means the equipment and components used
94 to achieve treatment of rainwater, most commonly filtration and disinfection.

95 “USBC” means the Uniform Statewide Building Code (§ 36-97 et seq. of the Code of Virginia).

96 “Water storage unit” means a cistern or tank used as the central storage component of the
97 rainwater harvesting system prior to treatment.

98 “Waterworks” means a system that serves piped water for human consumption to at least 15
99 service connections or 25 or more individuals for at least 60 days out of the year.

100 **Statutory Authority**

101 §§ 32.1-12 and 32.248.2 of the Code of Virginia.

102 **12VAC5-635-20. Applicability of regulations.**

103 A. This chapter does not apply to rainwater harvesting systems installed, altered, or
104 rehabilitated prior to the effective date of these regulations unless the rainwater harvesting system
105 is altered or rehabilitated after the effective date of these regulations.

106 B. The following are excluded from the requirements of this chapter.

107 1. Rain barrels (individual containers of up to 100 gallon capacity used to collect and
108 temporarily store rainwater solely for Tier 1 end use);

109 2. Rainwater harvesting systems that serve as a source for a waterworks as regulated by
110 12VAC5-590;

111 3. Rainwater harvesting systems for Tier 1, 2 or 3 end use conducted for an agricultural
112 operation as defined by § 3.2-300 of the Code of Virginia; and

113 4. Stormwater reclamation and reuse systems authorized by the Department of
114 Environmental Quality in accordance with regulations adopted pursuant to § 62.1-
115 44.15:28, including stormwater reclamation and reuse systems that may reclaim combined
116 stormwater and harvested rainwater.

117 **Statutory Authority**

118 § 32.1-12 and 32.248.2 of the Code of Virginia.

119 **12VAC5-635-30. Relationship to Virginia Sewage Handling and Disposal Regulations.**

120 This chapter supersedes 12VAC5-610-1170 of the Virginia Sewage Handling and Disposal
121 Regulations, which addresses cisterns, in cases where a cistern is used solely as a component
122 of a rainwater harvesting system subject to the requirements of this chapter.

123 **Statutory Authority**

124 §§ 32.1-12 and 32.248.2 of the Code of Virginia.

125 **12VAC5-635-40. Relationship to the State Water Control Board.**

126 This chapter addresses the standards for the collection and use of that portion of stormwater
127 not regulated in accordance with 9VAC25-31, 9VAC25-32, 9VAC25-151, 9VAC25-840, 9VAC25-
128 870, 9VAC25-880, and 9VAC25-890.

129 **Statutory Authority**

130 §§ 32.1-12 and 32.1-248.2 of the Code of Virginia.

131 **12VAC5-635-50. Relationship to the Uniform Statewide Building Code.**

132 A. This chapter is independent of and in addition to the requirements of the USBC in
133 accordance with § 36-98 of the Code of Virginia.

134 B. All persons required to obtain a rainwater harvesting system installation permit for a system
135 for Tier 4 end use shall furnish a copy of the installation permit to the local building official when
136 making application for a building permit.

137 C. The applicant for a rainwater harvesting system for Tier 4 end use shall furnish the local
138 building official with a copy of the operating permit demonstrating the potable water supply has
139 been inspected, sampled, and approved by the local health department.

140 **Statutory Authority**

141 §§ 32.1-12 and 32.1-248.2 of the Code of Virginia.

142 **12VAC5-635-60. Right of Entry and Inspections.**

143 In accordance with § 32.1-25 of the Code of Virginia, the commissioner or a designee shall
144 have the right to enter any property to ensure compliance with this chapter.

145 **Statutory Authority**

146 §§ 32.1-12 and 32.1-248.2 of the Code of Virginia.

147 Part II

148 Procedural Regulations

149 **12VAC5-635-70. End use tiers for rainwater harvesting systems.**

150 The end use tier categorization of harvested rainwater is based on water quality, intended end
151 uses, and associated potential for human contact through ingestion, inhalation, and skin contact.
152 The examples of common-use applications are not intended to represent all possible applications.
153 Where end use applications are not listed, or are subject to interpretation, the application shall be
154 categorized based on the highest numbered applicable end use tier description. The end use tiers
155 are as follows:

156 1. Tier 1. Low exposure end use: Non-potable water use where humans will rarely come
157 into contact with the treated rainwater due to the nature of the installation that limits direct
158 or indirect contact under normal operation. Examples include trap primers, restricted
159 access spray irrigation, surface and subsurface irrigation, and ice rinks. In this context,
160 restricted access spray irrigation means spray irrigation in fenced or remote locations
161 where human visitation is controlled or prevented.

162 2. Tier 2. Medium exposure end use: Non-potable water use where human contact with
163 treated rainwater is indirect or limited. Examples include toilet and urinal flushing, clothes
164 washing, HVAC evaporative cooling, and rooftop thermal cooling.

165 3. Tier 3. High exposure end use: Non-potable water use where human contact with
166 treated rainwater is direct. Examples include hose bibs, pressure washing, fire fighting or
167 protection and fire suppression, decorative fountains, vehicle washing, and non-restricted
168 spray irrigation.

169 4. Tier 4. Potable water end use: intended for human consumption.

170 **Statutory Authority**

171 §§ 32.1-12 and 32.1-248.2 of the Code of Virginia.

172 **12VAC5-635-80. Reserved.**

173 **Statutory Authority**

174 §§ 32.1-12 and 32.1-248.2 of the Code of Virginia.

175 **12VAC5-635-90. Permits for rainwater harvesting systems; general.**

176 A. No person may install, alter, or rehabilitate, or allow the installation, alteration, or
177 rehabilitation of a rainwater harvesting system intended for Tier 4 end use without a written
178 construction permit from the commissioner.

179 B. The commissioner may impose conditions on the issuance of a permit and no rainwater
180 harvesting system intended for Tier 4 end use may be installed or modified in violation of those
181 conditions.

182 B. Unless suspended or revoked pursuant to 12VAC5-635-190, construction permits for a
183 rainwater harvesting system intended for Tier 4 end use shall be valid for a period of 36 months
184 from the date of issuance.

185 C. An owner may install and operate a rainwater harvesting systems intended for Tier 1, 2 or
186 3 end-use without a permit. The owner of a Tier 1, 2, or 3 end use rainwater harvesting system
187 shall file a registration form with the department within 30 days of the following:

188 1. Installing a rainwater harvesting system;

189 2. Change of ownership of a rainwater harvesting system; or

190 3. Permanently closing a rainwater harvesting system.

191 **Statutory Authority**

192 §§ 32.1-12 and 32.1-248.2 of the Code of Virginia.

193 **12VAC5-635-100. Application procedures for a construction permit for a rainwater**
194 **harvesting system for Tier 4 end use.**

195 A. The owner of a proposed rainwater harvesting system shall sign and submit a written permit
196 application to the local health department for the locality where the proposed rainwater harvesting
197 system would be located, on an application form provided by the local health department, that
198 contains the following information:

199 1. The property owner's name, address, and telephone number;

200 2. The applicant's name, address, and telephone number (if different from the property
201 owner's);

202 3. A statement signed by the property owner, or agent, granting the department access to
203 the site to conduct a sanitary survey if underground water storage is proposed, and to
204 inspect the rainwater harvesting system after it is installed; and

205 4. Plans for the proposed rainwater harvesting system, including specifications, design
206 criteria, manufacturer's literature, a proposed schematic, a general layout of any
207 underground water storage, formal plans for multiple service connection systems, the
208 operation and maintenance manual required pursuant to 12VAC5-635-390, and other
209 supporting information or data the local health department or commissioner may request.

210 C. If underground storage of harvested rainwater is proposed, a general layout shall be
211 provided, and shall include topography, elevations, contour lines, existing or proposed streets and
212 all potential sources of contamination, bodies of water, ditches, buildings, springs, cisterns and
213 wells within 100 feet horizontally of the proposed storage units.

214 D. If the proposed rainwater harvesting system will provide Tier-4 end use water to multiple
215 service connections, the applicant shall include a formal plan as follows:

216 1. The plan shall have a cover sheet with suitable title showing the name of the owner,
217 date the plan was prepared, and the name of the licensed individual by or under whom
218 the plans were prepared. The cover sheet and each subsequent page shall bear the same
219 general title and each shall be numbered. Appropriate subtitles shall be included on
220 individual sheets.

221 2. The plan shall be clear and legible, and prepared to a scale that will permit necessary
222 information to be plainly shown.

223 3. The plan shall consist of plan views, elevations, sections, and supplementary views
224 which together with the specifications and general layouts provide the working information
225 for the contract and construction of the proposed rainwater harvesting system, including
226 dimensions and relative elevations of structures, the location and outline form of
227 equipment, the location and size of piping, water levels, ground elevations, and erosion
228 control abatement facilities.

229 4. The plan shall include the technical specifications for the construction of the rainwater
230 harvesting system and all appurtenances. The specifications shall include all construction
231 information not shown on the drawings, which is necessary to inform the builder in detail
232 of the design requirements as to the quality of material workmanship and fabrication of the
233 project; the type, size, strength, operating characteristics, and rating of equipment and
234 materials used in the construction and operation of the rainwater harvesting system;
235 allowable infiltration, machinery, valves, piping, and jointing of pipe, electrical apparatus,
236 wiring and meters; operating tools and construction materials; miscellaneous
237 appurtenances; chemicals when used; instructions for testing materials and equipment as
238 necessary to meet design standards and operating test for the complete works and
239 component units.

240 E. An application shall be deemed complete upon receipt by the local health department of a
241 signed and dated application on the approved application form.

242 **Statutory Authority**

243 §§ 32.1-12 and 32.1-248.2 of the Code of Virginia.

244 **12VAC5-635-110. Issuance of a construction permit.**

245 The commissioner shall issue construction permit to the owner no later than 60 days after
246 receipt of a complete application if:

247 1. According to the information on the application form, the proposed rainwater harvesting
248 system is compliant with this chapter and other applicable laws, ordinances and
249 regulations; and

250 2. The owner has obtained the easements pursuant to this chapter and attached the
251 documentation of the easement to the application.

252 **Statutory Authority**

253 §§ 32.1-12 and 32.1-248.2 of the Code of Virginia.

254 **12VAC5-635-120. Denial of a construction permit.**

255 If the commissioner determines that the proposed rainwater harvesting system is inadequate,
256 does not comply with this chapter, or that the installation and operation of the system would create
257 an actual or potential health hazard or nuisance, the commissioner shall deny the construction
258 permit application and notify the owner in writing, no later than 60 days after receipt of the
259 complete application, with the basis for the denial. The notification shall also state that the owner
260 has the right to appeal the denial in accordance with 12VAC5-635-190.

261 **Statutory Authority**

262 §§ 32.1-12 and 32.1-248.2 of the Code of Virginia.

263 **12VAC5-635-130. Revision of approved plans.**

264 A. The rainwater harvesting system designer, with the consent of the owner, may make certain
265 design changes to a proposed rainwater harvesting system for which a valid construction permit
266 has been issued without prior approval from the department if:

- 267 1. The design change does not change the design flow, the proposed filtration means and
268 standard, the proposed disinfection means and standard, or the log reduction targets;
269 2. The changed design for the rainwater harvesting system complies with applicable
270 statutes, codes, regulations, and policies;
271 3. The designer provides the department with complete documentation including a list of
272 changes and revised specifications, calculations and drawings as part of a revised design
273 package; and
274 4. The designer and owner ensure that design changes are communicated to the installer
275 of the rainwater harvesting system.

276 B. The commissioner may suspend or revoke a construction permit if a design change made
277 to the proposed rainwater harvesting system does not comply with this chapter. If the
278 commissioner revokes the construction permit, the owner must submit a new application before
279 continuing with the installation of the rainwater harvesting system.

280 C. The commissioner shall review changes made to the rainwater harvesting system before
281 issuing an operation permit pursuant to 12VAC5-635-170.

282 **Statutory Authority**

283 §§ 32.1-12 and 32.1-248.2 of the Code of Virginia.

284 **12VAC5-635-140. Installation inspection and correction.**

285 A. Upon completion of the installation, alteration, or rehabilitation of a rainwater harvesting
286 system intended for Tier 4 end use:

287 1. The owner or agent shall submit to the local health department a statement signed by
288 the installer certifying that the rainwater harvesting system was installed, altered or
289 rehabilitated in accordance with the construction permit and that the rainwater harvesting
290 system complies with applicable state and local regulations, ordinances and laws;

291 2. The designer shall thoroughly inspect the system installation to determine whether the
292 installation was completed substantially in accordance with the approved evaluation and
293 design, including any revisions made pursuant to 12VAC5-635-130; and

294 3. The designer shall submit to the local health department a signed inspection report
295 stating that the installation was completed substantially in accordance with the approved
296 evaluation and design revised only in accordance with the provisions of 12VAC5-635-130.

297 B. If the designer observes deficiencies during the inspection, the designer shall note the
298 deficiencies in their inspection report and include with the report a plan of correction that includes
299 the specific corrective actions that will be taken to bring the rainwater harvesting system into
300 compliance with this chapter, the date on which the corrective actions are to be completed, and
301 the date on which the designer will perform a follow-up inspection of the corrected rainwater
302 harvesting system.

303 C. After the follow-up inspection, the designer shall submit a signed inspection report to the
304 local health department stating whether the corrective actions have been taken and whether the
305 rainwater harvesting system is at that time installed in compliance with the approved evaluation
306 and design.

307 D. If the owner does not ensure completion of the corrective actions or the rainwater
308 harvesting system is otherwise not able to operate in compliance with this chapter, the
309 commissioner shall not issue an operation permit and may suspend or revoke the construction
310 permit pursuant to 12VAC5-635-190.

311 **Statutory Authority**

312 §§ 32.1-12 and 32.1-248.2 of the Code of Virginia.

313 **12VAC5-635-150. Requirement for an easement.**

314 A. If a rainwater harvesting system or a portion of the rainwater harvesting system is proposed
315 to be installed on property other than the owner's, the owner must obtain an easement in
316 perpetuity of sufficient area to permit access to install, maintain, and operate the rainwater
317 harvesting system components from the appropriate property owner and record the easement
318 with the clerk of the circuit court before issuance of a construction permit.

319 B. The owner shall submit legal documentation of the easement's recordation, or a signed
320 statement that the easement will be recorded within 45 days, to the appropriate local health
321 department with the application for a construction permit.

322 C. If the owner does not obtain, properly record, and submit documentation of the easement,
323 the owner may not install or operate the rainwater harvesting system on the property for which
324 the easement was denied.

325 **Statutory Authority**

326 §§ 32.1-12 and 32.1-248.2 of the Code of Virginia.

327 **12VAC5-635-160. Land records.**

328 A. Before the commissioner may issue an operation permit for a rainwater harvesting system
329 for Tier 4 end use, the owner must:

330 1. Record an instrument describing applicable annual water quality testing and
331 maintenance requirements for each component of the rainwater harvesting system in the
332 land records of the circuit court having jurisdiction over the site of the rainwater harvesting
333 system; and

334 2. Submit to the local health department legal documentation indicating that the instrument
335 has been duly recorded in the land records.

336 B. The instrument recorded pursuant to this section shall be transferred with the title to the
337 property upon the sale or other transfer of the property in which the rainwater harvesting system
338 is located.

339 **Statutory Authority**

340 §§ 32.1-12 and 32.1-248.2 of the Code of Virginia.

341 **12VAC5-635-170. Issuance of operation permit.**

342 A. No rainwater harvesting system intended for Tier 4 end use may be operated, except for
343 the purposes of testing the system, until the commissioner has issued an operation permit to the
344 owner.

345 B. If the owner has complied with the requirements of 12VAC5-635-140, 12VAC5-635-160,
346 and 12VAC5-635-170, the commissioner shall issue to the owner a permit to operate the
347 rainwater harvesting system intended for Tier 4 end use.

348 C. The issuance of an operation permit does not denote or imply a warranty or guarantee by
349 the department that the rainwater harvesting system will function for any specified period of time.
350 The owner shall maintain, repair, or replace a rainwater harvesting system that ceases to operate
351 as defined in the operation permit and operation and maintenance manual.

352 **Statutory Authority**

353 §§ 32.1-12 and 32.1-248.2 of the Code of Virginia.

354 **12VAC5-635-180. Variances.**

355 A. In accordance with § 32.1-12 of the Code of Virginia and this chapter, the commissioner
356 may grant a variance to a regulation of this chapter. A variance is a conditional waiver of a specific
357 regulation which is granted to a specific owner relating to a specific situation or facility and may
358 be for a specified time period.

359 B. The commissioner may grant a variance if an investigation reveals that, in the opinion of
360 the commissioner, a hardship imposed by a regulation within this chapter, including economic,
361 outweighs the benefits that may be received by the public and that granting the a variance does
362 not subject the public to unreasonable health risks or environmental pollution.

363 C. The owner shall submit a signed, written application for a variance to the appropriate local
364 health department. The application shall include:

- 365 1. A citation to the section to which a variance is requested;
- 366 2. The nature and duration of the variance requested;
- 367 3. Any relevant analytical results including results of relevant tests conducted pursuant to
368 the requirements of this chapter;
- 369 4. The specific hardship created by the regulation to which a variance is requested;
- 370 5. Statements or evidence that establishes that the public health, welfare, and the
371 environment, would not be adversely affected if the variance were granted;
- 372 6. Suggested conditions that might be imposed on the granting of a variance that would
373 limit the detrimental impact on the public health and welfare;
- 374 7. Other information believed pertinent by the applicant; and
- 375 8. Other information the local health department or commissioner may require.

376 D. In the evaluation of a variance application, the commissioner shall consider:

- 377 1. The effect that the variance would have on the construction, location, or operation of
378 the rainwater harvesting system;
- 379 2. The cost and other economic considerations imposed by the regulation to which the
380 variance is sought;
- 381 3. The effect that such a variance would have on protection of the public health, welfare,
382 and the environment;
- 383 4. Relevant analytical results including results of relevant tests conducted pursuant to the
384 requirements of this chapter; and
- 385 5. Information or materials on the application for a variance submitted per this section.

386 E. The commissioner shall not recognize as a hardship the cost to correct an error created by
387 a design change initiated by the owner or designer for which approval by the department was
388 required pursuant to 12VAC5-635-130 but was not obtained.

389 F. If the commissioner proposes to deny a variance request submitted pursuant to this section,
390 the commissioner shall notify the owner of the proposed denial within 60 calendar days of receipt
391 of the variance request and provide an opportunity for an informal fact-finding conference as
392 provided in § 2.2-4019 of the Code of Virginia. Following this opportunity for an informal fact-
393 finding conference the commissioner may deny an application for a variance by sending a written
394 denial notice to the owner that states the reasons for the denial.

395 G. If the commissioner proposes to grant a variance request submitted pursuant to this
396 section, the commissioner shall notify the owner, in writing, of the decision within 60 calendar
397 days of receipt of the variance request. The notice shall identify the regulation to which the
398 variance is granted, the rainwater harvesting system covered, the period of time for which the
399 variance will be effective, and the conditions imposed pursuant to issuing the variance.

400 H. The owner shall attach a physical copy of the variance to the permit.

401 I. Unless otherwise stated in the terms or conditions of the variance, the variance shall be
402 transferred with the permit if the owner of a rainwater harvesting system sells or otherwise
403 transfers ownership of the rainwater harvesting system to a new owner.

404 J. If a permit is revoked or suspended, variances attached to it shall also be revoked or
405 suspended.

406 **Statutory Authority**

407 §§ 32.1-12 and 32.1-248.2 of the Code of Virginia.

408 **12VAC5-635-190. Enforcements, notices, informal conferences, appeals.**

409 A. Rainwater harvesting systems shall be installed, operated, and maintained in compliance
410 with the requirements as set forth in this chapter. The commissioner may enforce this chapter
411 through the means lawfully available pursuant to Title 32.1 of the Code of Virginia, and nothing in
412 this chapter shall be construed as preventing the commissioner from making efforts to obtain
413 compliance through warning, conference, or other appropriate enforcement means.

414 B. The commissioner may deny a permit application or suspend or revoke a permit issued
415 pursuant to this chapter if:

416 1. The permit holder fails to comply with this chapter, applicable law, or a condition
417 imposed on the permit; or

418 2. The commissioner is made aware that:

419 a. The facts upon which the approval of a construction permit was based were
420 knowingly and willfully misrepresented; or

421 b. The installation or operation of the proposed rainwater harvesting system could
422 create a substantial or imminent public health or environmental hazard.

423 C. The commissioner shall notify the owner in writing via certified mail or via hand delivery.
424 Immediately upon receipt of a notice of suspension, the owner shall cease operation of the
425 rainwater harvesting system.

426 D. The owner of a permitted rainwater harvesting system shall ensure the continuity of water
427 supply to persons who use the rainwater harvesting system's treated water for human
428 consumption. If the owner demonstrates, to the satisfaction of the commissioner, that ceasing the
429 operation of a permitted rainwater harvesting system would endanger the health of the persons
430 who use the rainwater harvesting system's finished water, the commissioner may issue a variance
431 to the requirement to cease operation pursuant to 12VAC5-635-180.

432 E. Within 10 days of receipt of a notice of denial of an application or suspension of a permit,
433 the owner may request an informal conference in accordance with § 2.2-4019 of the Code of
434 Virginia. The owner must file the request for an informal conference, in writing, with the local
435 health department within the locality that the rainwater harvesting system is located. If a request
436 for an informal conference is not filed within 10 working days, the denial or suspension is
437 sustained.

438 F. Within 10 days of receipt of a notice of denial, suspension, or intent to revoke, the owner
439 shall submit to the appropriate local health department a plan of correction that includes:

440 1. The specific corrective actions that will be taken to address the reasons for denial,
441 suspension or revocation and bring the rainwater harvesting system into compliance with
442 this chapter and other applicable requirements;

443 2. The date on which the corrective actions are expected to be completed; and

444 3. If the rainwater harvesting system is in operation, an application for a construction
445 permit for alteration, repair, or rehabilitation of the rainwater harvesting system pursuant
446 to 12VAC5635-100.

447 G. Within 10 days of the receipt of the plan of correction, the department shall:

448 1. Notify the owner, in writing, if any item is determined to be unacceptable; and

449 2. Act on an application for a construction permit to perform repairs pursuant to this
450 section.

451 H If the owner does not submit a plan of correction or request an informal conference within
452 10 working days, the department shall notify the owner, in writing, that the application for a permit
453 is denied or that the permit is deemed suspended or revoked.

454 I. The department shall arrange for an informal conference to be held within seven working
455 days of receipt of a request for an informal conference pursuant to this section.

456 J. The commissioner may end a suspension and re-instate a permit at any time if the
457 conditions under which the permit was suspended have changed or no longer exist.

458 K. The owner must reapply for a permit in order to continue installing or operating a rainwater
459 harvesting system for which the permit has been revoked.

460 L. A plan of correction implemented pursuant to this section shall be attached to the operation
461 permit for the rainwater harvesting system.

462 **Statutory Authority**

463 §§ 32.1-12 and 32.1-248.2 of the Code of Virginia.

464

Part III

465 Design and Installation

466 **12VAC5-635-200. Cross connection abatement.**

467 A. "Cross connection" means a physical connection or arrangement between two otherwise
468 separate piping systems whereby there exists the possibility for flow from one system to the other,
469 with the direction of flow depending on the pressure differential between the two systems.

470 B. No rainwater harvesting system may be installed, operated, or allowed on any premises
471 where cross connection to a waterworks or a private well exists, unless the cross connections are
472 abated or controlled by means including cross connection control and backflow prevention in
473 accordance with the USBC. Where cross connection to a waterworks exists, the cross connection
474 shall be abated or controlled to the satisfaction of the waterworks.

475 **Statutory Authority**

476 §§ 32.1-12 and 32.1-248.2 of the Code of Virginia.

477 **12VAC5-635-210. Backflow prevention.**

478 A. "Backflow" means (i) the flow of water, other liquids, mixtures, or substances into the
479 distribution system of a pure water system from one or more sources other than its intended
480 source; or (ii) the reversal of the normal direction of flow.

481 B. A rainwater harvesting system shall be designed, installed, and maintained to prevent
482 contamination of secondary water supplies by backflow. Backflow prevention shall be achieved
483 by one or more of the following:

- 484 1. Backflow elimination methods including air gap separation or physical disconnection;
- 485 2. Backflow prevention assemblies including the reduced pressure principle, double check
486 valve, and pressure vacuum breaker assemblies; or
- 487 3. If backflow prevention is not generally required to withstand continuous pressure over
488 12 hours or to control high hazards, a backflow prevention device, including atmospheric
489 type vacuum breakers and dual check valve devices.

490 C. Backflow prevention assemblies and backflow prevention devices shall be suitable to the
491 application and shall conform to the USBC.

492 **Statutory Authority**

493 §§ 32.1-12 and 32.1-248.2 of the Code of Virginia.

494 **12VAC5-635-220. Water storage unit location.**

495 A. An underground water storage unit for a rainwater harvesting system shall be sited with
496 appropriate consideration given to distance from potential contamination sources, vulnerability to
497 known or suspected natural risks (e.g., flooding, sink holes, etc.), potential for interference with
498 utilities, and safety.

499 B. If the rainwater harvesting system will include an underground installation of a water
500 storage unit, the designer shall conduct a sanitary survey, including investigation of obvious
501 sources of toxic or dangerous substances within 200 feet of the water storage unit. Sources of
502 contamination may include items listed in Table 1. The minimum separation distance between an
503 underground water storage unit and sources of contamination shall comply with the minimum
504 distances shown in Table 1.

505 TABLE 1.

506 Separation distance between underground water storage unit and potential source of
507 contamination

<u>Potential Source of Contamination</u>	<u>Separation Distance (feet)</u>
<u>Active or permitted septic tank, holding tank, pump tank, aerobic unit, house sewer line, sewer line, sewer main, sewerage system</u>	<u>50</u>
<u>Active or permitted drainfield, including reserve drainfield</u>	<u>50</u>
<u>Permanently abandoned onsite sewage disposal system</u>	<u>35</u>
<u>Petroleum storage tank, drum, tote or other container (underground)</u>	<u>100</u>
<u>Petroleum storage tank, drum, tote or other container (aboveground)</u>	<u>50</u>

508 C. An aboveground water storage unit shall be installed on a sturdy and level foundation or
509 platform with adequate drainage capable of bearing the weight of the unit at capacity. If multiple
510 storage units are connected, compliant fittings must be used and installed in a manner that
511 provides adequate flexibility to allow for unit settlement or movement.

512 D. A water storage unit and associated pipes and pipe fittings and appurtenances to be
513 installed in locations subject to direct sunlight shall be constructed of materials stable under
514 ultraviolet light exposure anticipated over the life of the system.

515 E. A water storage unit shall be supported and restrained to prevent lateral movement.
516 Support and restraint devices may not be placed in a manner that will obstruct access for cleaning
517 and maintenance.

518 F. A water storage unit subject to a shallow water table shall be ballasted or otherwise secured
519 to prevent floatation or lateral movement. The unit shall be designed to withstand structural
520 stresses of hydrostatic pressure and buoyancy. If partially buried, design shall include provision
521 to withstand the weight of backfill.

522 G. A water storage unit subject to vehicular traffic shall be installed in accordance with
523 manufacturer's installation instructions and the USBC.

524 H. A water storage unit shall have at least one access opening to allow inspection and
525 cleaning of the unit interior. The access opening shall be located to facilitate pumping and
526 servicing of inlets and outlets. The access opening shall be locked or otherwise secured to prevent
527 unauthorized access and shall be located at a finished grade such that surface water ponding
528 does not occur under annual precipitation extreme conditions.

529 I. A water storage unit shall be fitted with an overflow discharge system with the following
530 requirements:

- 531 1. Overflow is not less than the capacity of the inlets;
- 532 2. Unit overflow pipes are protected from insects and vermin;
- 533 3. Piping associated with unit overflow discharge water away from the unit and in
534 accordance with the USBC;
- 535 4. Discharge of unit overflow is directed to prevent hazardous conditions;
- 536 5. No shutoff valves are incorporated into discharge piping;
- 537 6. Cleanouts are provided on overflow piping in accordance with the USBC;
- 538 7. If connected to storm drainage systems, they have a means to prevent backflow; and
- 539 8. Overflows are not directed to onsite sewage systems or sanitary sewers.

540 J. A water storage unit shall be fitted with a vent pipe having a minimum 38.1 mm diameter
541 protected with 1.5 mm mesh to prevent the entry of vermin and particulates.

542 **Statutory Authority**

543 §§ 32.1-12 and 32.1-248.2 of the Code of Virginia.

544 **12VAC5-635-230. Materials and equipment.**

545 A. Materials and equipment used in rainwater harvesting systems shall be labeled to
546 demonstrate compliance with applicable NSF 61 and NSF P151 standards, as appropriate.

547 B. Collection surfaces shall comply with the following requirements:

- 548 1. Collection roofing are composed of non-toxic materials;
- 549 2. Paint used on surfaces used for collection of rainwater for potable purposes is labeled
550 to be certified to NSF/ANSI/CAN Standard 61-2020 or P151 and applied per the
551 manufacturer's installation instructions;
- 552 3. Lead- chromium-, or zinc- based paints are not used;
- 553 4. Galvanized metal is not used;
- 554 5. Flat roof products are labeled as meeting NSF Protocol P151;
- 555 6. Equipment and appliances mounted on collection surfaces have a means of preventing
556 the introduction of contaminants into the rainwater harvesting system;
- 557 7. Equipment and appliances containing toxic fluids or other potentially harmful
558 substances are not installed on collection surfaces or in locations where a release of
559 contained substances will flow by gravity to collection surfaces; and
- 560 8. Materials used for collection surfaces conform to end use tier criteria pursuant to Table
561 2.

562 TABLE 2.

563 <u>Collection Surface Materials</u>	
<u>Roofing Material (including flashing)</u>	<u>Acceptable for End Use Tier</u>
<u>Asbestos cement</u>	<u>Not acceptable for any end use</u>

<u>Asphalt</u>	<u>1, 2, 3, 4</u>
<u>Asphalt felt and bituminous and tar membranes</u>	<u>1, 2, 3</u>
<u>Ceramic</u>	<u>1, 2, 3, 4</u>
<u>Clay</u>	<u>1, 2, 3, 4</u>
<u>Concrete</u>	<u>1, 2, 3, 4</u>
<u>Copper</u>	<u>1, 2, 3</u>
<u>Fiberglass</u>	<u>1, 2, 3, 4</u>
<u>Glass</u>	<u>1, 2, 3, 4</u>
<u>Polyethylene membrane</u>	<u>1, 2, 3, 4</u>
<u>Polymer and acrylic</u>	<u>1, 2, 3</u>
<u>Rubber/Butyl/EPDM membrane</u>	<u>1, 2, 3</u>
<u>Steel, coated</u>	<u>1, 2, 3, 4</u>
<u>Steel, stainless</u>	<u>1, 2, 3, 4</u>
<u>Tin</u>	<u>1, 2, 3, 4</u>
<u>Wood, untreated</u>	<u>1, 2, 3</u>
<u>Wood, treated</u>	<u>1, 2, 3</u>
<u>PVC</u>	<u>1, 2, 3, 4</u>
<u>TPO</u>	<u>1, 2, 3</u>
<u>Public pedestrian accessible roofs</u>	<u>1, 2, 3</u>
<u>Vegetated roofs</u>	<u>1, 2, 3</u>
<u>Pedestrian and parking surfaces (rooftop)</u>	<u>1, 2, 3</u>

564 C. The conveyance system shall be protected to prevent the entrance of vermin. Inlets, debris
565 excluders, filters, first-flush diverters, cleanouts, and conveyance system components requiring
566 service shall be accessible. To convey captured rainwater, rainwater harvesting systems shall
567 use drainage piping suitable for use with plumbing drainage or pressure systems. Conveyance
568 system materials shall be labeled to demonstrate compliance with NSF/ANSI/CAN Standard 61-
569 2020.

570 D. A cistern or water storage unit, liners, coatings, pipes, pipe fittings, and appurtenances
571 shall be labeled to demonstrate compliance with the applicable requirements of NSF
572 61/ANSI/CAN Standard 61-2020 and NSF 372. The water storage unit shall be manufactured
573 from previously unused materials, and no cistern or storage unit previously used to store anything
574 other than water may be incorporated into a rainwater harvesting system. The water storage unit
575 may be installed either above or below grade, and provided a means for emptying and cleaning.
576 If gravity drainage is not possible, a provision for pumping water from the unit shall be provided.

577 E. Water contained in an aboveground water storage unit shall be protected from direct
578 sunlight through the use of opaque, ultraviolet-resistant materials or a sun barrier.

579 F. An underground water storage unit shall be installed in compliance with OSHA Standard
580 1926 Subpart P, and shall be provided with manhole risers a minimum of 6 inches above
581 surrounding grade.

582 G. Pump and pump components shall be capable of delivering a minimum of 15 pounds per
583 square inch in gauge residual pressure at the highest and most remote outlet served. Maximum
584 pressure should not exceed 80 pounds per square inch in gauge.

585 H. Water piping, fittings, and related system components shall be appropriate for use in
586 accordance with the USBC. Where plastic piping is exposed to sunlight, it shall be protected by a
587 factory applied protective coating or painted with compatible latex paint.

588 **Statutory Authority**

589 §§ 32.1-12 and 32.1-248.2 of the Code of Virginia.

590 **12VAC5-635-240. Design and installation.**

591 A. The rainwater harvesting system shall be designed, installed, operated, and maintained to
592 prevent contamination of water supplies and distribution piping.

593 B. Rainwater harvesting system components shall be protected from external contamination
594 and entry by insects and vermin.

595 C. The rainwater harvesting system shall be sited and designed to produce and store water
596 under local site conditions that include:

597 1. Excessive heat;

598 2. Freezing;

599 3. Flooding; and

600 4. Sunlight exposure.

601 D. The owner shall control access to rainwater harvesting system components to minimize
602 unauthorized access.

603 E. Gutters, downspouts, and conveyance systems leading to the water storage unit shall be
604 fitted with a screen or debris excluder to prevent the accumulation of leaves, needles, or other
605 debris into the water storage tank or cistern.

606 F. Vegetation above roofs and gutters shall be removed to reduce organic matter falling on
607 and decomposing in rainwater collection surfaces and conveyances, and to reduce or remove
608 locations for animals to introduce contaminants.

609 G Rainwater shall pass through a pre-filtration system prior to entering the water storage unit
610 or cistern. Appropriate pre-filtration devices include a gutter screen, inline filters, and vortex filters
611 to reduce organic matter, debris, and particulates from entering and accumulating in the bottom
612 of the unit or cistern. Pre-filtration devices without a self-cleaning design shall incorporate a
613 corrosion resistant debris screen having openings no larger than 0.15 cm.

614 H. A first flush device shall be used to remove accumulated debris from the collection surface
615 before rainwater is introduced to the water storage unit. First flush diverters shall:

616 1. Be placed after pre-filtration;

617 2. Operate automatically and not rely on mechanically operated valves or devices;

618 3. Discharge diverted rainwater in a manner consistent with local stormwater runoff
619 requirements so as not to cause damage to a property or erosion; and

620 4. Be readily accessible for maintenance.

621 I. Inlets and outlets on the water storage unit shall be installed and supported in accordance
622 with the manufacturer's instructions. Water storage units, including units used in series, shall each
623 be fitted as follows:

624 1. Rainwater inlets to a water storage unit shall be arranged to minimize turbulent flow by
625 means of a calming device such as a return bend elbow pointed upward at least 10 cm
626 above the bottom of the tank.

627 2. Outlets shall be positioned and floating collared offtakes shall be used below the top
628 water level in the unit to draw water from the cleanest strata of the unit.

629 3. Overflow outlets or flap valves shall be protected with a screen having openings no
630 greater than 1.5 mm to prevent entrance of insects or vermin into the unit.

631 4. The vent shall be minimum 38.1 mm diameter and be protected with mesh having
632 openings no greater than 1.5 mm to prevent entrance of vermin and particulates.

633 5. Rainwater outlets and pump suction shall be located at least 100 mm above the bottom
634 of the unit. If a floating pump is used, it shall draw water from below the water surface.

635 6. Pipe penetrations through unit walls shall be watertight and shall comply with the USBC.
636 Pipe penetrations shall not prevent access to the unit for inspection or cleaning.

637 J. A rainwater harvesting system shall be equipped with filtration systems conforming to the
638 standards specified in 12VAC5-635-250 and 12VAC5-635-340 and shall:

639 1. Be installed in accordance with the USBC;

640 2. Be accessible for inspection and maintenance;

641 3. Provide indication when servicing or replacement is due; and

642 4. Incorporate shutoff valves immediately upstream and downstream to allow for isolation
643 during maintenance.

644 K. A rainwater harvesting system shall be equipped with disinfection systems that:

645 1. Conform with the standards specified in 12VAC5-635-260 and 12VAC5-635-340; and

646 2. Are designed and installed in accordance with the manufacturer's instructions and the
647 USBC.

648 L. A rainwater harvesting system for Tier 3 and Tier 4 end use shall be equipped with a fail-
649 safe system for disinfection systems, with alerts and alarms as follows:

650 1. Alerts shall be provided for critical control points identified in the operation and
651 maintenance manual to indicate when the rainwater harvesting system is operating
652 outside design parameters but not causing a hazard to health or safety or damage to
653 system components.

654 2. Alerts shall have a visible output and may have an audible output.

655 3. Alarms shall be provided for critical control points identified in the operation and
656 maintenance manual to indicate when the rainwater harvesting system is operating
657 outside the design parameters and potentially causing a hazard to health or safety or
658 damage to system components.

659 4. Alarms shall have visible and audible outputs.

660 5. A remote alarm of an alert system using electronic communication shall be used to
661 notify the operator that the system has failed or that failure is imminent.

662 M. Separation shall be maintained between potable and non-potable distribution systems by
663 means of color coded and labeled piping and cross connection control in accordance with the
664 USBC.

665 N. Controls for rainwater harvesting systems supplying water for fire sprinkler systems or
666 standpipes shall comply with the Virginia Statewide Fire Prevention Code Act (§ 27-94 et seq. of
667 the Code of Virginia).

668 O. If a rainwater harvesting system is applied to any building, facility, or residence, it shall be
669 so indicated as follows:

670 1. Fixtures not specifically treated for potable water use shall be labeled for non-potable
671 use in accordance with the USBC.

672 2. Fixtures not subject to the USBC and not specifically treated for potable water use, shall
673 be prominently labeled "CAUTION: NON-POTABLE WATER – DO NOT DRINK" and
674 "ATENCIÓN: AGUA NO-POTABLE – NO BEBER." Labels shall be indelibly printed on a
675 tag or sign constructed of a corrosion resistant, waterproof material permanently mounted
676 in a visible location. The letters of the labels and markings shall be at least 0.5 inches in
677 height and shall be of a color that contrasts with the background on which they are printed.

678 In addition to the required words, a pictograph consistent with the following shall appear
679 in the tag or sign:



680
681 **Statutory Authority**

682 §§ 32.1-12 and 32.1-248.2 of the Code of Virginia.

683 **12VAC5-635-250. Filtration.**

684 A. The owner shall ensure that harvested rainwater for Tier 2, Tier 3, and Tier 4 end use is
685 filtered.

686 B. Filtration is not required for Tier 2 end use water used outdoors.

687 C. If ultraviolet disinfection is used, particulate filtration systems shall be located downstream
688 of the water storage tank and upstream of the ultraviolet system.

689 D. If ozone or chemical based disinfection is used, particulate filtration systems shall be
690 installed downstream of the disinfection equipment. Filtration shall be installed as required for the
691 disinfection system and in accordance with manufacturer's installation requirements.

692 E. Filters shall be sized to extend service time and shall be labeled to demonstrate compliance
693 with NSF 42 for the reduction of taste or odor or NSF 53 for organic and cyst removal based on
694 the end use tier.

695 **Statutory Authority**

696 §§ 32.1-12 and 32.1-248.2 of the Code of Virginia.

697 **12VAC5-635-260. Disinfection.**

698 A. The owner shall ensure that harvested rainwater intended for Tier 2, 3, or 4 end use is
699 disinfected and that water meeting the quality standards in 12VAC5-635-310 is delivered to the
700 point of use.

701 B. The owner shall ensure that disinfection systems are designed and installed in accordance
702 with the manufacturer's instructions and the USBC.

703 C. If a rainwater harvesting system requires a disinfection system pursuant to this section, the
704 owner shall use one of the following acceptable methods:

705 1. An ultraviolet (UV) disinfection system that (i) treats water for distribution downstream
706 of the water storage unit and upstream of the point of use; (ii) is sized based on the
707 required dose, taking into consideration the design flow and minimum UV Transmittance
708 required to achieve the end use tier standard; and (iii) for Tier 4 end use, is labeled to be
709 certified to Class A of NSF 55;

710 2. An ozone disinfection system that maintains adequate contact time based on end use
711 tier and off-gasses to a safe environment; or

712 3. A chemical systems that:

713 a. Has means to measure and control the disinfection and oxidation levels to achieve
714 the performance requirements in 12VAC5-635-310;

715 b. Uses chemical feed pumps that are controlled to prevent operation unless there is
716 flow through the system;

717 c. Is labeled to be certified to provide the required log-reductions for protozoa and
718 bacteria pursuant to NSF 53 or NSF/ANSI 419-2018;

719 d. Uses chemicals that are labeled to demonstrate compliance with NSF/ANSI/CAN
720 Standard 60-2020 if water is provided for Tier 4 end use; and

721 e. Maintains a chlorine residual of at least 0.5 mg/L and control disinfection by-
722 products if untreated harvested rainwater is stored at temperatures higher than 77°F
723 and chlorine disinfection is used.

724 D. A rainwater harvesting system for end use in a single-family home shall only use ultraviolet
725 or ozone disinfection methods.

726 E. The department may approve other disinfection methods on a case-by-case basis.

727 **Statutory Authority**

728 §§ 32.1-12 and 32.1-248.2 of the Code of Virginia.

729 **12VAC5-635-270. General certification.**

730 A. Pre-manufactured treatment systems, and equipment and materials used to assemble
731 treatment systems that are not pre-manufactured, shall be labeled to demonstrate that the
732 systems, equipment and materials comply with NSF standards, as follows:

733 1. NSF/ANSI 53-2020 for point-of-entry or point-of-use filtration systems;

734 2. NSF/ANSI 55-2020 for ultraviolet disinfection systems;

735 3. NSF/ANSI/CAN 60-2020 for water treatment chemicals;

736 4. NSF/ANSI/CAN 61-2020 for protective barrier materials, joining and sealing materials,
737 mechanical devices, plumbing devices, pipes, hoses, pipe fittings, process media, and
738 non-metallic potable water materials; and

739 5. NSF/ANSI 350-2020 and NSF/ANSI/CAN 350.1-2017 for material, design, construction,
740 and performance requirements for reuse water.

741 B. Harvested rainwater is not reuse water. However, NSF/ANSI 350-2020 and
742 NSF/ANSI/CAN 350.1-2017 establish baseline standards suitable for equipment and materials
743 used in the design, installation and operation of rainwater harvesting systems.

744 C. A person providing design, installation, or inspection of rainwater harvesting systems shall
745 be certified by the American Society of Sanitary Engineering (ASSE) as follows:

746 1. Rainwater Harvesting System Designers shall maintain ASSE 21120 Rainwater
747 Catchment Systems Designer certification.

748 2. Rainwater Harvesting System Installers shall maintain ASSE 21110 Rainwater
749 Catchment Systems Installer certification.

750 3. Rainwater Harvesting System Inspectors shall maintain ASSE 21130 Rainwater and
751 Stormwater Catchment Systems Inspector certification.

752 **Statutory Authority**

753 §§ 32.1-12 and 32.1-248.2 of the Code of Virginia.

754 **12VAC5-635-280. Temporary removal from service.**

755 If a rainwater harvesting system is seasonally or temporarily removed from service, the owner
756 or operator shall:

- 757 1. Lock out or disable piping connected to a waterworks;
- 758 2. Secure water storage units from unauthorized access;
- 759 3. Divert inlet piping as necessary; and
- 760 4. Disconnect electrical power.

761 **Statutory Authority**

762 §§ 32.1-12 and 32.1-248.2 of the Code of Virginia.

763 Part VI

764 Performance Requirements

765 **12VAC5-635-290. Performance requirements; general.**

766 A. The owner shall ensure that a rainwater harvesting system operates in compliance with the
767 following performance requirements:

- 768 1. For a rainwater harvesting system designed to supply water for Tier 2, 3 or 4 end use,
769 the owner or operator shall conduct treatment using a combination of filtration and
770 disinfection technologies to the minimum standards described in 12VAC5-635-310.
- 771 2. If a rainwater harvesting system provides water for multiple end uses and treatment is
772 not separated by end use, the highest treatment standard shall apply for all uses.
- 773 3. If a rainwater harvesting system provides water for multiple end uses and treatment is
774 separated by end use, connection to distribution for each end use shall comply with the
775 USBC.
- 776 4. The designer of water treatment systems shall consider the anticipated harvested
777 rainwater characteristics and flow, including consideration of extremes of precipitation
778 patterns. Excess precipitation not captured for storage shall be discharged as runoff.
779 Insufficient precipitation that does not allow a rainwater harvesting system permitted for
780 Tier 2, 3, 4 end use to maintain sufficient storage shall be managed as described in
781 12VAC5-635-300.
- 782 5. The designer of a rainwater harvesting system shall allow for the prevention of
783 potentially harmful precipitation, such as that which could incorporate particulates from
784 fires, from being captured and contained in the system.
- 785 6. The designer of a rainwater harvesting system shall incorporate components of
786 sufficient structural integrity to minimize the potential of physical harm to humans and
787 animals.

788 B. The designer shall size the system in recognition of both the available collection area and
789 number of users of the harvested rainwater. A rainwater harvesting system designed to supply
790 water for Tier 4 end use for a residence shall be capable of providing 150 gallons per bedroom
791 per day. If Tier 4 end use will not include residential use, the designer shall provide calculations
792 supporting the anticipated demand.

793 **Statutory Authority**

794 §§ 32.1-12 and 32.1-248.2 of the Code of Virginia.

795 **12VAC5-635-300. Continuity of water supply.**

796 A. "Continuity of water supply" means that a continuous supply of water can be provided to a
797 distribution system supplied by a rainwater harvesting system in the event of insufficient
798 precipitation or other circumstances affecting the supply of harvested rainwater.

799 B. If a rainwater harvesting system serves as a secondary supply for a distribution system and
 800 the primary supply is a waterworks, the rainwater harvesting system shall be an auxiliary water
 801 system pursuant to the requirements of the USBC and 12VAC5-900.

802 C. If a rainwater harvesting system serves as a primary supply for a distribution system for a
 803 Tier 2, 3, or 4 end use, a secondary water supply shall be provided by a waterworks, a Class III
 804 private well, or commercially hauled water meeting pure water standards.

805 D. A secondary water supply from a waterworks or private well shall be supplied by a means
 806 to refill the water storage unit or a bypass that provides water directly to the distribution system.

807 E. Commercially hauled water shall only be used to refill a water storage unit prior to filtration
 808 and treatment.

809 F. When water from a secondary water supply is added to a water storage unit, it shall be
 810 introduced through a reverse pressure principle backflow device or an air gap pursuant to the
 811 USBC.

812 **Statutory Authority**

813 §§ 32.1-12 and 32.1-248.2 of the Code of Virginia.

814 **12VAC5-635-310. Water quality standards.**

815 A. The owner shall perform initial water quality testing before the use of water from the
 816 rainwater harvesting system and subsequent water quality sampling and testing consistent with
 817 the schedule in 12VAC5-635-320 and in accordance with the operation and maintenance manual
 818 requirements of this chapter.

819 B. The owner shall:

- 820 1. Flush the system at least once with treated harvested rainwater before water quality
 821 testing and discharge the flush water as wastewater;
- 822 2. Collect samples for water quality testing from a point-of-use outlet intended for regular
 823 use, such as a kitchen sink;
- 824 3. Collect first draw samples of one liter for lead testing;
- 825 4. Ensure that water quality samples are analyzed by a laboratory certified by the Division
 826 of Consolidated Laboratory Services for drinking water samples; and
- 827 5. Ensure that the water is tested in accordance with the minimum performance criteria in
 828 Tables 3 and 4 and, at minimum, for total coliform or E. coli present, total nitrate and nitrite
 829 content, protozoan cysts, cryptosporidium, pH, and lead content.

830 TABLE 3.

831 Minimum Performance Requirements

		<u>Application</u>			<u>Log Reduction Target</u>			
<u>End Use Tier</u>	<u>Category</u>	<u>Potential for Human Contact</u>	<u>Example Use</u>	<u>Viruses</u>	<u>Bacteria</u>	<u>Protozoa</u>	<u>pH</u>	
1	<u>Non-potable</u>	<u>Low</u>	<u>Trap primers</u> <u>Spray irrigation (restricted access)</u>	<u>0*</u>	<u>0</u>	<u>0</u>	<u>na</u>	

				<u>Surface and subsurface irrigation</u>				
				<u>Ice rinks</u>				
				<u>Toilet and urinal flushing</u>				
				<u>Clothes washing</u>				
2	<u>Non-potable</u>	<u>Medium</u>		<u>HVAC evaporative cooling</u>	<u>0*</u>	<u>2 log</u>	<u>2 log</u>	<u>na</u>
				<u>Rooftop thermal cooling</u>				
				<u>Hose bibs</u>				
				<u>Pressure washing</u>				
				<u>Decorative fountains</u>				
				<u>Vehicle washing</u>				
3	<u>Non-potable</u>	<u>High</u>		<u>Spray irrigation (non-restricted access)</u>	<u>0*</u>	<u>3 log</u>	<u>3log</u>	<u>na</u>
				<u>Fire fighting or protection and fire suppression</u>				
				<u>Human consumption</u>	<u>0*</u>	<u>6 log</u>	<u>6 log</u>	<u>7-10.5</u>

832 * It is unlikely that human infectious viruses are present in harvested rainwater. However, if
833 underground water storage tanks are used where there is a potential for sewage contamination
834 or surface water infiltration, a 4 log reduction for viruses shall be required.

835 TABLE 4.

836 Requirements for Tier 4 Potable Water

Design standards

Filtration 5 µm

Disinfection 40 mi/cm² and labeled certified to Class A of NSF/ANSI 55

Water Quality Parameters

Turbidity <0.3 NTU

Lead <15 µg/L

Nitrates <10 µg/L

837 C. Before the commissioner issues an operation permit for a rainwater harvesting system
838 intended for Tier 4 use, the owner must document that the treated harvested rainwater has been
839 tested and meets primary and secondary U.S. Environmental Protection Agency drinking water

840 standards. If a primary drinking water standard is exceeded, the owner may provide additional
841 treatment to address the exceedance and shall resample the treated harvest rainwater to ensure
842 compliance with the primary drinking water standard.

843 D. The owner shall conduct water quality sampling and monitoring in accordance with the
844 procedures approved under 40 CFR Part 136 or alternative methods approved by the department,
845 unless other procedures have been specified in this chapter.

846 E. The designer shall identify the rainwater harvesting system's water quality sampling points,
847 which shall be downstream of the treatment steps and upstream of the point of use. If Total
848 Residual Chlorine is used to measure compliance in a system using chlorine disinfection, the
849 sampling point must be downstream of the chlorine contact tank. If UV disinfection is used, the
850 owner may not use water samples collected upstream of UV disinfection units for dosage
851 adjustment for the purposes of water quality testing pursuant to this section.

852 **Statutory Authority**

853 §§ 32.1-12 and 32.1-248.2 of the Code of Virginia.

854 Part V

855 Operation and Maintenance Requirements

856 **12VAC5-635-320. Operator requirements; Frequency of inspection.**

857 A. The owner of a rainwater harvesting system shall ensure that the rainwater harvesting
858 system is inspected by an operator in accordance with Table 5.

859 TABLE 5.

860 Minimum operator visit frequency for rainwater harvesting systems

<u>End Use Tier</u>	<u>Initial Inspection</u>	<u>Regular Inspection Schedule</u>
<u>1</u>	<u>Prior to the system entering service</u>	<u>As needed</u>
<u>2, 3</u>	<u>Prior to the system entering service</u>	<u>Every 12 months while structure is occupied. If system only provides water for outdoor use, then as needed</u>
<u>4 (single service connection)</u>	<u>Condition of issuance of Operation Permit</u>	<u>Every 180 days while structure is occupied.*</u>
<u>4 (multiple service connections)</u>	<u>Condition of issuance of Operation Permit</u>	<u>Every 90 days while any connection serves an occupied structure.*</u>

861 *If a structure is vacant longer than the regular inspection cycle in Table 5, an operator shall
862 inspect the rainwater harvesting system prior to the structure becoming reoccupied.

863 B. The operator shall collect water quality samples from a rainwater harvesting system
864 pursuant to 12VAC5-635-300 during the initial and regular inspections by the operator.

865 **Statutory Authority**

866 §§ 32.1-12 and 32.1-248.2 of the Code of Virginia.

867 **12VAC5-635-330. Operation and maintenance; operator's responsibility.**

868 A. The operator of the rainwater harvesting system shall be certified as a designer, installer,
869 or inspector pursuant to 12VAC5-635-270 C. Nothing in this chapter shall preclude the owner
870 from being an operator if they are appropriately certified.

871 B. When the operator performs an inspection of the rainwater harvesting system, the operator
872 shall perform the assessments required by this chapter through visual or other observations and
873 through laboratory or other tests as required and may use additional observation methods or tests
874 that the operator deems appropriate.

875 C. The operator shall maintain a written log for each rainwater harvesting system for which
876 the operator is responsible that contains, at minimum, the following items:

- 877 1. Results of testing and sampling;
- 878 2. Information regarding reportable incidents, including the corrective action required and
879 taken;
- 880 3. Maintenance, corrective actions, and repair activities that are performed for purposes
881 other than a reportable incident; and
- 882 4. Recommendations for repair and replacement of system components.

883 D. If the owner of a rainwater harvesting system is not the operator, the operator shall provide
884 an updated copy of the log to the owner each time it is updated and shall document the dates the
885 copies are given to the owner in the log. The operator shall also make an accurate, up-to-date
886 copy of the log available to the department upon request.

887 E. When performing activities pursuant to an inspection required by this chapter, the operator
888 is responsible for the entire rainwater harvesting system, including treatment components,
889 collection area components, and associated piping.

890 F. The operator shall follow the procedures and instructions provided in the approved
891 operation and maintenance manual for the rainwater harvesting system.

892 **Statutory Authority**

893 §§ 32.1-12 and 32.1-248.2 of the Code of Virginia.

894 **12VAC5-635-340. Operation and maintenance; owner's responsibilities.**

895 The owner shall:

- 896 1. Ensure the rainwater harvesting system is operated and maintained by a qualified
897 operator;
- 898 2. Ensure that the operator performs the required duties;
- 899 3. Maintain a copy of the log provided by the operator on the property where the rainwater
900 harvesting system is located, make the log available to the department upon request, and
901 make a reasonable effort to transfer the log to the subsequent owner;
- 902 4. Follow the approved operation and maintenance manual and keep a copy of the
903 operation and maintenance manual for the rainwater harvesting system on the property
904 where the system is located, make the operation and maintenance manual available to
905 the department upon request, and make a reasonable effort to transfer the operation and
906 maintenance manual to the subsequent owner;
- 907 5. Comply with applicable rainwater harvesting system requirements contained in this
908 chapter; and
- 909 6. If applicable, inform users of the system of reportable incidents.

910 **Statutory Authority**

911 §§ 32.1-12 and 32.1-248.2 of the Code of Virginia.

912 **12VAC5-635-350. Operation and maintenance manual.**

913 A. The owner and operator shall maintain and operate a rainwater harvesting system in
914 accordance with the approved operation and maintenance manual.

915 B. The manual shall be easily understandable to the owner and operator and include, at
916 minimum, the following items:

917 1. Basic identifying information for the rainwater harvesting system, including the location
918 and intended end use;

919 2. Basic information regarding the rainwater harvesting system design including treatment
920 unit capacity, a list of components in the system, a schematic of the system, sampling
921 locations, and contact information for replacement parts for each unit;

922 3. A list of control functions and how to use them;

923 4. Operation, maintenance, sampling, inspection, and reporting schedules for the
924 rainwater harvesting system;

925 5. The design limits of the rainwater harvesting system design and how to operate the
926 system within those design limits;

927 6. Technical information, including:

928 a. Catchment area dimensions;

929 b. Roofing materials and sealants;

930 c. Vertical conveyance materials;

931 d. Water storage unit information including volume, size dimensions, whether the unit
932 is covered or uncovered, whether the unit is above or below ground, construction
933 materials, and location;

934 e. Pre-filtration information including type of pre-filtration used, quantity, filtration
935 particle size, and location;

936 f. Pump system information including the brand, make, model, capacity and heads,
937 and horsepower;

938 g. Disinfection system information including the brand, make, model, parts numbers,
939 date of manufacture, and date of installation for each component;

940 h. Additional manufacturer's instructions, such as schematics and diagrams provided
941 with components of the rainwater harvesting system; and

942 i. Water quality verification procedures, frequency, parameters, sampling locations,
943 records policies and procedures, and a sample log entry form;

944 7. Inspection and maintenance procedures, to include (i) the procedures for inspecting
945 and cleaning water storage tanks and piping, and (ii) periodic cross connection inspection;
946 and

947 8. Other information deemed necessary or appropriate by the designer.

948 C. The manual for a rainwater harvesting system intended for Tier 4 end use shall also contain
949 the following:

950 1. A list of water quality monitoring requirements, including sample locations, tests to be
951 performed, testing methods, and the applicable water quality standard;

952 2. Provisions for the determination of temporary or emergency alternate water supply, the
953 conditions under which an alternate water supply is required, the procedures for ensuring
954 continuity of water supply, when bottled water should be used, and the conditions that
955 require boil water practices for cooking and drinking;

956 3. Criteria for ensuring the continuity of water supply, to include (i) a low capacity alarm
957 for water storage, (ii) bypass protocol, including backflow and cross-connection
958 prevention, and (iii) applicable reporting criteria;

959 4. Provisions for documenting the easement and land records requirements of this
960 chapter; and

961 5. Identification of what incidents qualify as a reportable incident and the appropriate
962 response, including:

- 963 a. An alarm event lasting more than 24 hours;
- 964 b. An alarm event that reoccurs following corrective action;
- 965 c. Failure to achieve one or more performance requirements;
- 966 d. Failure to achieve one or more quality standards;
- 967 e. Replacement of a major component of the system, including electric and electronic
968 components; and
- 969 f. Actual or suspected contamination.

970 D. If the manual includes requirements for operation, maintenance, sampling, or inspection
971 schedules that exceed the minimum requirements of this chapter, the designer shall determine
972 the additional requirements based on the proposed end use of the harvested rainwater, design
973 flow and unit treatment processes of the rainwater harvesting system, and other factors.

974 E. The manual shall include regional, local, and site-specific water concerns.

975 **Statutory Authority**

976 §§ 32.1-12 and 32.1-248.2 of the Code of Virginia.

977 **12VAC5-635-360. Inspection requirements.**

978 A. During an inspection, the operator shall review and evaluate the operation of the rainwater
979 harvesting system, perform routine maintenance, make adjustments, and replace worn or
980 dysfunctional components with functionally equivalent parts such that the system can reasonably
981 be expected to return to normal operation.

982 B. If a rainwater harvesting system permitted for Tier 4 end use is not functioning as designed
983 or in accordance with the performance requirements of this chapter and, in the operator's
984 professional judgment, cannot be reasonably expected to return to normal operation through
985 routine operation and maintenance, the operator shall report immediately to the owner the
986 remediation efforts necessary to return the rainwater harvesting system to normal operation,
987 including recommendation for temporary or emergency alternate water supply if the system does
988 not provide water acceptable for human consumption.

989 **Statutory Authority**

990 §§ 32.1-12 and 32.1-248.2 of the Code of Virginia.

991 **12VAC5-635-370. Inspection Reports.**

992 A. For an inspection conducted for a rainwater harvesting system intended for Tier 2 or 3 end
993 use, the operator shall document the observations and findings of the inspection and provide
994 documentation to the department if requested by the department.

995 B. For an inspection conducted for a rainwater harvesting system permitted for Tier 4 end use,
996 the operator shall file an inspection report, on a form approved by the department, with the local
997 health department in the locality where the rainwater harvesting system is located. The report
998 shall be filed no later than 45 calendar days following the date on which the inspection occurred
999 and shall include the following minimum elements:

- 1000 1. The name and certification number of the operator;
- 1001 2. The date and time of the inspection;
- 1002 3. The purpose of the inspection, such as required inspection, follow-up, or reportable
1003 incident;
- 1004 4. A summary stating:

1005 a. Whether the rainwater harvesting system is functioning as designed and in
1006 accordance with the performance requirements of this chapter;

1007 b. Whether the operator believes the rainwater harvesting system will return to normal
1008 operation after providing maintenance; or

1009 c. If the rainwater harvesting system is not functioning as designed or in accordance
1010 with the performance requirements of this chapter, (i) the actions required to return the
1011 rainwater harvesting system to normal operation, including provisions for a temporary
1012 alternate water supply, if applicable; and (ii) that the owner has been advised that
1013 failure to take action to return the system to normal operation represents a risk to public
1014 health and may subject the owner to enforcement action from the department.

1015 5. Maintenance performed or adjustments made, including parts replaced;

1016 6. The results of field measurements, water quality sampling, and observations;

1017 7. The name of the laboratory that analyzed samples, and

1018 8. A statement certifying the date the operator provided a written copy of the report to the
1019 owner.

1020 C. If actions are required by the owner to return the rainwater harvesting system to normal
1021 operation or provide a temporary alternate water supply, or the operator has identified that failure
1022 to repair the rainwater harvesting system may result in a hazard to public health or the
1023 environment, the operator shall file the report summary with the local health department within 24
1024 hours of the inspection.

1025 **Statutory Authority**

1026 §§ 32.1-12 and 32.1-248.2 of the Code of Virginia.

1027 FORMS (12VAC5-635)

1028 FORMS (12VAC5-635)

1029 Commonwealth of Virginia Application for Tier 4 End Use Rainwater Harvesting System (eff.
1030 04/22).

1031 Commonwealth of Virginia Inspection Report: Tier 4 End Use Rainwater Harvesting System
1032 (eff. 04/22).

1033 Registration for Rainwater Harvesting System: Tier 1, 2, or 3 End Use (eff. 04/22).



COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448
RICHMOND, VA 23218

COLIN M. GREENE, MD, MPH
STATE HEALTH COMMISSIONER

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

MEMORANDUM

DATE: April 18, 2022

TO: Virginia State Board of Health

FROM: Julie Henderson
Director, Office of Environmental Health Services

SUBJECT: Fast Track Action - Amend Food Regulations(12VAC5-421) to conform to Chapter 853 of the 2020 Acts of Assembly; General Medication Storage

Enclosed for your review is a Fast Track Action to conform the Food Regulations (12VAC5-421) to the requirements of Chapter 853 of the 2020 Acts of Assembly. Chapter 853 of the 2020 Acts of Assembly authorizes any employee of a licensed restaurant to possess and administer epinephrine on the premises of a restaurant at which the employee is employed, provided that such employee is authorized by a prescriber, and is trained in the administration of epinephrine. In addition, trained employees who provide, administer, or assist in the administration of epinephrine to someone who in good faith they believe is having an anaphylactic reaction, shall not be liable for certain civil damages.

Currently, the Food Regulations allow only those medications necessary for the health of employees on the premises of a food establishment. The proposed amendments to the Food Regulations would allow those restaurants that elect to possess epinephrine on the premises in order to respond to an anaphylaxis event to remain in compliance with the regulations which govern the operation of their establishment. In addition, the proposed amendments clarifies the allowance of medication belonging to children attending a day care center to be stored in a food refrigerator on the premises of the day care's food establishment.

The Virginia Department of Health recommends that the Board act pursuant to its authority provided in § 35.1-11 of the Code of Virginia, and approve the Fast Track Regulations. Should the Board of Health approve the Fast Track Regulations, they will be submitted to the Office of the Attorney General to begin the Executive Branch review process, as specified by the Administrative Process Act. Following Executive Branch review and approval, the proposed regulations will be published in the *Virginia Register of Regulations* and on the Virginia Regulatory Town Hall website and a 30 day public comment period will begin. Fifteen days after the close of the public comment period the Regulations will become effective.



townhall.virginia.gov

Fast-Track Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC 5-421
VAC Chapter title(s)	Food Regulations
Action title	Amend Food Regulations to conform to Chapter 853 of the 2020 Acts of Assembly; General Medication Storage
Date this document prepared	May 2, 2022

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

Brief Summary

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

A regulatory change to the Food Regulations (12VAC5-421 et seq.) is required in order to conform to changes made to § 8.01-225.17 of the Code of Virginia in Chapter 853 of the 2020 Acts of Assembly. The statutory amendment made by Ch. 853 (2020) authorizes any employee of a licensed restaurant to possess and administer epinephrine on the premises of a restaurant at which the employee is employed, provided that such employee is authorized by a prescriber, and is trained in the administration of epinephrine. In addition, trained employees who provide, administer, or assist in the administration of epinephrine to someone who, in good faith they believe is having an anaphylactic reaction, shall not be liable for certain civil damages.

Lastly, the proposed regulatory change will allow the storage of medications for use by children at a day care center on the premise of a food establishment.

Currently, the Food Regulations allow only those medications necessary for the health of employees on the premises of a food establishment. The proposed amendments to the Food Regulations would allow those food establishments that elect to possess epinephrine on the premises in order to respond to an anaphylaxis remain in compliance with the regulations which govern the operation of their establishment.

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the "Definitions" section of the regulation.

No technical terms are used that are not defined in the regulations.

Statement of Final Agency Action

Provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

<insert>

Mandate and Impetus

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

As required by Virginia Code § 2.2-4012.1, also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track process.

Chapter 853 of the 2020 Acts of Assembly authorizes any employee of a licensed restaurant to possess and administer epinephrine on the premises of a restaurant at which the employee is employed, provided that such employee is authorized by a prescriber, and is trained in the administration of epinephrine. In addition, trained employees who provide, administer, or assist in the administration of epinephrine to someone who in good faith they believe is having an anaphylactic reaction, shall not be liable for certain civil damages. Lastly, Chapter 853 of the 2020 Acts of Assembly required the Virginia Department of Health, in collaboration with the Department of Health Professions, to develop policies and guidelines for the recognition and treatment of anaphylaxis in restaurants with input from select stakeholders.

While the legislative mandate was directed at the development of policies and guidelines, without a regulatory amendment, the possession or storage of epinephrine on the premises of a food establishment is currently not allowed under 12VAC5-421.

In addition, the regulatory change would correct an issue in the current regulations, and allow medication belonging to the children in a day care center to be stored in a food refrigerator on the premises of the day care food establishment. The current language prohibits the storage of any medication on the premises of a food establishment unless it is specifically for the use of employees; whereas 12VAC5-421-3470 allows the storage of medication for children of a day care center on the premises under certain conditions. The proposed language would remove this conflict, allowing the storage of not only

epinephrine, but other life-saving medications such as insulin, inhalers, and over the counter medication, in day care centers.

For these reasons, the proposed regulatory action is expected to be noncontroversial, allowing use of the fast-track process.

Legal Basis

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

Sections 35.1-11 and 14 of the Code of Virginia authorize the Board to make, adopt, promulgate, and enforce regulations governing restaurants in accordance with the provisions of Title 35.1 of the Code of Virginia.

Purpose

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

Chapter 853 of the 2020 Acts of Assembly adds language to § 8.01-225 to authorize any employee of a licensed restaurant to possess and administer epinephrine in response to an individual having an anaphylactic reaction on the premises of a restaurant at which the employee is employed, provided that such employee is authorized by a prescriber and trained in the administration of epinephrine.

The Food Regulations prohibits medications on the premises of a food establishment unless it is specifically for the use of an employee. Approximately 32 million people (1 in every 13 children) in the United States have food allergies, and each year nearly 200,000 people require emergency medical care for allergic reactions to food.¹ Other common allergens include latex allergies (4.3% of population), insect allergies (5% of the population), and drug allergies (10% of the population).²

In addition, this regulatory action would allow properly trained food establishment employees to act as a first line of response to serious medical emergencies where time is of the essence, and remain in compliance with the regulatory standards pertaining to storage of medication on the premises. The proposed language would also allow day care centers with a license to operate as a food establishment to store the medications of the children within their care. Current regulatory sections are in conflict and the proposed language will resolve this issue.

Substance

¹ Food Allergy Research and Education (2020, June 4) *Food Allergy Facts and Statistics for the U.S.* <https://www.foodallergy.org/media/1012/download>

² Asthma and Allergy Foundation of America (2021) *Allergy Facts and Figure.* <https://www.aafa.org/allergy-research/>

Briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the “Detail of Changes” section below.

In Section 12VAC5-421-3460, the proposed regulations were amended to allow the storage of epinephrine on the premises of a food establishment and to allow the storage of medication for children attending day care in a facility that also has a food establishment license.

Issues

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

The primary advantage of the proposed regulatory action to the public is the accessibility of epinephrine to properly trained food establishment employees to assist facility patrons who are experiencing anaphylaxis due to an allergic reaction. In the event of an allergic reaction, food establishment staff can serve as the first response to administer aid until medical professionals arrive to further assist. In addition, the proposed regulations would allow the storage of epinephrine in a food refrigerator of a day care center. This is particularly advantageous when space is limited in a facility. There are no known disadvantages to the public.

There are no known disadvantages to the agency or the Commonwealth.

Requirements More Restrictive than Federal

Identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements, or no requirements that exceed applicable federal requirements, include a specific statement to that effect.

There are no requirements more restrictive than applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

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

Other State Agencies Particularly Affected

No other state agencies will be particularly affected.

Localities Particularly Affected

No localities will be particularly affected.

Other Entities Particularly Affected

The food establishments licensed pursuant to the Food Regulations will be affected.

Economic Impact

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

Impact on State Agencies

<i>For your agency:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	None
<i>For other state agencies:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	None
<i>For all agencies:</i> Benefits the regulatory change is designed to produce.	None

Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	None
Benefits the regulatory change is designed to produce.	None

Impact on Other Entities

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	Only those food establishments that elect to obtain and store epinephrine on the premises or who operate as a day care with a food establishment license would be impacted by the regulatory change.
Agency's best estimate of the number of such entities that will be affected. Include an estimate of the number of small businesses affected.	The Virginia Department of Health permits approximately 30,000+ food establishments of which some or none could elect to obtain and

<p>Small business means a business entity, including its affiliates, that:</p> <ul style="list-style-type: none"> a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million. 	<p>store epinephrine on the premises. The number of food establishments that could classify as “small business” is unknown.</p> <p>Approximately 1,500 food establishments are associated with child day care centers.</p>
<p>All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to:</p> <ul style="list-style-type: none"> a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements. 	<p>Only those food establishments that elect to obtain and store epinephrine on the premise will bear any of the following costs: (1) a epi-pen pack (two auto-injectors) can range from \$150 to \$400 and (2) staff member training on epinephrine administration can range from \$35 to \$50.</p>
<p>Benefits the regulatory change is designed to produce.</p>	<p>This regulatory change is intended to allow the storage of epinephrine on the premises of food establishments for the use of trained employees to administer epinephrine in response to anaphylaxis in a patron. In addition, the proposed language is intended to remove a conflict in the regulations to allow the storage of medication belonging to children of a day care center that also possesses a restaurant license.</p>

Alternatives to Regulation

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

No alternative to this regulation was considered, as the proposed change is required to allow those food establishments and child day care centers who elect to obtain and store epinephrine on their premises to do so and remain in compliance with 12VAC5-421.

Regulatory Flexibility Analysis

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

There are no regulatory alternatives that would be less stringent that are consistent with protecting public health. The proposed language would allow those food establishments who elect to obtain and store epinephrine on the premises for the use by trained employees in response to potential anaphylactic events to do so while remaining in compliance with the Food Regulations.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below.

As required by § 2.2-4011 of the Code of Virginia, if an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

If you are objecting to the use of the fast-track process as the means of promulgating this regulation, please clearly indicate your objection in your comment. Please also indicate the nature of, and reason for, your objection to using this process.

The Board is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal and any alternative approaches, (ii) the potential impacts of the regulation, and (iii) the agency's regulatory flexibility analysis stated in this background document.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall website at: <https://townhall.virginia.gov>. Comments may also be submitted by mail, email or fax to Kristin Marie Clay, Senior Policy Analyst, 109 Governor Street, Office of Environmental Health Services, 5th Floor, Richmond, VA 23219, Phone: 804-864-7474, Email: Kristin.Clay@vdh.virginia.gov. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

If an existing VAC Chapter(s) is being amended or repealed, use Table 1 to describe the changes between existing VAC Chapter(s) and the proposed regulation. If existing VAC Chapter(s) or sections are being repealed and replaced, ensure Table 1 clearly shows both the current number and the new number for each repealed section and the replacement section.

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
3460		<p>12VAC5-421-3460. Medicines - restriction and storage.</p> <p>A. Except for medicines that are stored or displayed for retail sale, only those medicines that are necessary for the health of employees shall be allowed in a food establishment. ^{Pf}</p> <p>B. Medicines that are in a food establishment for the employees' use shall be labeled as specified under 12VAC5-421-3320 and located to prevent the contamination of food, equipment, utensils, linens, and single-service and single-use articles. ^P</p>	<p>CHANGE: The Board is proposing the following amendments:</p> <p>12VAC5-421-3460. Medicines - restriction and storage.</p> <p>A. Except for medicines that are stored or displayed for retail sale, only those medicines that are necessary for the health of employees shall be allowed in a food establishment. ^{Pf}</p> <p>B. Medicines that are in a food establishment for the employees' use shall be labeled as specified under 12VAC5-421-3320 and located to prevent the contamination of food, equipment, utensils, linens, and single-service and single-use articles. ^P</p> <p><u>A. No food establishment may display medicines other than medicines for retail sale. ^{Pf}</u></p> <p><u>B. No food establishment may store medicines other than the following:</u></p> <ol style="list-style-type: none"> <u>1. Medicines for the use of children in a day care center ^P;</u> <u>2. Medicines that are referenced in subdivision A 17 of § 8.01-225 of the Code of Virginia ^P; and</u> <u>3. Medicines that are necessary for the health of employees. ^P</u> <p><u>C. Medicines that are stored or displayed in a food establishment shall be labeled as specified under 12VAC5-421-3320 and located to prevent the contamination of food, equipment, utensils, linens, and single-service and single-use articles. ^P</u></p> <p>INTENT: The intent of the change is to conform 12VAC5-421-3460 to the Code of Virginia and clarify the requirements regarding the storing of medications for children in a day care center.</p> <p>RATIONALE: The rationale for the change is that Code of Virginia § 8.01-225 was amended to authorize employees of a licensed restaurant to provide, administer, or assist in the administration of epinephrine to an individual believed to be having an anaphylactic reaction on the premises.</p>

			<p>Additionally, 12VAC5-421-3470 currently lists storage requirements for the medicine of employees or of children in a day care center, but section 3460 does not provide for the storage of medicine other than for retail sale or the health of employees.</p> <p>LIKELY IMPACT: The likely impact of the change is that restaurant employees may elect to store epinephrine on the premises, and children in day care centers associated with a licensed food establishment store their medications on the premises.</p>
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Project 6860 - None

Department Of Health

Revision of Food Regulations Pursuant to SB530 of the 2020 General Assembly Session

12VAC5-421-3460. Medicines - restriction and storage.

~~A. Except for medicines that are stored or displayed for retail sale, only those medicines that are necessary for the health of employees shall be allowed in a food establishment.^{Pf}~~

~~B. Medicines that are in a food establishment for the employees' use shall be labeled as specified under 12VAC5-421-3320 and located to prevent the contamination of food, equipment, utensils, linens, and single-service and single-use articles.^P~~

A. No food establishment may display medicines other than medicines for retail sale.^{Pf}

B. No food establishment may store medicines other than the following:

1. Medicines for the use of children in a day care center^P;

2. Medicines that are referenced in subdivision A 17 of § 8.01-225 of the Code of Virginia^P; and

3. Medicines that are necessary for the health of employees.^P

C. Medicines that are stored or displayed in a food establishment shall be labeled as specified under 12VAC5-421-3320 and located to prevent the contamination of food, equipment, utensils, linens, and single-service and single-use articles.^P



COMMONWEALTH of VIRGINIA

Department of Health
P O BOX 2448
RICHMOND, VA 23218

Colin M. Greene, MD, MPH
State Health Commissioner

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

MEMORANDUM

DATE: May 17, 2022

TO: State Board of Health

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

SUBJECT: Fast Track Action – Regulations for the Licensure of Hospitals in Virginia – Amend Regulation after Enactment of Chapters 712 and 772 of the 2022 Acts of Assembly

Enclosed for your review are proposed amendments to Regulations for the Licensure of Hospitals in Virginia (12VAC5-410).

Chapters 712 and 722 of the 2022 Acts of Assembly require the State Board of Health to amend its hospital regulation to exempt from licensure a temporary increase in the total number of beds in an existing hospital to include “a temporary increase in the total number of beds resulting from the addition of beds at a temporary structure or satellite location operated by the hospital..., provided that the ability remains to safely staff services across the existing hospital.” These acts also amended the exemption to now also be triggered by an emergency order entered pursuant to Va. Code § 32.1-13 or 32.1-20 for the purpose of suppressing a nuisance dangerous to public health or a communicable, contagious, or infectious disease or other danger to the public life and health. The duration of the exemption has also been amended by these acts.

The State Board of Health is requested to approve the Fast Track Action. Should the State Board of Health approve the Fast Track Action, the amendments will be submitted to the Office of the Attorney General to begin the Executive Branch review process, as specified by the Administrative Process Act. Following Executive Branch review and approval, the proposed regulatory text will be published in the Virginia Register of Regulations and on the Virginia Regulatory Town Hall website. A 30-day public comment period will begin. Fifteen days after the close of the public comment period, the regulation will become effective.



townhall.virginia.gov

Fast-Track Regulation Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-410-10 <i>et seq.</i>
VAC Chapter title(s)	Regulations for the Licensure of Hospitals in Virginia
Action title	Amend Regulation after Enactment of Chapters 712 and 772 of the 2022 Acts of Assembly
Date this document prepared	May 17, 2022

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

Brief Summary

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

Chapters 712 and 722 of the 2022 Acts of Assembly require the State Board of Health to amend its hospital regulation to exempt from licensure temporary increase in the total number of beds in an existing hospital to include “a temporary increase in the total number of beds resulting from the addition of beds at a temporary structure or satellite location operated by the hospital..., provided that the ability remains to safely staff services across the existing hospital...” These acts also amended the exemption to now also be triggered by an emergency order entered pursuant to Va. Code § 32.1-13 or 32.1-20 for the purpose of suppressing a nuisance dangerous to public health or a communicable, contagious, or infectious disease or other danger to the public life and health.

The duration of this exemption was amended to be either “a period of no more than the duration of the Commissioner’s determination plus 30 days...when the Commissioner has determined that a natural or man-made disaster has caused the evacuation of a hospital or nursing home and that a public health

emergency exists due to a shortage of hospital or nursing home beds” or “a period of no more than the duration of the emergency order entered pursuant to § 32.1-13 or 32.1-20 plus 30 days.”

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the “Definitions” section of the regulation.

“Board” means the State Board of Health.

“Commissioner” means the State Health Commissioner.

“VDH” means the Virginia Department of Health.

Statement of Final Agency Action

Provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

Insert text here

Mandate and Impetus

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

As required by Virginia Code § 2.2-4012.1, also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track process.

Chapters 712 and 722 of the 2022 Acts of Assembly require the State Board of Health to amend its hospital regulation to exempt from licensure a temporary increase in the total number of beds in an existing hospital to include “a temporary increase in the total number of beds resulting from the addition of beds at a temporary structure or satellite location operated by the hospital..., provided that the ability remains to safely staff services across the existing hospital...” These acts also amended the exemption to now also be triggered by an emergency order entered pursuant to Va. Code § 32.1-13 or 32.1-20 for the purpose of suppressing a nuisance dangerous to public health or a communicable, contagious, or infectious disease or other danger to the public life and health. These acts also amended the duration of the exemption.

It is anticipated that this action will be noncontroversial and therefore appropriate for the fast-track process because the minimum information required when requesting temporary beds and the process described in the regulatory action is consistent with the minimum information that was requested of hospitals and the process that was utilized during the COVID-19 pandemic pursuant to Executive Orders 52 (2020), 84 (2022), 11 (2022), and 16 (2022).

Legal Basis

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

This regulation is promulgated under the authority of Va. Code §§ 32.1-12 and 32.1-127(B)(24). Va. Code § 32.1-12 grants the Board the legal authority “to make, adopt, promulgate, and enforce such regulations...as may be necessary to carry out the provisions of this title and other laws of the Commonwealth administered by it, the Commissioner, or the Department.”

Va. Code § 32.1-127(B)(24) states that the Board shall promulgate regulations that “establish an exemption from the requirement to obtain a license to add temporary beds in an existing hospital..., including beds located in a temporary structure or satellite location operated by the hospital..., provided that the ability remains to safely staff services across the existing hospital..., (i) for a period of no more than the duration of the Commissioner's determination plus 30 days when the Commissioner has determined that a natural or man-made disaster has caused the evacuation of a hospital or nursing home and that a public health emergency exists due to a shortage of hospital or nursing home beds or (ii) for a period of no more than the duration of the emergency order entered pursuant to § 32.1-13 or 32.1-20 plus 30 days when the Board, pursuant to § 32.1-13, or the Commissioner, pursuant to § 32.1-20, has entered an emergency order for the purpose of suppressing a nuisance dangerous to public health or a communicable, contagious, or infectious disease or other danger to the public life and health [.]”

Purpose

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

The rationale or justification of the regulatory change is that the General Assembly has mandated that the existing regulatory flexibilities for hospital licensure for man-made or natural disasters be modified in light of the Commonwealth's experience during the COVID-19 pandemic and the impact of hospital licensure statutes and regulations on the ability of hospitals to rapidly expand bed capacity.

The specific reason the regulatory change is essential to protect the health, safety, or welfare of citizens are that normal state controls on the hospital and nursing home bed inventory in the Commonwealth have proven to be too inflexible during certain public health emergencies where demand for beds outstrips both the current inventory and the mandated processes by which additional inventory can be authorized. These amended exemption regulations will allow hospitals to temporarily increase their bed inventory in response to disasters and other public health emergencies, while still allowing the Commissioner sufficient oversight to ensure the beds are being operated and staffed safely.

The goals of the regulatory change is to create an expeditious process by which hospitals can request temporary beds while ensuring that the Commissioner and VDH have sufficient information to take action on the request.

Substance

Briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the “Detail of Changes” section below.

12VAC5-410-110. Bed capacity.

Creates a new process that is exempt from licensure to allow hospitals to temporarily increase their bed inventory during disasters or other public health emergencies.

12VAC5-410-9998. FORMS.

A new section created to include the new form specified in Section 110.

Issues

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

The primary advantages to the public of implementing the amended provisions are the ability to rapidly and temporarily increase hospital and nursing home bed inventory during disasters or other public health emergencies while preserving life safety code protections and safe staffing. The primary advantages to the Commonwealth of implementing the amended provisions are a new exemption process that grants more discretion and flexibility to the Board and Commissioner in responding to public health emergencies for which additional bed inventory is needed without needing either a legislative amendment to the Code of Virginia or an executive order from the Governor. There are no primary disadvantages to the public or the Commonwealth.

Requirements More Restrictive than Federal

Identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements, or no requirements that exceed applicable federal requirements, include a specific statement to that effect.

There are no applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

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

Other State Agencies Particularly Affected

No other state agencies are particularly affected by this proposed regulatory change.

Localities Particularly Affected

Chesapeake Hospital Authority may be particularly affected by this proposed regulatory change since it operates a general hospital and would be subject to the new regulatory requirements, unlike other localities that do not operate a hospital.

Other Entities Particularly Affected

Existing general hospitals are particularly affected by this proposed regulatory change as they would be subject to the new regulatory requirements.

Economic Impact

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

Impact on State Agencies

<p><i>For your agency:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources</p>	<p>There are no projected costs, savings, fees or revenues resulting from the regulatory change.</p>
<p><i>For other state agencies:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.</p>	<p>There are no projected costs, savings, fees or revenues resulting from the regulatory change.</p>
<p><i>For all agencies:</i> Benefits the regulatory change is designed to produce.</p>	<p>The benefits of this regulatory change is creation of an expeditious process by which hospitals can request temporary beds during disasters or emergencies.</p>

Impact on Localities

<p>Projected costs, savings, fees or revenues resulting from the regulatory change.</p>	<p>There are no projected costs, savings, fees or revenues resulting from the regulatory change.</p>
<p>Benefits the regulatory change is designed to produce.</p>	<p>The benefits of this regulatory change is creation of an expeditious process by which hospitals can request temporary beds during disasters or emergencies.</p>

Impact on Other Entities

<p>Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.</p>	<p>Existing general hospitals. VDH does not anticipate that outpatient surgical hospitals will likely be affected because these medical care facilities do not have beds and would be unlikely to be able to adequately staff beds in situations where a disaster has forced an evacuation or where an emergency order is needed. No outpatient surgical hospitals were approved to</p>
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	have temporary beds during the COVID-19 pandemic.
Agency's best estimate of the number of such entities that will be affected. Include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.	There are 105 general hospitals. VDH does not have any data about the number of full-time employees that these medical care facilities employ.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	There are no projected costs, savings, fees or revenues resulting from the regulatory change.
Benefits the regulatory change is designed to produce.	The benefits of this regulatory change is creation of an expeditious process by which hospitals can request temporary beds during disasters or emergencies.

Alternatives to Regulation

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

There are no viable alternatives to the regulatory change as the Board has no other method other than the promulgation or amendment of regulations to create the mandated regulatory exemption from hospital licensure.

Regulatory Flexibility Analysis

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

There are no alternative regulatory methods that will accomplish the objectives of applicable law. The Board is required by the General Assembly to regulate the hospitals under a licensure program. The Board has no other method other than the promulgation or amendment of regulations to create the mandated regulatory exemption from hospital licensure. The Board has put forth thoughtful consideration about the burdens of the new regulatory requirements and has limited these amendments to those necessary to protect the health, safety, and welfare of the public.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below.

As required by § 2.2-4011 of the Code of Virginia, if an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

If you are objecting to the use of the fast-track process as the means of promulgating this regulation, please clearly indicate your objection in your comment. Please also indicate the nature of, and reason for, your objection to using this process.

The Board is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal and any alternative approaches, (ii) the potential impacts of the regulation, and (iii) the agency's regulatory flexibility analysis stated in this background document.

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

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

If an existing VAC Chapter(s) is being amended or repealed, use Table 1 to describe the changes between existing VAC Chapter(s) and the proposed regulation. If existing VAC Chapter(s) or sections are being repealed and replaced, ensure Table 1 clearly shows both the current number and the new number for each repealed section and the replacement section.

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-	New chapter-section	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
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section number	number, if applicable		
410-110		<p>12VAC5-410-110. Bed capacity.</p> <p>A. Each license issued by the commissioner shall specify the maximum allowable number of beds. The number of beds allowed shall be determined by the OLC and shall so appear on the license issued by the OLC.</p> <p>B. Request for licensed bed increase or decrease shall be made in writing to the OLC. No increase will be granted without an approved Certificate of Public Need.</p> <p>C. Hospitals shall be exempt from the requirement to obtain a license to add temporary beds, for a period of no more than 30 days, when the commissioner has determined that a natural or man-made disaster has caused the evacuation of a hospital or nursing home and that a public health emergency exists due to a shortage of hospital or nursing home beds.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-127 of the Code of Virginia.</p>	<p>CHANGE: The Board is proposing the following change:</p> <p>12VAC5-410-110. Bed capacity.</p> <p>A. Each license issued by the commissioner shall specify the maximum allowable number of <u>beds, excluding temporary beds added pursuant to subsection C of this section.</u> The number of beds allowed shall be determined by the OLC and shall so appear on the license issued by the OLC.</p> <p>B. Request for licensed bed increase or decrease shall be made in writing to the OLC. No increase will be granted without an approved Certificate of Public <u>Need, except as provided in subsection C of this section.</u></p> <p>C. <u>Provided that a hospital complies with subsections D, E, G, and H of this section, Hospitals a hospital shall be exempt from the requirement to obtain a Certificate of Public Need or a license to add temporary beds, including beds located in a temporary structure or satellite location operated by a hospital:</u></p> <ol style="list-style-type: none"> <u>1. for a period of no more than 30 days, when If the commissioner has determined that a natural disaster or man-made disaster has caused the evacuation of a hospital or nursing home and that a public health emergency exists due to a shortage of hospital or nursing home beds; or</u> <u>2. If the board has entered an emergency order pursuant to § 32.1-13 of the Code of Virginia or if the commissioner has entered an emergency order pursuant to §§ 32.1-13 and 32.1-20 of the Code of Virginia</u>

			<p><u>for the purpose of suppressing:</u></p> <ul style="list-style-type: none"><u>a. A nuisance dangerous to public health;</u><u>b. A communicable, contagious, or infectious disease; or</u><u>c. Other danger to the public life and health.</u> <p><u>D. A hospital may request temporary beds by filing a Request for Temporary Beds, OLC-1009-F (eff. 06/22), with the OLC that includes:</u></p> <ul style="list-style-type: none"><u>1. The hospital's name;</u><u>2. The hospital's license number;</u><u>3. The hospital chief executive officer's or his designee's name;</u><u>4. The hospital chief executive officer's or his designee's telephone number;</u><u>5. The hospital chief executive officer's or his designee's email address;</u><u>6. The number and type of temporary beds the hospital anticipates adding;</u><u>7. The planned use of the temporary beds;</u><u>8. The plans for staffing the temporary beds;</u><u>9. The efforts undertaken or to be undertaken to reduce or eliminate the number of temporary beds needed;</u><u>10. The address of the building, temporary structure, or satellite location where the hospital intends to locate the temporary beds;</u><u>11. The specific locations within the building, temporary structure, or satellite location where the hospital intends to locate the temporary beds;</u>
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			<p><u>12. Whether the locations identified in subdivision D 11 of this section meet life safety code requirements for the type of patients expected to occupy those temporary beds;</u></p> <p><u>13. If life safety code requirements are not currently met for the locations identified in subdivision D 11 of this section, what action the hospital will take to meet life safety code requirements; and</u></p> <p><u>14. Any other information that the board or commissioner may request.</u></p> <p><u>E. The hospital shall provide additional information as may be requested or required by the commissioner to evaluate the temporary bed request.</u></p> <p><u>F. The commissioner shall notify the hospital in writing of the commissioner's decision on the temporary bed request. If granted, the commissioner may attach conditions to the approval that, in the sole judgment of the commissioner, protects the public's or patients' health, safety, or welfare.</u></p> <p><u>G. The hospital may not add temporary beds unless its request has been granted and may not operate temporary beds more than 30 days after the expiration of:</u></p> <ul style="list-style-type: none"><u>1. The commissioner's determination pursuant to subdivision C 1 of this section;</u><u>or</u><u>2. The board's or the commissioner's emergency order pursuant to subdivision C 2 of this section.</u> <p><u>H. The hospital shall notify the OLC in writing within 24 hours of opening a temporary bed and within 24 hours of closing a temporary bed.</u></p> <p><u>I. The OLC shall promptly inform the Department of Medical Assistance</u></p>
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			<p><u>Services and the Centers for Medicare and Medicaid Services of the identity of any hospital certified as a Medicare provider or Medicaid provider or both that fails to comply with subsection G of this section.</u></p> <p><u>J. The commissioner may rescind or modify the approval of a temporary bed request if:</u></p> <ol style="list-style-type: none"> <u>1. Additional information becomes known that alters the basis for the original approval, including if the hospital added temporary beds prior to receiving the approval; or</u> <u>2. The hospital fails to meet any conditions attached to the approval.</u> <p>Statutory Authority §§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> <p>INTENT: The intent of the new requirements is detail the minimum required information to request temporary beds, the process for requesting temporary beds, and what the obligations are of each party in the process.</p> <p>RATIONALE: The rationale for the new requirements is to recreate a level of information-sharing and processes familiar to hospitals that were utilized during the COVID-19 pandemic to temporary increase bed capacity.</p> <p>LIKELY IMPACT: The likely impact of the new requirements is clarity regarding what hospitals should do when temporary beds are needed when a disaster has caused an evacuation of another hospital or nursing home or when an emergency order from the Board or the Commissioner has been issued.</p>
	410-9998	This is a new section.	<p>CHANGE: The Board is proposing the following change:</p> <p>FORMS (12VAC5-410) <u>Request for Temporary Beds, OLC-1009-F (eff. 06/22).</u></p>

			<p>INTENT: The intent of the new requirements is for hospitals to use this form when requesting temporary beds.</p> <p>RATIONALE: The rationale for the new requirements is to standardize the information being provided to VDH when temporary beds are being requested.</p> <p>LIKELY IMPACT: The likely impact of the new requirements is consistency in the information and data being received by VDH.</p>
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1 **Project 7195 - Fast-Track**

2 **Department of Health**

3 **Amend Regulation after Enactment of Chapters 712 and 772 of the 2022 Acts of**
4 **Assembly and to Add Forms**

5 **12VAC5-410-110. Bed capacity.**

6 A. Each license issued by the commissioner shall specify the maximum allowable number of
7 beds, excluding temporary beds added pursuant to subsection C of this section. The number of
8 beds allowed shall be determined by the OLC and shall so appear on the license issued by the
9 OLC.

10 B. Request for licensed bed increase or decrease shall be made in writing to the OLC. No
11 increase will be granted without an approved Certificate of Public Need, except as provided in
12 subsection C of this section.

13 C. Provided that a hospital complies with subsections D, E, G, and H of this section, Hospitals
14 a hospital shall be exempt from the requirement to obtain a Certificate of Public Need or a license
15 to add temporary beds, including beds located in a temporary structure or satellite location
16 operated by a hospital:

17 1. for a period of no more than 30 days, when If the commissioner has determined that a
18 natural disaster or man-made disaster has caused the evacuation of a hospital or nursing
19 home and that a public health emergency exists due to a shortage of hospital or nursing
20 home beds; or

21 2. If the board has entered an emergency order pursuant to § 32.1-13 of the Code of
22 Virginia or if the commissioner has entered an emergency order pursuant to §§ 32.1-13
23 and 32.1-20 of the Code of Virginia for the purpose of suppressing:

24 a. A nuisance dangerous to public health;

25 b. A communicable, contagious, or infectious disease; or

26 c. Other danger to the public life and health.

27 D. A hospital may request temporary beds by filing a Request for Temporary Beds, OLC-
28 1009-F (eff. 06/22), with the OLC that includes:

29 1. The hospital's name;

30 2. The hospital's license number;

31 3. The hospital chief executive officer's or his designee's name;

32 4. The hospital chief executive officer's or his designee's telephone number;

33 5. The hospital chief executive officer's or his designee's email address;

34 6. The number and type of temporary beds the hospital anticipates adding;

35 7. The planned use of the temporary beds;

36 8. The plans for staffing the temporary beds;

37 9. The efforts undertaken or to be undertaken to reduce or eliminate the number of
38 temporary beds needed;

39 10. The address of the building, temporary structure, or satellite location where the
40 hospital intends to locate the temporary beds;

41 11. The specific locations within the building, temporary structure, or satellite location
42 where the hospital intends to locate the temporary beds;

43 12. Whether the locations identified in subdivision D 11 of this section meet life safety
44 code requirements for the type of patients expected to occupy those temporary beds;

45 13. If life safety code requirements are not currently met for the locations identified in
46 subdivision D 11 of this section, what action the hospital will take to meet life safety code
47 requirements; and

48 14. Any other information that the board or commissioner may request.

49 E. The hospital shall provide additional information as may be requested or required by the
50 commissioner to evaluate the temporary bed request.

51 F. The commissioner shall notify the hospital in writing of the commissioner's decision on the
52 temporary bed request. If granted, the commissioner may attach conditions to the approval that,
53 in the sole judgment of the commissioner, protects the public's or patients' health, safety, or
54 welfare.

55 G. The hospital may not add temporary beds unless its request has been granted and may
56 not operate temporary beds more than 30 days after the expiration of:

57 1. The commissioner's determination pursuant to subdivision C 1 of this section; or

58 2. The board's or the commissioner's emergency order pursuant to subdivision C 2 of this
59 section.

60 H. The hospital shall notify the OLC in writing within 24 hours of opening a temporary bed and
61 within 24 hours of closing a temporary bed.

62 I. The OLC shall promptly inform the Department of Medical Assistance Services and the
63 Centers for Medicare and Medicaid Services of the identity of any hospital certified as a Medicare
64 provider or Medicaid provider or both that fails to comply with subsection G of this section.

65 J. The commissioner may rescind or modify the approval of a temporary bed request if:

66 1. Additional information becomes known that alters the basis for the original approval,
67 including if the hospital added temporary beds prior to receiving the approval; or

68 2. The hospital fails to meet any conditions attached to the approval.

69 **Statutory Authority**

70 §§ 32.1-12 and 32.1-127 of the Code of Virginia.

71 **Historical Notes**

72 Derived from VR355-33-500 § 1.11, eff. July 28, 1993; amended, Virginia Register Volume 11,
73 Issue 8, eff. April 1, 1995; Volume 11, Issue 16, eff. June 1, 1995; Volume 23, Issue 10, eff. March
74 1, 2007; Volume 35, Issue 24, eff. August 23, 2019.

75 **FORMS (12VAC5-410)**

76 Request for Temporary Beds, OLC-1009-F (eff. 06/22).



COMMONWEALTH of VIRGINIA

Department of Health
P O BOX 2448
RICHMOND, VA 23218

Colin M. Greene, MD, MPH
State Health Commissioner

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

MEMORANDUM

DATE: May 17, 2022

TO: State Board of Health

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

SUBJECT: Fast Track Action – Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations – Amend Regulation after Enactment of Chapters 712 and 772 of the 2022 Acts of Assembly

Enclosed for your review are proposed amendments to Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations (12VAC5-220).

Chapters 712 and 722 of the 2022 Acts of Assembly require the State Board of Health to amend its regulation about exemptions for certificates of public need for projects that involve a temporary increase in the total number of beds in an existing hospital or nursing home to include “a temporary increase in the total number of beds resulting from the addition of beds at a temporary structure or satellite location operated by the hospital or nursing home, provided that the ability remains to safely staff services across the existing hospital or nursing home.” These acts also amended the exemption to now also be triggered by an emergency order entered pursuant to Va. Code § 32.1-13 or 32.1-20 for the purpose of suppressing a nuisance dangerous to public health or a communicable, contagious, or infectious disease or other danger to the public life and health. The duration of the exemption has also been amended by these acts.

The State Board of Health is requested to approve the Fast Track Action. Should the State Board of Health approve the Fast Track Action, the amendments will be submitted to the Office of the Attorney General to begin the Executive Branch review process, as specified by the Administrative Process Act. Following Executive Branch review and approval, the proposed regulatory text will be published in the Virginia Register of Regulations and on the Virginia Regulatory Town Hall website. A 30-day public comment period will begin. Fifteen days after the close of the public comment period, the regulation will become effective.



townhall.virginia.gov

Fast-Track Regulation Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-220-10 <i>et seq.</i>
VAC Chapter title(s)	Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations
Action title	Amend Regulation after Enactment of Chapters 712 and 772 of the 2022 Acts of Assembly
Date this document prepared	May 24, 2022

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

Brief Summary

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

Chapters 712 and 722 of the 2022 Acts of Assembly require the State Board of Health to amend its regulation about exemptions for certificates of public need for projects that involve a temporary increase in the total number of beds in an existing hospital or nursing home to include “a temporary increase in the total number of beds resulting from the addition of beds at a temporary structure or satellite location operated by the hospital or nursing home, provided that the ability remains to safely staff services across the existing hospital or nursing home.” These acts also amended the exemption to now also be triggered by an emergency order entered pursuant to Va. Code § 32.1-13 or 32.1-20 for the purpose of suppressing a nuisance dangerous to public health or a communicable, contagious, or infectious disease or other danger to the public life and health.

The duration of this exemption was amended to be either “a period of no more than the duration of the Commissioner’s determination plus 30 days...when the Commissioner has determined that a natural or

man-made disaster has caused the evacuation of a hospital or nursing home and that a public health emergency exists due to a shortage of hospital or nursing home beds” or “a period of no more than the duration of the emergency order entered pursuant to § 32.1-13 or 32.1-20 plus 30 days.”

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the “Definitions” section of the regulation.

“Board” means the State Board of Health.

“Commissioner” means the State Health Commissioner.

“COPN” means a Certificate of Public Need.

“VDH” means the Virginia Department of Health.

Statement of Final Agency Action

Provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

Insert text here

Mandate and Impetus

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

As required by Virginia Code § 2.2-4012.1, also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track process.

Chapters 712 and 722 of the 2022 Acts of Assembly require the State Board of Health to amend its regulation about exemptions for certificates of public need for projects that involve a temporary increase in the total number of beds in an existing hospital or nursing home to include “a temporary increase in the total number of beds resulting from the addition of beds at a temporary structure or satellite location operated by the hospital or nursing home, provided that the ability remains to safely staff services across the existing hospital or nursing home.” These acts also amended the exemption to now also be triggered by an emergency order entered pursuant to Va. Code § 32.1-13 or 32.1-20 for the purpose of suppressing a nuisance dangerous to public health or a communicable, contagious, or infectious disease or other danger to the public life and health. These acts also amended the duration of the exemption.

It is anticipated that this action will be noncontroversial and therefore appropriate for the fast-track process because the minimum information required when requesting temporary beds and the process described in the regulatory action is consistent with the minimum information that was requested of hospitals and nursing homes and the process that was utilized during the COVID-19 pandemic pursuant to Executive Orders 52 (2020), 84 (2022), 11 (2022), and 16 (2022).

Legal Basis

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

This regulation is promulgated under the authority of Va. Code §§ 32.1-12 and 32.1-102.2(A)(4). Va. Code § 32.1-12 grants the Board the legal authority “to make, adopt, promulgate, and enforce such regulations...as may be necessary to carry out the provisions of this title and other laws of the Commonwealth administered by it, the Commissioner, or the Department.”

Va. Code § 32.1-102.2(A)(4) states that the Board shall promulgate regulations that are consistent with this article and “[...]shall establish an exemption from the requirement for a certificate for a project involving a temporary increase in the total number of beds in an existing hospital or nursing home, including a temporary increase in the total number of beds resulting from the addition of beds at a temporary structure or satellite location operated by the hospital or nursing home, provided that the ability remains to safely staff services across the existing hospital or nursing home, (i) for a period of no more than the duration of the Commissioner’s determination plus 30 days when the Commissioner has determined that a natural or man-made disaster has caused the evacuation of a hospital or nursing home and that a public health emergency exists due to a shortage of hospital or nursing home beds or (ii) for a period of no more than the duration of the emergency order entered pursuant to § 32.1-13 or 32.1-20 plus 30 days when the Board, pursuant to § 32.1-13, or the Commissioner, pursuant to § 32.1-20, has entered an emergency order for the purpose of suppressing a nuisance dangerous to public health or a communicable, contagious, or infectious disease or other danger to the public life and health[.]”

Purpose

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

The rationale or justification of the regulatory change is that the General Assembly has mandated that the existing regulatory exemption from COPN for man-made or natural disasters be modified in light of the Commonwealth’s experience during the COVID-19 pandemic and the impact of COPN statutes and regulations on the ability of hospitals and nursing homes to rapidly expand bed capacity.

The specific reason the regulatory change is essential to protect the health, safety, or welfare of citizens are that normal state controls on the hospital and nursing home bed inventory in the Commonwealth have proven to be too inflexible during certain public health emergencies where demand for beds outstrips both the current inventory and the mandated processes by which additional inventory can be authorized. These amended exemption regulations will allow hospitals and nursing homes to temporarily increase their bed inventory in response to disasters and other public health emergencies, while still allowing the Commissioner sufficient oversight to ensure the beds are being operated and staffed safely.

The goals of the regulatory change is to create an expeditious process by which hospitals and nursing homes can request temporary beds while ensuring that the Commissioner and VDH have sufficient information to take action on the request.

Substance

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

12VAC5-220-100. Requirements for reviewable medical care facility projects; exceptions.

Creates a new process that is exempt from COPN to allow hospitals and nursing homes to temporarily increase their bed inventory during disasters or other public health emergencies.

12VAC5-220-9998. FORMS.

Amended to include the new form specified in Section 100.

Issues

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

The primary advantages to the public of implementing the amended provisions are the ability to rapidly and temporarily increase hospital or nursing home bed inventory during disasters or other public health emergencies while preserving life safety code protections and safe staffing. The primary advantages to the Commonwealth of implementing the amended provisions are a new exemption process that grants more discretion and flexibility to the Board and Commissioner in responding to public health emergencies for which additional bed inventory is needed without needing either a legislative amendment to the Code of Virginia or an executive order from the Governor. There are no primary disadvantages to the public or the Commonwealth.

Requirements More Restrictive than Federal

Identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements, or no requirements that exceed applicable federal requirements, include a specific statement to that effect.

There are no applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

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

Other State Agencies Particularly Affected

No other state agencies are particularly affected by this proposed regulatory change.

Localities Particularly Affected

Bedford County and Chesapeake Hospital Authority may be particularly affected by this proposed regulatory change since these two operate a nursing home and a general hospital respectively and would be subject to the new regulatory requirements, unlike other localities that do not operate a nursing home or hospital.

Other Entities Particularly Affected

Existing nursing homes and general hospitals are particularly affected by this proposed regulatory change as they would be subject to the new regulatory requirements.

Economic Impact

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

Impact on State Agencies

<i>For your agency:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	There are no projected costs, savings, fees or revenues resulting from the regulatory change.
<i>For other state agencies:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	There are no projected costs, savings, fees or revenues resulting from the regulatory change.
<i>For all agencies:</i> Benefits the regulatory change is designed to produce.	The benefits of this regulatory change is creation of an expeditious process by which hospitals and nursing homes can request temporary beds during disasters or emergencies.

Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	There are no projected costs, savings, fees or revenues resulting from the regulatory change.
Benefits the regulatory change is designed to produce.	The benefits of this regulatory change is creation of an expeditious process by which hospitals and nursing homes can request temporary beds during disasters or emergencies.

Impact on Other Entities

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be	Existing nursing homes and general hospitals. VDH does not anticipate that outpatient surgical hospitals will likely be affected because these medical care facilities do not have beds and
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<p>affected, include a specific statement to that effect.</p>	<p>would be unlikely to be able to adequately staff beds in situations where a disaster has forced an evacuation or where an emergency order is needed. No outpatient surgical hospitals were approved to have temporary beds during the COVID-19 pandemic.</p>
<p>Agency's best estimate of the number of such entities that will be affected. Include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>There are 105 general hospitals and 287 nursing homes. VDH does not have any data about the number of full-time employees that these medical care facilities employ.</p>
<p>All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.</p>	<p>There are no projected costs, savings, fees or revenues resulting from the regulatory change.</p>
<p>Benefits the regulatory change is designed to produce.</p>	<p>The benefits of this regulatory change is creation of an expeditious process by which hospitals and nursing homes can request temporary beds during disasters or emergencies.</p>

Alternatives to Regulation

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

There are no viable alternatives to the regulatory change as the Board has no other method other than the promulgation or amendment of regulations to create the mandated regulatory exemption for COPNs.

Regulatory Flexibility Analysis

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

regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the regulatory change.

There are no alternative regulatory methods that will accomplish the objectives of applicable law. The Board is required by the General Assembly to regulate the COPN program. The Board has no other method other than the promulgation or amendment of regulations to create the mandated regulatory exemption for COPNs. The Board has put forth thoughtful consideration about the burdens of the new regulatory requirements and has limited these amendments to those necessary to protect the health, safety, and welfare of the public.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below.

As required by § 2.2-4011 of the Code of Virginia, if an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

If you are objecting to the use of the fast-track process as the means of promulgating this regulation, please clearly indicate your objection in your comment. Please also indicate the nature of, and reason for, your objection to using this process.

The Board is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal and any alternative approaches, (ii) the potential impacts of the regulation, and (iii) the agency's regulatory flexibility analysis stated in this background document.

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

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

If an existing VAC Chapter(s) is being amended or repealed, use Table 1 to describe the changes between existing VAC Chapter(s) and the proposed regulation. If existing VAC Chapter(s) or sections are being repealed and replaced, ensure Table 1 clearly shows both the current number and the new number for each repealed section and the replacement section.

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
220-100	N/A	<p>12VAC5-220-100. Requirements for reviewable medical care facility projects; exceptions.</p> <p>A. Prior to initiating a reviewable medical care facility project the owner or sponsor shall obtain a certificate of public need from the commissioner. In the case of an acquisition of an existing medical care facility, the notification requirement set forth in 12VAC5-220-120 shall be met.</p> <p>B. Projects involving a temporary increase in the total number of beds in an existing hospital or nursing home shall be exempt from the requirement for a certificate, for a period of no more than 30 days, if the commissioner has determined that a natural or man-made disaster has caused the evacuation of a hospital or nursing home and that a public health emergency exists due to a shortage of hospital or nursing home beds.</p> <p>Statutory Authority</p> <p>§§ 32.1-12 and 32.1-102.2 of the Code of Virginia.</p>	<p>CHANGE: The Board is proposing the following change:</p> <p>12VAC5-220-100. Requirements for reviewable medical care facility projects; exceptions.</p> <p>A. Prior to initiating a reviewable medical care facility project the owner or sponsor shall obtain a certificate of public need from the <u>commissioner, except as provided in subsection B of this section.</u> In the case of an acquisition of an existing medical care facility, the notification requirement set forth in 12VAC5-220-120 shall be met.</p> <p>B. <u>Provided that an existing hospital or nursing home complies with subsection C, D, and F of this section, Projects a project</u> involving a temporary increase in the total number of beds in an existing hospital or nursing home shall be exempt from the requirement for a certificate, <u>;</u></p> <ol style="list-style-type: none"> <u>1. for a period of no more than 30 days, if</u> <u>If the commissioner has determined that a natural disaster or man-made disaster has caused the evacuation of a hospital or nursing home and that a public health emergency exists due to a shortage of hospital or nursing home beds.;</u> <u>or</u> <u>2. If the board has entered an emergency order pursuant to § 32.1-13 of the Code of Virginia or if the commissioner has entered an emergency order pursuant to §§ 32.1-13 and 32.1-20 of the Code of Virginia for the purpose of suppressing:</u> <ol style="list-style-type: none"> <u>a. A nuisance dangerous to public health;</u> <u>b. A communicable, contagious, or infectious disease; or</u> <u>c. Other danger to the public life and health.</u> <p>C. <u>An existing hospital or nursing home may request a temporary increase in its total number of beds by filing a Request for Temporary Beds, OLC-1009-F (rev. 07/22), with the department that includes:</u></p>

			<ol style="list-style-type: none"> 1. <u>The name of the hospital or nursing home;</u> 2. <u>The license number of the hospital or nursing home;</u> 3. <u>The name of the nursing home's administrator, the hospital's chief executive officer, or his designee;</u> 4. <u>The telephone number of the nursing home's administrator, the hospital's chief executive officer, or his designee;</u> 5. <u>The email address of the nursing home's administrator, the hospital's chief executive officer, or his designee;</u> 6. <u>The number and type of temporary beds the hospital or nursing home anticipates adding;</u> 7. <u>The planned use of the temporary beds;</u> 8. <u>The plans for staffing the temporary beds;</u> 9. <u>The efforts undertaken or to be undertaken to reduce or eliminate the number of temporary beds needed;</u> 10. <u>The address of the building, temporary structure, or satellite location where the hospital or nursing home intends to locate the temporary beds;</u> 11. <u>The specific locations within the building, temporary structure, or satellite location where the hospital or nursing home intends to locate the temporary beds;</u> 12. <u>Whether the locations identified in subdivision C 11 of this section meet life safety code requirements for the type of patients or residents expected to occupy those temporary beds;</u> 13. <u>If life safety code requirements are not currently met for the locations identified in subdivision C 11 of this section, what action the hospital or nursing home will take to meet life safety code requirements; and</u> 14. <u>Any other information that the board or commissioner may request.</u> <p>D. <u>The hospital or nursing home shall provide additional information as may be requested or required by the commissioner to evaluate the temporary bed request.</u></p>
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			<p><u>E. The commissioner shall notify the hospital or nursing home in writing of the commissioner's decision on the temporary bed request. If granted, the commissioner may attach conditions to the approval that, in the sole judgment of the commissioner, protects the public's, patients', or residents' health, safety, or welfare.</u></p> <p><u>F. The hospital or nursing home may not add temporary beds unless its request has been granted and may not operate temporary beds more than 30 days after the expiration of:</u></p> <ol style="list-style-type: none"> <u>1. The commissioner's determination pursuant to subdivision B 1 of this section; or</u> <u>2. The board's or the commissioner's emergency order pursuant to subdivision B 2 of this section.</u> <p><u>G. The department shall promptly inform the Department of Medical Assistance Services and the Centers for Medicare and Medicaid Services of the identity of any hospital or nursing home certified as a Medicare provider or Medicaid provider or both that fails to comply with subsection F of this section.</u></p> <p><u>H. The commissioner may rescind or modify the approval of a temporary bed request if:</u></p> <ol style="list-style-type: none"> <u>1. Additional information becomes known that alters the basis for the original approval, including if the hospital or nursing home added temporary beds prior to receiving the approval; or</u> <u>2. The hospital or nursing home fails to meet any conditions attached to the approval.</u> <p>Statutory Authority §§ 32.1-12 and 32.1-102.2 of the Code of Virginia.</p> <p>INTENT: The intent of the new requirements is detail the minimum required information to request temporary beds, the process for requesting temporary beds, and what the obligations are of each party in the process.</p>
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			<p>RATIONALE: The rationale for the new requirements is to recreate a level of information-sharing and processes familiar to hospitals and nursing homes that were utilized during the COVID-19 pandemic to temporary increase bed capacity.</p> <p>LIKELY IMPACT: The likely impact of the new requirements is clarity regarding what hospitals and nursing homes should do when temporary beds are needed when a disaster has caused an evacuation of another hospital or nursing home or when an emergency order from the Board or the Commissioner has been issued.</p>
<p>220-9998</p>	<p>N/A</p>	<p>FORMS (12VAC5-220)</p> <p>Application for Expedited Review for Certificate of Public Need (eff. 6/94).</p> <p>Registration Form for Capital Expenditures of \$1,000,000 or More But Less than \$2,000,000 Which are Not Defined as a Project on or After July 1, 1993.</p> <p>Request for Extension of a Certificate of Public Need Beyond Two Years from Date of Issuance.</p> <p>Request for Extension of a Certificate of Public Need Beyond One Year, But Less then Two Years from Date of Issuance (Rev. 7/26/93).</p> <p>Application for a Medical Care Facilities Certificate of Public Need - Outpatient Facilities (Rev. 12/10/92).</p> <p>Application for a Medical Care Facilities Certificate of Public Need - Hospitals (Rev. 12/10/92).</p> <p>Application for a Medical Care Facilities Certificate of</p>	<p>CHANGE: The Board is proposing the following change:</p> <p>FORMS (12VAC5-220)</p> <p>Application for Expedited Review for Certificate of Public Need (eff. 6/94).</p> <p>Registration Form for Capital Expenditures of \$1,000,000 or More But Less than \$2,000,000 Which are Not Defined as a Project on or After July 1, 1993.</p> <p>Request for Extension of a Certificate of Public Need Beyond Two Years from Date of Issuance.</p> <p>Request for Extension of a Certificate of Public Need Beyond One Year, But Less then Two Years from Date of Issuance (Rev. 7/26/93).</p> <p>Application for a Medical Care Facilities Certificate of Public Need - Outpatient Facilities (Rev. 12/10/92).</p> <p>Application for a Medical Care Facilities Certificate of Public Need - Hospitals (Rev. 12/10/92).</p> <p>Application for a Medical Care Facilities Certificate of Public Need - Long-Term Care Facilities (Rev. 10/2007).</p>

		<p>Public Need - Long-Term Care Facilities (Rev. 10/2007).</p>	<p><u>Request for Temporary Beds, OLC-1009-F (eff. 06/22).</u></p> <p>INTENT: The intent of the new requirements is for hospitals and nursing homes to use this form when requesting temporary beds.</p> <p>RATIONALE: The rationale for the new requirements is to standardize the information being provided to VDH when temporary beds are being requested.</p> <p>LIKELY IMPACT: The likely impact of the new requirements is consistency in the information and data being received by VDH.</p>
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1 **Project 7197 - Fast-Track**

2 **Department of Health**

3 **Amend Regulation after Enactment of Chapters 712 and 772 of the 2022 Acts of**
4 **Assembly**

5 **12VAC5-220-100. Requirements for reviewable medical care facility projects; exceptions.**

6 A. Prior to initiating a reviewable medical care facility project the owner or sponsor shall obtain
7 a certificate of public need from the commissioner, except as provided in subsection B of this
8 section. In the case of an acquisition of an existing medical care facility, the notification
9 requirement set forth in 12VAC5-220-120 shall be met.

10 B. Provided that an existing hospital or nursing home complies with subsection C, D, and F of
11 this section, Projects a project involving a temporary increase in the total number of beds in an
12 existing hospital or nursing home shall be exempt from the requirement for a certificate;

13 1. for a period of no more than 30 days, if If the commissioner has determined that a
14 natural disaster or man-made disaster has caused the evacuation of a hospital or nursing
15 home and that a public health emergency exists due to a shortage of hospital or nursing
16 home beds; or

17 2. If the board has entered an emergency order pursuant to § 32.1-13 of the Code of
18 Virginia or if the commissioner has entered an emergency order pursuant to §§ 32.1-13
19 and 32.1-20 of the Code of Virginia for the purpose of suppressing;

20 a. A nuisance dangerous to public health;

21 b. A communicable, contagious, or infectious disease; or

22 c. Other danger to the public life and health.

23 C. An existing hospital or nursing home may request a temporary increase in its total number
24 of beds by filing a Request for Temporary Beds, OLC-1009-F (eff. 06/22), with the department
25 that includes:

26 1. The name of the hospital or nursing home;

27 2. The license number of the hospital or nursing home;

28 3. The name of the nursing home's administrator, the hospital's chief executive officer, or
29 his designee;

30 4. The telephone number of the nursing home's administrator, the hospital's chief
31 executive officer, or his designee;

32 5. The email address of the nursing home's administrator, the hospital's chief executive
33 officer, or his designee;

34 6. The number and type of temporary beds the hospital or nursing home anticipates
35 adding;

36 7. The planned use of the temporary beds;

37 8. The plans for staffing the temporary beds;

38 9. The efforts undertaken or to be undertaken to reduce or eliminate the number of
39 temporary beds needed;

40 10. The address of the building, temporary structure, or satellite location where the
41 hospital or nursing home intends to locate the temporary beds;

42 11. The specific locations within the building, temporary structure, or satellite location
43 where the hospital or nursing home intends to locate the temporary beds;

44 12. Whether the locations identified in subdivision C 11 of this section meet life safety
45 code requirements for the type of patients or residents expected to occupy those
46 temporary beds;

47 13. If life safety code requirements are not currently met for the locations identified in
48 subdivision C 11 of this section, what action the hospital or nursing home will take to meet
49 life safety code requirements; and

50 14. Any other information that the board or commissioner may request.

51 D. The hospital or nursing home shall provide additional information as may be requested or
52 required by the commissioner to evaluate the temporary bed request.

53 E. The commissioner shall notify the hospital or nursing home in writing of the commissioner's
54 decision on the temporary bed request. If granted, the commissioner may attach conditions to the
55 approval that, in the sole judgment of the commissioner, protects the public's, patients', or
56 residents' health, safety, or welfare.

57 F. The hospital or nursing home may not add temporary beds unless its request has been
58 granted and may not operate temporary beds more than 30 days after the expiration of:

59 1. The commissioner's determination pursuant to subdivision B 1 of this section; or

60 2. The board's or the commissioner's emergency order pursuant to subdivision B 2 of this
61 section.

62 G. The department shall promptly inform the Department of Medical Assistance Services and
63 the Centers for Medicare and Medicaid Services of the identity of any hospital or nursing home
64 certified as a Medicare provider or Medicaid provider or both that fails to comply with subsection
65 F of this section.

66 H. The commissioner may rescind or modify the approval of a temporary bed request if:

67 1. Additional information becomes known that alters the basis for the original approval,
68 including if the hospital or nursing home added temporary beds prior to receiving the
69 approval; or

70 2. The hospital or nursing home fails to meet any conditions attached to the approval.

71 **Statutory Authority**

72 §§ 32.1-12 and 32.1-102.2 of the Code of Virginia.

73 **Historical Notes**

74 Derived from VR355-30-000 § 3.1, eff. June 30, 1993; amended, Virginia Register Volume 10,
75 Issue 17, eff. June 15, 1994; Volume 35, Issue 24, eff. August 23, 2019.

76 **FORMS (12VAC5-220)**

77 Application for Expedited Review for Certificate of Public Need (eff. 6/94).

78 Registration Form for Capital Expenditures of \$1,000,000 or More But Less than \$2,000,000
79 Which are Not Defined as a Project on or After July 1, 1993.

80 Request for Extension of a Certificate of Public Need Beyond Two Years from Date of
81 Issuance.

82 Request for Extension of a Certificate of Public Need Beyond One Year, But Less than Two
83 Years from Date of Issuance (Rev. 7/26/93).

84 Application for a Medical Care Facilities Certificate of Public Need - Outpatient Facilities (Rev.
85 12/10/92).

86 Application for a Medical Care Facilities Certificate of Public Need - Hospitals (Rev. 12/10/92).

87 Application for a Medical Care Facilities Certificate of Public Need - Long-Term Care Facilities
88 (Rev. 10/2007).
89 [Request for Temporary Beds, OLC-1009-F \(eff. 06/22\).](#)



COMMONWEALTH of VIRGINIA

Colin M. Greene, MD, MPH
State Health Commissioner

Department of Health
P O BOX 2448
RICHMOND, VA 23218

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

MEMORANDUM

DATE: May 17, 2022

TO: State Board of Health

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

SUBJECT: Fast Track Action – Regulations for the Licensure of Nursing Facilities – Amend Regulation after Enactment of Chapters 712 and 772 of the 2022 Acts of Assembly

Enclosed for your review are proposed amendments to Regulations for the Licensure of Nursing Facilities (12VAC5-371).

Chapters 712 and 722 of the 2022 Acts of Assembly require the State Board of Health to amend its nursing home regulation to exempt from licensure a temporary increase in the total number of beds in an existing nursing home to include “a temporary increase in the total number of beds resulting from the addition of beds at a temporary structure or satellite location operated by the...nursing home, provided that the ability remains to safely staff services across the existing...nursing home.” These acts also amended the exemption to now also be triggered by an emergency order entered pursuant to Va. Code § 32.1-13 or 32.1-20 for the purpose of suppressing a nuisance dangerous to public health or a communicable, contagious, or infectious disease or other danger to the public life and health. The duration of the exemption has also been amended by these acts.

The State Board of Health is requested to approve the Fast Track Action. Should the State Board of Health approve the Fast Track Action, the amendments will be submitted to the Office of the Attorney General to begin the Executive Branch review process, as specified by the Administrative Process Act. Following Executive Branch review and approval, the proposed regulatory text will be published in the Virginia Register of Regulations and on the Virginia Regulatory Town Hall website. A 30-day public comment period will begin. Fifteen days after the close of the public comment period, the regulation will become effective.



townhall.virginia.gov

Fast-Track Regulation Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-371-10 <i>et seq.</i>
VAC Chapter title(s)	Regulations for the Licensure of Nursing Facilities
Action title	Amend Regulation after Enactment of Chapters 712 and 772 of the 2022 Acts of Assembly
Date this document prepared	May 17, 2022

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

Brief Summary

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

Chapters 712 and 722 of the 2022 Acts of Assembly require the State Board of Health to amend its nursing home regulation to exempt from licensure temporary increase in the total number of beds in an existing nursing home to include “a temporary increase in the total number of beds resulting from the addition of beds at a temporary structure or satellite location operated by the...nursing home, provided that the ability remains to safely staff services across the existing...nursing home.” These acts also amended the exemption to now also be triggered by an emergency order entered pursuant to Va. Code § 32.1-13 or 32.1-20 for the purpose of suppressing a nuisance dangerous to public health or a communicable, contagious, or infectious disease or other danger to the public life and health.

The duration of this exemption was amended to be either “a period of no more than the duration of the Commissioner’s determination plus 30 days...when the Commissioner has determined that a natural or man-made disaster has caused the evacuation of a hospital or nursing home and that a public health

emergency exists due to a shortage of hospital or nursing home beds” or “a period of no more than the duration of the emergency order entered pursuant to § 32.1-13 or 32.1-20 plus 30 days.”

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the “Definitions” section of the regulation.

“Board” means the State Board of Health.

“Commissioner” means the State Health Commissioner.

“COPN” means a Certificate of Public Need.

“VDH” means the Virginia Department of Health.

Statement of Final Agency Action

Provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

Insert text here

Mandate and Impetus

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

As required by Virginia Code § 2.2-4012.1, also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track process.

Chapters 712 and 722 of the 2022 Acts of Assembly require the State Board of Health to amend its nursing home regulation to exempt from licensure a temporary increase in the total number of beds in an existing nursing home to include “a temporary increase in the total number of beds resulting from the addition of beds at a temporary structure or satellite location operated by the...nursing home, provided that the ability remains to safely staff services across the existing...nursing home.” These acts also amended the exemption to now also be triggered by an emergency order entered pursuant to Va. Code § 32.1-13 or 32.1-20 for the purpose of suppressing a nuisance dangerous to public health or a communicable, contagious, or infectious disease or other danger to the public life and health. These acts also amended the duration of the exemption.

It is anticipated that this action will be noncontroversial and therefore appropriate for the fast-track process because the minimum information required when requesting temporary beds and the process described in the regulatory action is consistent with the minimum information that was requested of nursing homes and the process that was utilized during the COVID-19 pandemic pursuant to Executive Orders 52 (2020), 84 (2022), 11 (2022), and 16 (2022).



Legal Basis

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

This regulation is promulgated under the authority of Va. Code §§ 32.1-12 and 32.1-127(B)(24). Va. Code § 32.1-12 grants the Board the legal authority “to make, adopt, promulgate, and enforce such regulations...as may be necessary to carry out the provisions of this title and other laws of the Commonwealth administered by it, the Commissioner, or the Department.”

Va. Code § 32.1-127(B)(24) states that the Board shall promulgate regulations that “establish an exemption from the requirement to obtain a license to add temporary beds in an existing...nursing home, including beds located in a temporary structure or satellite location operated by the...nursing home, provided that the ability remains to safely staff services across the existing...nursing home, (i) for a period of no more than the duration of the Commissioner's determination plus 30 days when the Commissioner has determined that a natural or man-made disaster has caused the evacuation of a hospital or nursing home and that a public health emergency exists due to a shortage of...nursing home beds or (ii) for a period of no more than the duration of the emergency order entered pursuant to § 32.1-13 or 32.1-20 plus 30 days when the Board, pursuant to § 32.1-13, or the Commissioner, pursuant to § 32.1-20, has entered an emergency order for the purpose of suppressing a nuisance dangerous to public health or a communicable, contagious, or infectious disease or other danger to the public life and health [.]”

Purpose

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

The rationale or justification of the regulatory change is that the General Assembly has mandated that the existing regulatory flexibilities for nursing home licensure for man-made or natural disasters be modified in light of the Commonwealth’s experience during the COVID-19 pandemic and the impact of nursing home licensure statues and regulations on the ability of nursing homes to rapidly expand bed capacity.

The specific reason the regulatory change is essential to protect the health, safety, or welfare of citizens are that normal state controls on the nursing home bed inventory in the Commonwealth have proven to be too inflexible during certain public health emergencies where demand for beds outstrips both the current inventory and the mandated processes by which additional inventory can be authorized. These amended exemption regulations will allow nursing homes to temporarily increase their bed inventory in response to disasters and other public health emergencies, while still allowing the Commissioner sufficient oversight to ensure the beds are being operated and staffed safely.

The goals of the regulatory change is to create an expeditious process by which nursing homes can request temporary beds while ensuring that the Commissioner and VDH have sufficient information to take action on the request.

Substance

Briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the “Detail of Changes” section below.

12VAC5-371-30. License.

Clarifies what information appears on the face of the nursing home license and where the new exemption process is located in the regulations.

12VAC5-371-40. Licensing process.

Removes the existing disaster exemption language.

12VAC5-371-45. Exemption from licensure.

Creates a new process that is exempt from licensure to allow nursing homes to temporarily increase their bed inventory during disasters or other public health emergencies.

12VAC5-371-9998. FORMS.

Amended to include the new form specified in Section 45.

Issues

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

The primary advantages to the public of implementing the amended provisions are the ability to rapidly and temporarily increase nursing home bed inventory during disasters or other public health emergencies while preserving life safety code protections and safe staffing. The primary advantages to the Commonwealth of implementing the amended provisions are a new exemption process that grants more discretion and flexibility to the Board and Commissioner in responding to public health emergencies for which additional bed inventory is needed without needing either a legislative amendment to the Code of Virginia or an executive order from the Governor. There are no primary disadvantages to the public or the Commonwealth.

Requirements More Restrictive than Federal

Identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements, or no requirements that exceed applicable federal requirements, include a specific statement to that effect.

There are no applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

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

Other State Agencies Particularly Affected

No other state agencies are particularly affected by this proposed regulatory change.

Localities Particularly Affected

Bedford County may be particularly affected by this proposed regulatory change since it operates a nursing home and would be subject to the new regulatory requirements, unlike other localities that do not operate a nursing home.

Other Entities Particularly Affected

Existing nursing homes are particularly affected by this proposed regulatory change as they would be subject to the new regulatory requirements.

Economic Impact

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

Impact on State Agencies

<i>For your agency:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	There are no projected costs, savings, fees or revenues resulting from the regulatory change.
<i>For other state agencies:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	There are no projected costs, savings, fees or revenues resulting from the regulatory change.
<i>For all agencies:</i> Benefits the regulatory change is designed to produce.	The benefits of this regulatory change is creation of an expeditious process by which nursing homes can request temporary beds during disasters or emergencies.

Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	There are no projected costs, savings, fees or revenues resulting from the regulatory change.
Benefits the regulatory change is designed to produce.	The benefits of this regulatory change is creation of an expeditious process by which nursing homes can request temporary beds during disasters or emergencies.

Impact on Other Entities

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	Existing nursing homes.
Agency's best estimate of the number of such entities that will be affected. Include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.	There are 287 nursing homes. VDH does not have any data about the number of full-time employees that these medical care facilities employ.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	There are no projected costs, savings, fees or revenues resulting from the regulatory change.
Benefits the regulatory change is designed to produce.	The benefits of this regulatory change is creation of an expeditious process by which hospitals and nursing homes can request temporary beds during disasters or emergencies.

Alternatives to Regulation

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

There are no viable alternatives to the regulatory change as the Board has no other method other than the promulgation or amendment of regulations to create the mandated regulatory exemption from nursing home licensure.

Regulatory Flexibility Analysis

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

regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the regulatory change.

There are no alternative regulatory methods that will accomplish the objectives of applicable law. The Board is required by the General Assembly to regulate the nursing homes under a licensure program. The Board has no other method other than the promulgation or amendment of regulations to create the mandated regulatory exemption from nursing home licensure. The Board has put forth thoughtful consideration about the burdens of the new regulatory requirements and has limited these amendments to those necessary to protect the health, safety, and welfare of the public.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below.

As required by § 2.2-4011 of the Code of Virginia, if an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

If you are objecting to the use of the fast-track process as the means of promulgating this regulation, please clearly indicate your objection in your comment. Please also indicate the nature of, and reason for, your objection to using this process.

The Board is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal and any alternative approaches, (ii) the potential impacts of the regulation, and (iii) the agency's regulatory flexibility analysis stated in this background document.

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

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

If an existing VAC Chapter(s) is being amended or repealed, use Table 1 to describe the changes between existing VAC Chapter(s) and the proposed regulation. If existing VAC Chapter(s) or sections are being repealed and replaced, ensure Table 1 clearly shows both the current number and the new number for each repealed section and the replacement section.

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
371-30	N/A	<p>12VAC5-371-30. License.</p> <p>A. This chapter is not applicable to:</p> <ol style="list-style-type: none"> 1. Those entities listed in § 32.1-124 of the Code of Virginia; and 2. Facilities established or operated for the practice of religious tenets pursuant to § 32.1-128 of the Code of Virginia, except that such facilities shall comply with the statutes and regulations on environmental protection and life safety. <p>B. A license to operate a nursing facility is issued to a person or organization. An organization may be a partnership, association, corporation, or public entity.</p> <p>C. Each license and renewal thereof shall be issued for one year. A nursing facility shall operate within the terms of its license, which include the:</p> <ol style="list-style-type: none"> 1. Name of the nursing facility; 2. Name of the operator; 3. Physical location of the nursing facility; 4. Maximum number of beds allowed; and 5. Date the license expires. <p>D. A separate license shall be required for nursing facilities maintained on</p>	<p>CHANGE: The Board is proposing the following change:</p> <p>12VAC5-371-30. License.</p> <p>A. This chapter is not applicable to:</p> <ol style="list-style-type: none"> 1. Those entities listed in § 32.1-124 of the Code of Virginia; and 2. Facilities established or operated for the practice of religious tenets pursuant to § 32.1-128 of the Code of Virginia, except that such facilities shall comply with the statutes and regulations on environmental protection and life safety. <p>B. A license to operate a nursing facility is issued to a person or organization. An organization may be a partnership, association, corporation, or public entity.</p> <p>C. Each license and renewal thereof shall be issued for one year. A nursing facility shall operate within the terms of its license, which include the <u>Each license issued by the commissioner shall specify:</u></p> <ol style="list-style-type: none"> 1. Name of the nursing facility; 2. Name of the operator; 3. Physical location of the nursing facility; 4. Maximum number of beds allowed, <u>excluding temporary beds added pursuant to 12VAC5-371-45;</u> and 5. Date the license expires. <p>D. A separate license shall be required for nursing facilities maintained on separate premises, even though they are owned or are operated under the same management.</p> <p>E. Every nursing facility shall be designated by a permanent and unique name.</p> <p>F. The number of resident beds allowed in a nursing facility shall be determined by the department. Requests</p>

		<p>separate premises, even though they are owned or are operated under the same management.</p> <p>E. Every nursing facility shall be designated by a permanent and unique name.</p> <p>F. The number of resident beds allowed in a nursing facility shall be determined by the department. Requests to increase beds must be made in writing and must include an approved Certificate of Public Need, except as provided in 12VAC5-371-40 G.</p> <p>G. Nursing facility units located in and operated by hospitals shall be licensed under Regulations for the Licensure of Hospitals in Virginia (12VAC5-410). Approval for such units shall be included on the annual license issued to each hospital.</p> <p>H. Any person establishing, conducting, maintaining, or operating a nursing facility without a license shall be guilty of a Class 6 felony.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-127 of the Code of Virginia.</p>	<p>to increase beds must be made in writing and must include an approved Certificate of Public Need, except as provided in 12VAC5-371-40 <u>12VAC5-371-45</u>.</p> <p>G. Nursing facility units located in and operated by hospitals shall be licensed under Regulations for the Licensure of Hospitals in Virginia (12VAC5-410). Approval for such units shall be included on the annual license issued to each hospital.</p> <p>H. Any person establishing, conducting, maintaining, or operating a nursing facility without a license shall be guilty of a Class 6 felony.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> <p>INTENT: The intent for the new requirements is conform the regulatory text about nursing home licenses to that found in 12VAC5-410 for hospitals.</p> <p>RATIONALE: The rationale for the new requirements is the current language is unclear that the items listed in subsection C are what actually appear on the face of a nursing home license.</p> <p>LIKELY IMPACT: The likely impact of the new requirements is improved clarity about what the face of a nursing home license will and will not contain.</p>
371-40	N/A	<p>12VAC5-371-40. Licensing process.</p> <p>A. Upon request, the OLC will provide consultation to any person seeking information about obtaining a license. The purpose of such consultation is to:</p> <ol style="list-style-type: none"> 1. Explain the standards and the licensing process; 2. Provide assistance in locating other sources of information; 	<p>CHANGE: The Board is proposing the following change:</p> <p>12VAC5-371-40. Licensing process.</p> <p>A. Upon request, the OLC will provide consultation to any person seeking information about obtaining a license. The purpose of such consultation is to:</p> <ol style="list-style-type: none"> 1. Explain the standards and the licensing process; 2. Provide assistance in locating other sources of information; 3. Review the potential applicant's proposed program plans, forms, and other

		<p>3. Review the potential applicant's proposed program plans, forms, and other documents, as they relate to standards; and</p> <p>4. Alert the potential applicant regarding the need to meet other state and local ordinances, such as fire and building codes and environmental health standards, where applicable.</p> <p>B. Licensees and applicants shall obtain licensure applications from the OLC.</p> <p>C. The OLC shall consider the application complete when all requested information and the application fee is submitted with the form required. If the OLC finds the application incomplete, the applicant will be notified of receipt of the incomplete application.</p> <p>D. The applicant shall complete and submit the initial application to the OLC at least 30 days prior to a planned opening date to allow the OLC time to act on the application. An application for a license may be withdrawn at any time.</p> <p>E. A nursing facility may not be licensed without first complying with the requirements for a Certificate of Public Need as required by Article 1.1. (§ 32.1-102.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia.</p> <p>1. Application for initial license of a nursing facility shall include a statement</p>	<p>documents, as they relate to standards; and</p> <p>4. Alert the potential applicant regarding the need to meet other state and local ordinances, such as fire and building codes and environmental health standards, where applicable.</p> <p>B. Licensees and applicants shall obtain licensure applications from the OLC.</p> <p>C. The OLC shall consider the application complete when all requested information and the application fee is submitted with the form required. If the OLC finds the application incomplete, the applicant will be notified of receipt of the incomplete application.</p> <p>D. The applicant shall complete and submit the initial application to the OLC at least 30 days prior to a planned opening date to allow the OLC time to act on the application. An application for a license may be withdrawn at any time.</p> <p>E. A nursing facility may not be licensed without first complying with the requirements for a Certificate of Public Need as required by Article 1.1. (§ 32.1-102.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia.</p> <p>1. Application for initial license of a nursing facility shall include a statement of any agreement made with the commissioner as a condition for Certificate of Public Need approval to provide a level of care at a reduced rate to indigents or accept patients requiring specialized care.</p> <p>2. Any initial license issued to any nursing facility that made such agreement as a condition of its Certificate of Public Need approval shall not be renewed without demonstrating prior to or at the time of applying for renewal that it is substantially complying with its agreement.</p> <p>F. The renewal of a nursing facility license shall be conditioned upon the up-to-date payment of any civil penalties</p>
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		<p>of any agreement made with the commissioner as a condition for Certificate of Public Need approval to provide a level of care at a reduced rate to indigents or accept patients requiring specialized care.</p> <p>2. Any initial license issued to any nursing facility that made such agreement as a condition of its Certificate of Public Need approval shall not be renewed without demonstrating prior to or at the time of applying for renewal that it is substantially complying with its agreement.</p> <p>F. The renewal of a nursing facility license shall be conditioned upon the up-to-date payment of any civil penalties owed as a result of willful refusal, failure, or neglect to honor certain conditions established in their award of a Certificate of Public Need pursuant to § 32.1-102.4 B of the Code of Virginia.</p> <p>G. Nursing facilities shall be exempt, for a period of no more than 30 days, from the requirement to obtain a license to add temporary beds when the commissioner has determined that a natural or man-made disaster has caused the evacuation of a hospital or nursing home and that a public health emergency exists due to a shortage of hospital or nursing home beds.</p>	<p>owed as a result of willful refusal, failure, or neglect to honor certain conditions established in their award of a Certificate of Public Need pursuant to § 32.1-102.4 B of the Code of Virginia.</p> <p>G. Nursing facilities shall be exempt, for a period of no more than 30 days, from the requirement to obtain a license to add temporary beds when the commissioner has determined that a natural or man-made disaster has caused the evacuation of a hospital or nursing home and that a public health emergency exists due to a shortage of hospital or nursing home beds.</p> <p>H. G. The licensee shall submit the completed renewal application form along with any required attachments and the application fee by the date indicated in the cover letter.</p> <p>† H. It is the licensee's responsibility to complete and return the application to assure timely processing. Should a current license expire before a new license is issued, the current license shall remain in effect provided the complete and accurate application was filed on time.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> <p>INTENT: The intent for this change is to remove the prior disaster exemption language</p> <p>RATIONALE: The rationale for this change is that the new regulatory requirements for exemption from licensure during disasters or public health emergencies should be in a separate regulatory section due to their length and that it is not a licensing process but rather an exception to it.</p> <p>LIKELY IMPACT: The likely impact of the new requirements is improved organization with the regulatory chapter, resulting in improved accessibility of the material.</p>
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		<p>H. The licensee shall submit the completed renewal application form along with any required attachments and the application fee by the date indicated in the cover letter.</p> <p>I. It is the licensee's responsibility to complete and return the application to assure timely processing. Should a current license expire before a new license is issued, the current license shall remain in effect provided the complete and accurate application was filed on time.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-127 of the Code of Virginia.</p>	
N/A	371-45	This is a new section	<p>CHANGE: The Board is proposing the following change:</p> <p><u>12VAC5-371-45. Exemption from licensure.</u></p> <p>A. A nursing home shall be exempt from the requirement to obtain a <u>Certificate of Public Need or a license to add temporary beds, including beds located in a temporary structure or satellite location operated by a nursing home:</u></p> <ol style="list-style-type: none"> 1. <u>If the commissioner has determined that a natural disaster or man-made disaster has caused the evacuation of a hospital or nursing home and that a public health emergency exists due to a shortage of nursing home beds;</u> or 2. <u>If the board has entered an emergency order pursuant to § 32.1-13 of the Code of Virginia or if the commissioner has entered an emergency order pursuant to §§ 32.1-13 and 32.1-20 of the Code of Virginia for the purpose of suppressing:</u> <ol style="list-style-type: none"> a. <u>A nuisance dangerous to public health;</u>

			<p><u>b. A communicable, contagious, or infectious disease; or</u></p> <p><u>c. Other danger to the public life and health.</u></p> <p><u>B. A nursing home may request temporary beds by filing a Request for Temporary Beds, OLC-1009-F (eff. 06/22), with the OLC that includes:</u></p> <ol style="list-style-type: none"> <u>1. The nursing home's name;</u> <u>2. The nursing home's license number;</u> <u>3. The nursing home administrator's or his designee's name;</u> <u>4. The nursing home administrator's or his designee's name telephone number;</u> <u>5. The nursing home administrator's or his designee's name email address;</u> <u>6. The number and type of temporary beds the nursing home anticipates adding;</u> <u>7. The planned use of the temporary beds;</u> <u>8. The plans for staffing the temporary beds;</u> <u>9. The efforts undertaken or to be undertaken to reduce or eliminate the number of temporary beds needed;</u> <u>10. The address of the building, temporary structure, or satellite location where the nursing home intends to locate the temporary beds;</u> <u>11. The specific locations within the building, temporary structure, or satellite location where the nursing home intends to locate the temporary beds;</u> <u>12. Whether the locations identified in subdivision B 11 of this section meet life safety code requirements for the type of residents expected to occupy those temporary beds;</u> <u>13. If life safety code requirements are not currently</u>
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			<p><u>met for the locations identified in subdivision B 11 of this section, what action the nursing home will take to meet life safety code requirements; and</u></p> <p><u>14. Any other information that the board or commissioner may request.</u></p> <p><u>C. The nursing home shall provide additional information as may be requested or required by the commissioner to evaluate the temporary bed request.</u></p> <p><u>D. The commissioner shall notify the nursing home in writing of the commissioner's decision on the temporary bed request. If granted, the commissioner may attach conditions to the approval that, in the sole judgment of the commissioner, protects the public's or residents' health, safety, or welfare.</u></p> <p><u>E. The nursing home may not add temporary beds unless its request has been granted and may not operate temporary beds more than 30 days after the expiration of:</u></p> <ol style="list-style-type: none"> <u>1. The commissioner's determination pursuant to subdivision A 1 of this section; or</u> <u>2. The board's or the commissioner's emergency order pursuant to subdivision A 2 of this section.</u> <p><u>F. The nursing home shall notify the OLC in writing within 24 hours of opening a temporary bed and within 24 hours of closing a temporary bed.</u></p> <p><u>G. The OLC shall promptly inform the Department of Medical Assistance Services and the Centers for Medicare and Medicaid Services of the identity of any nursing home certified as a Medicare provider or Medicaid provider or both that fails to comply with subsection E of this section.</u></p> <p><u>H. The commissioner may rescind or modify the approval of a temporary bed request if:</u></p> <ol style="list-style-type: none"> <u>1. Additional information becomes known that alters the basis for the original approval,</u>
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			<p><u>including if the nursing home added temporary beds prior to receiving the approval; or</u></p> <p><u>2. The nursing home fails to meet any conditions attached to the approval.</u></p> <p>Statutory Authority §§ 32.1-12 and 32.1-127 of the Code of Virginia.</p> <p>INTENT: The intent of the new requirements is detail the minimum required information to request temporary beds, the process for requesting temporary beds, and what the obligations are of each party in the process.</p> <p>RATIONALE: The rationale for the new requirements is to recreate a level of information-sharing and processes familiar to nursing homes that were utilized during the COVID-19 pandemic to temporary increase bed capacity.</p> <p>LIKELY IMPACT: The likely impact of the new requirements is clarity regarding what nursing homes should do when temporary beds are needed when a disaster has caused an evacuation of another hospital or nursing home or when an emergency order from the Board or the Commissioner has been issued.</p>
<p>371-9998</p>	<p>N/A</p>	<p>FORMS (12VAC5-371) Application for License Renewal: Nursing Homes (rev. 9/06). Application for License Renewal: Nursing Homes; Mid Year, Initial and Changes (rev. 9/06).</p>	<p>CHANGE: The Board is proposing the following change:</p> <p>FORMS (12VAC5-371) Application for License Renewal: Nursing Homes (rev. 9/06). Application for License Renewal: Nursing Homes; Mid Year, Initial and Changes (rev. 9/06). <u>Request for Temporary Beds, OLC-1009-F (eff. 06/22).</u></p> <p>INTENT: The intent of the new requirements is for nursing homes to use this form when requesting temporary beds.</p> <p>RATIONALE: The rationale for the new requirements is to standardize the</p>

			<p>information being provided to VDH when temporary beds are being requested.</p> <p>LIKELY IMPACT: The likely impact of the new requirements is consistency in the information and data being received by VDH.</p>
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1 **Project 7196 - Fast-Track**

2 **Department of Health**

3 **Amend Regulation after Enactment of Chapters 712 and 772 of the 2022 Acts of**
4 **Assembly**

5 **12VAC5-371-30. License.**

6 A. This chapter is not applicable to:

- 7 1. Those entities listed in § 32.1-124 of the Code of Virginia; and
- 8 2. Facilities established or operated for the practice of religious tenets pursuant to § 32.1-
9 128 of the Code of Virginia, except that such facilities shall comply with the statutes and
10 regulations on environmental protection and life safety.

11 B. A license to operate a nursing facility is issued to a person or organization. An organization
12 may be a partnership, association, corporation, or public entity.

13 C. Each license and renewal thereof shall be issued for one year. ~~A nursing facility shall~~
14 ~~operate within the terms of its license, which include the~~ Each license issued by the commissioner
15 shall specify:

- 16 1. Name of the nursing facility;
- 17 2. Name of the operator;
- 18 3. Physical location of the nursing facility;
- 19 4. Maximum number of beds allowed, excluding temporary beds added pursuant to
20 12VAC5-371-45; and
- 21 5. Date the license expires.

22 D. A separate license shall be required for nursing facilities maintained on separate premises,
23 even though they are owned or are operated under the same management.

24 E. Every nursing facility shall be designated by a permanent and unique name.

25 F. The number of resident beds allowed in a nursing facility shall be determined by the
26 department. Requests to increase beds must be made in writing and must include an approved
27 Certificate of Public Need, except as provided in ~~12VAC5-371-40 G~~ 12VAC5-371-45.

28 G. Nursing facility units located in and operated by hospitals shall be licensed under
29 Regulations for the Licensure of Hospitals in Virginia (12VAC5-410). Approval for such units shall
30 be included on the annual license issued to each hospital.

31 H. Any person establishing, conducting, maintaining, or operating a nursing facility without a
32 license shall be guilty of a Class 6 felony.

33 **Statutory Authority**

34 §§ 32.1-12 and 32.1-127 of the Code of Virginia.

35 **Historical Notes**

36 Derived from Virginia Register Volume 13, Issue 17, eff. July 1, 1997; amended, Virginia Register
37 Volume 23, Issue 10, eff. March 1, 2007; Volume 35, Issue 24, eff. August 23, 2019; Volume 37,
38 Issue 17, eff. May 27, 2021.

39 **12VAC5-371-40. Licensing process.**

40 A. Upon request, the OLC will provide consultation to any person seeking information about
41 obtaining a license. The purpose of such consultation is to:

- 42 1. Explain the standards and the licensing process;
- 43 2. Provide assistance in locating other sources of information;

44 3. Review the potential applicant's proposed program plans, forms, and other documents,
45 as they relate to standards; and

46 4. Alert the potential applicant regarding the need to meet other state and local ordinances,
47 such as fire and building codes and environmental health standards, where applicable.

48 B. Licensees and applicants shall obtain licensure applications from the OLC.

49 C. The OLC shall consider the application complete when all requested information and the
50 application fee is submitted with the form required. If the OLC finds the application incomplete,
51 the applicant will be notified of receipt of the incomplete application.

52 D. The applicant shall complete and submit the initial application to the OLC at least 30 days
53 prior to a planned opening date to allow the OLC time to act on the application. An application for
54 a license may be withdrawn at any time.

55 E. A nursing facility may not be licensed without first complying with the requirements for a
56 Certificate of Public Need as required by Article 1.1. (§ 32.1-102.1 et seq.) of Chapter 4 of Title
57 32.1 of the Code of Virginia.

58 1. Application for initial license of a nursing facility shall include a statement of any
59 agreement made with the commissioner as a condition for Certificate of Public Need
60 approval to provide a level of care at a reduced rate to indigents or accept patients
61 requiring specialized care.

62 2. Any initial license issued to any nursing facility that made such agreement as a condition
63 of its Certificate of Public Need approval shall not be renewed without demonstrating prior
64 to or at the time of applying for renewal that it is substantially complying with its agreement.

65 F. The renewal of a nursing facility license shall be conditioned upon the up-to-date payment
66 of any civil penalties owed as a result of willful refusal, failure, or neglect to honor certain
67 conditions established in their award of a Certificate of Public Need pursuant to § 32.1-102.4 B of
68 the Code of Virginia.

69 ~~G. Nursing facilities shall be exempt, for a period of no more than 30 days, from the~~
70 ~~requirement to obtain a license to add temporary beds when the commissioner has determined~~
71 ~~that a natural or man-made disaster has caused the evacuation of a hospital or nursing home and~~
72 ~~that a public health emergency exists due to a shortage of hospital or nursing home beds.~~

73 H. G. The licensee shall submit the completed renewal application form along with any
74 required attachments and the application fee by the date indicated in the cover letter.

75 ~~I.~~ H. It is the licensee's responsibility to complete and return the application to assure timely
76 processing. Should a current license expire before a new license is issued, the current license
77 shall remain in effect provided the complete and accurate application was filed on time.

78 **Statutory Authority**

79 §§ 32.1-12 and 32.1-127 of the Code of Virginia.

80 **Historical Notes**

81 Derived from Virginia Register Volume 13, Issue 17, eff. July 1, 1997; amended, Virginia Register
82 Volume 18, Issue 10, eff. February 28, 2002; Volume 23, Issue 10, eff. March 1, 2007; Volume
83 35, Issue 24, eff. August 23, 2019; Volume 37, Issue 17, eff. May 27, 2021.

84 **12VAC5-371-45. Exemption from licensure.**

85 A. A nursing home shall be exempt from the requirement to obtain a Certificate of Public Need
86 or a license to add temporary beds, including beds located in a temporary structure or satellite
87 location operated by a nursing home;

88 1. If the commissioner has determined that a natural disaster or man-made disaster has
89 caused the evacuation of a hospital or nursing home and that a public health emergency
90 exists due to a shortage of nursing home beds-; or

91 2. If the board has entered an emergency order pursuant to § 32.1-13 of the Code of
92 Virginia or if the commissioner has entered an emergency order pursuant to §§ 32.1-13
93 and 32.1-20 of the Code of Virginia for the purpose of suppressing:

94 a. A nuisance dangerous to public health;

95 b. A communicable, contagious, or infectious disease; or

96 c. Other danger to the public life and health.

97 B. A nursing home may request temporary beds by filing a [Request for Temporary Beds, OLC-](#)
98 [1009-F \(eff. 06/22\)](#), with the OLC that includes:

99 1. The nursing home's name;

100 2. The nursing home's license number;

101 3. The nursing home administrator's or his designee's name;

102 4. The nursing home administrator's or his designee's name telephone number;

103 5. The nursing home administrator's or his designee's name email address;

104 6. The number and type of temporary beds the nursing home anticipates adding;

105 7. The planned use of the temporary beds;

106 8. The plans for staffing the temporary beds;

107 9. The efforts undertaken or to be undertaken to reduce or eliminate the number of
108 temporary beds needed;

109 10. The address of the building, temporary structure, or satellite location where the nursing
110 home intends to locate the temporary beds;

111 11. The specific locations within the building, temporary structure, or satellite location
112 where the nursing home intends to locate the temporary beds;

113 12. Whether the locations identified in subdivision B 11 of this section meet life safety code
114 requirements for the type of residents expected to occupy those temporary beds;

115 13. If life safety code requirements are not currently met for the locations identified in
116 subdivision B 11 of this section, what action the nursing home will take to meet life safety
117 code requirements; and

118 14. Any other information that the board or commissioner may request.

119 C. The nursing home shall provide additional information as may be requested or required by
120 the commissioner to evaluate the temporary bed request.

121 D. The commissioner shall notify the nursing home in writing of the commissioner's decision
122 on the temporary bed request. If granted, the commissioner may attach conditions to the approval
123 that, in the sole judgment of the commissioner, protects the public's or residents' health, safety,
124 or welfare.

125 E. The nursing home may not add temporary beds unless its request has been granted and
126 may not operate temporary beds more than 30 days after the expiration of:

127 1. The commissioner's determination pursuant to subdivision A 1 of this section; or

128 2. The board's or the commissioner's emergency order pursuant to subdivision A 2 of this
129 section.

130 F. The nursing home shall notify the OLC in writing within 24 hours of opening a temporary
131 bed and within 24 hours of closing a temporary bed.

132 G. The OLC shall promptly inform the Department of Medical Assistance Services and the
133 Centers for Medicare and Medicaid Services of the identity of any nursing home certified as a
134 Medicare provider or Medicaid provider or both that fails to comply with subsection E of this
135 section.

136 H. The commissioner may rescind or modify the approval of a temporary bed request if:

137 1. Additional information becomes known that alters the basis for the original approval,
138 including if the nursing home added temporary beds prior to receiving the approval; or

139 2. The nursing home fails to meet any conditions attached to the approval.

140 **Statutory Authority**

141 §§ 32.1-12 and 32.1-127 of the Code of Virginia.

142 **FORMS (12VAC5-371)**

143 Application for License Renewal: Nursing Homes (rev. 9/06).

144 Application for License Renewal: Nursing Homes; Mid Year, Initial and Changes (rev. 9/06).

145 [Request for Temporary Beds, OLC-1009-F \(eff. 06/22\).](#)



COMMONWEALTH of VIRGINIA

Department of Health
P O BOX 2448
RICHMOND, VA 23218

Colin M. Greene, MD, MPH
State Health Commissioner

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

MEMORANDUM

DATE: May 4, 2022

TO: Virginia State Board of Health

FROM: Joe Hilbert, Deputy Commissioner for Governmental and Regulatory Affairs

SUBJECT: Fast Track Action – Public Participation Guidelines - Amend Following Periodic Review

Enclosed for your review are proposed Fast Track amendments to the Public Participation Guidelines (12VAC5-11-10 *et seq.*).

A Periodic Review was completed pursuant to Executive Order 14 (as amended July 16, 2018) during which VDH indicated a need to amend the Guidelines. VDH recommends that the Guidelines be updated for consistency with the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*. Additionally, VDH recommends incorporating the ability for public commenters to be accompanied and represented by legal counsel or another representative pursuant to §§ 2.2-4007.02 and 2.2-4009 of the Code

The State Board of Health is requested to approve the Fast Track Action. Should the State Board of Health approve the Fast Track Action, the amendments will be submitted to the Office of the Attorney General to begin the Executive Branch review process, as specified by the Administrative Process Act. Following Executive Branch review and approval, the proposed regulatory text will be published in the Virginia Register of Regulations and on the Virginia Regulatory Town Hall website. A 30-day public comment period will begin. Fifteen days after the close of the public comment period, the regulation will become effective.



townhall.virginia.gov

Fast-Track Regulation Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC5-11
VAC Chapter title(s)	Public Participation Guidelines
Action title	Amend Regulations Following Periodic Review
Date this document prepared	May 4, 2022

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

Brief Summary

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

The Board of Health promulgated the Public Participation Guidelines (“Guidelines”), 12VAC5-11, pursuant to § 2.2-4007.02 of the Code to provide a process for soliciting and receiving public comment during the Board’s regulatory processes. A Periodic Review was completed pursuant to Executive Order 14 (as amended July 16, 2018) during which the Board indicated a need to amend the Guidelines. This action will be used to conform the Guidelines to relevant statutes and regulations, as well as changes in style to conform to the *Form, Style and Procedure Manual for Publication of Virginia Regulations* (“Style Manual”).

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the “Definitions” section of the regulation.

“Board” means the State Board of Health
“Code” means Code of Virginia

Statement of Final Agency Action

Provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

Insert text here.

Mandate and Impetus

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

As required by Virginia Code § 2.2-4012.1, also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track process.

The impetus for this change was the most recent Periodic Review of the Guidelines, the result of which was posted December, 2019.

VDH is required, pursuant to Va. Code § 2.2-4007.02, to promulgate public participation guidelines and the changes made in this action either 1) conform the Guidelines to the Code of Virginia, or 2) are changes in style only. Thus, the action is expected to be noncontroversial.

Legal Basis

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

The regulation is promulgated under the authority of §§ 2.2-4007.02 and 32.1-12 of the Code. Section 32.1-12 grants the Board of Health the legal authority “to make, adopt, promulgate, and enforce such regulations necessary to carry out the provisions of Title 32.1 of the Code.” Section 2.2-4007.02 requires public participation guidelines for soliciting the input of interested parties in the formation and development of an agency’s regulations to be developed, adopted, and used by each agency.

Purpose

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

Section 2.2-4007.02 requires public participation guidelines for soliciting the input of interested parties in the formation and development of an agency's regulations to be developed, adopted, and used by each agency.

Substance

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

The Guidelines are being updated for consistency with the *Form, Style and Procedure Manual for Publication of Virginia Regulations* ("Style Manual"). Additionally, the board will be incorporating the ability for public commenters to be accompanied and represented by legal counsel or another representative pursuant to Chapter 795 of the 2012 Acts of Assembly. Other revisions to the Regulations will be considered to ensure they are up to date and consistent with the Code of Virginia and other applicable law or regulations.

Issues

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

The primary advantages to both the public and to the agency are guidelines for participation in VDH's regulatory process that are clearer, more readable, and consistent with the Code. No disadvantages to the public or the Commonwealth were identified.

Requirements More Restrictive than Federal

Identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements, or no requirements that exceed applicable federal requirements, include a specific statement to that effect.

There are no applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Identify any other state agencies, localities, or other entities particularly affected by the regulatory change. "Particularly affected" are those that are likely to bear any identified disproportionate material impact

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

Other State Agencies Particularly Affected

None

Localities Particularly Affected

None

Other Entities Particularly Affected

None

Economic Impact

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

Impact on State Agencies

<p><i>For your agency:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources</p>	<p>There is no projected economic impact on the State Board of Health or the Virginia Department of Health.</p>
<p><i>For other state agencies:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.</p>	<p>There is no projected economic impact anticipated for other agencies.</p>
<p><i>For all agencies:</i> Benefits the regulatory change is designed to produce.</p>	<p>The regulatory change will conform the Guidelines to the Code of Virginia and update the style for clarity and readability.</p>

Impact on Localities

<p>Projected costs, savings, fees or revenues resulting from the regulatory change.</p>	<p>There are no localities that will be affected by this change.</p>
<p>Benefits the regulatory change is designed to produce.</p>	<p>The regulatory change will conform the Guidelines to the Code of Virginia and update the style for clarity and readability.</p>

Impact on Other Entities

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	There are no other entities that will be affected by this change.
Agency's best estimate of the number of such entities that will be affected. Include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.	There are no entities that will be affected by this change.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	There are no other entities that will be affected by this change.
Benefits the regulatory change is designed to produce.	The regulatory change will conform the Guidelines to the Code of Virginia and update the style for clarity and readability.

Alternatives to Regulation

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

The regulation complies with the statutory mandate to promulgate public participation guidelines and is the least burdensome alternative for adequately addressing the mandate of the law.

Regulatory Flexibility Analysis

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

Section 2.2-4007.02 requires public participation guidelines for soliciting the input of interested parties in the formation and development of an agency's regulations to be developed, adopted, and used by each agency. The promulgation of these Guidelines and this regulatory change pose no adverse impact on the public or small businesses.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below.

As required by § 2.2-4011 of the Code of Virginia, if an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

If you are objecting to the use of the fast-track process as the means of promulgating this regulation, please clearly indicate your objection in your comment. Please also indicate the nature of, and reason for, your objection to using this process.

The Board is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal and any alternative approaches, (ii) the potential impacts of the regulation, and (iii) the agency's regulatory flexibility analysis stated in this background document.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: <https://townhall.virginia.gov>. Comments may also be submitted by mail, email or fax to Michael Capps, Legislative & Regulatory Coordinator, 109 Governor St., 13th Floor, Richmond, VA 23219, (804) 864-7190, fax: (805) 864-7022 and boardofhealth@vdh.virginia.gov. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements

<p>12VAC5-11</p>		<p>12VAC5-11-10. Purpose. The purpose of this chapter is to promote public involvement in the development, amendment or repeal of the regulations of the State Board of Health. This chapter does not apply to regulations, guidelines, or other documents exempted or excluded from the provisions of the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).</p>	<p>CHANGE: 12VAC5-11-10. Purpose. <u>A.</u> The purpose of this chapter is to promote <u>transparency and</u> public involvement in the development, amendment or repeal of the regulations of the State Board of Health. <u>B.</u> This chapter does not apply to regulations, guidelines, or other documents exempted or excluded from the provisions of the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).</p> <p>INTENT: The intent of the change is to emphasize that transparency is important to the Board in promulgating regulations and to make the section more readable.</p> <p>RATIONALE: The rationale of the change is that separating requirements into multiple subsections is more readable than a larger block of text</p> <p>LIKELY IMPACT: The likely impact is that the section will be easier to read.</p>
<p>12VAC5-11-20</p>		<p>12VAC5-11-20. Definitions. ... "Basic law" means provisions in the Code of Virginia that delineate the basic authority and responsibilities of an agency. "Commonwealth Calendar" means the electronic calendar for official government meetings open to the public as required by § 2.2-3707 C of the Freedom of Information Act. "Negotiated rulemaking panel" or "NRP" means an ad hoc advisory panel of interested parties established by an agency to consider issues that are controversial with the assistance of a facilitator or mediator, for the purpose of reaching a consensus in the development of a proposed regulatory action. "Notification list" means a list used to notify persons pursuant to this chapter. Such a list may include an electronic list maintained through the Virginia Regulatory Town Hall</p>	<p>CHANGE: 12VAC5-11-20. Definitions. ... "Basic law" means provisions in the Code of Virginia that delineate the basic authority and responsibilities of an agency <u>or public body.</u> <u>"Closed meeting" means a meeting from which the public is excluded.</u> "Commonwealth Calendar" means the electronic calendar for official government meetings open to the public as required by § 2.2-3707 C of the <u>Virginia Freedom of Information Act (§ 2.2-3700 et seq. of the Code).</u> <u>"Meeting" or "meetings" shall have the same meaning as in § 2.2-3701 of the Code.</u> "Negotiated rulemaking panel" or "NRP" means an ad hoc advisory panel of interested parties established by an agency to consider issues that are controversial with the assistance of a facilitator or mediator, for the</p>

		<p>or other list maintained by the agency.</p> <p>"Open meeting" means any scheduled gathering of a unit of state government empowered by an agency's basic law to make regulations or decide cases, which is related to promulgating, amending or repealing a regulation.</p> <p>...</p> <p>"Public hearing" means a scheduled time at which members or staff of the agency will meet for the purpose of receiving public comment on a regulatory action.</p> <p>...</p> <p>"Virginia Register" means the Virginia Register of Regulations, the publication that provides official legal notice of new, amended and repealed regulations of state agencies, which is published under the provisions of Article 6 (§ 2.2-4031 et seq.) of the Administrative Process Act.</p>	<p>purpose of reaching a consensus in the development of a proposed regulatory action.</p> <p>"Notification list" means a list used to notify persons pursuant to this chapter. Such a list, which may include an electronic list maintained through the Virginia Regulatory Town Hall or other list maintained by the agency.</p> <p>"Open meeting" or "public meeting" means any scheduled gathering of a unit of state government empowered by an agency's basic law to make regulations or decide cases, which is related to promulgating, amending or repealing a regulation <u>a meeting at which the public may be present.</u></p> <p>...</p> <p>"Public hearing" means a scheduled time at which members or staff of the agency will meet for the purpose of receiving public comment on a regulatory action.</p> <p>...</p> <p>"Virginia Register of Regulations" or "Register" means the Virginia Register of Regulations, the publication that provides official legal notice of new, amended and repealed regulations of state agencies, which is published <u>issued</u> under the provisions of Article 6 (§ 2.2-4031 et seq.) of the Administrative Process Act.</p> <p>INTENT: The intent of the change is to conform the definitions to the Code, the <i>Style Manual</i>, and add definitions for "Closed meeting" and "Meeting."</p> <p>RATIONALE: The rationale of the change is to conform definitions of certain terms to the definitions of the same terms in relevant sections of the Code and add definitions of other terms that are used in the Guidelines.</p> <p>LIKELY IMPACT: The likely impact is that the updated definitions sections will provide more clarity and consistency throughout the Guidelines and with the Code.</p>
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<p>12VAC5-11-30</p>	<p>12VAC5-11-30. Notification list. A. The agency shall maintain a list of persons who have requested to be notified of regulatory actions being pursued by the agency. B. Any person may request to be placed on a notification list by registering as a public user on the Town Hall or by making a request to the agency. Any person who requests to be placed on a notification list shall elect to be notified either by electronic means or through a postal carrier. C. The agency may maintain additional lists for persons who have requested to be informed of specific regulatory issues, proposals, or actions. D. When electronic mail is returned as undeliverable on multiple occasions at least 24 hours apart, that person may be deleted from the list. A single undeliverable message is insufficient cause to delete the person from the list. E. When mail delivered by a postal carrier is returned as undeliverable on multiple occasions, that person may be deleted from the list. F. The agency may periodically request those persons on the notification list to indicate their desire to either continue to be notified electronically, receive documents through a postal carrier, or be deleted from the list.</p>	<p>CHANGE: 12VAC5-11-30. Notification list. A. The agency shall maintain a list of persons who have requested to be notified of <u>a regulatory actions action</u> being pursued by the agency. B. Any <u>A</u> person may request to be placed on a notification list by registering as a public user on the Town Hall or by making a request to the agency. Any <u>A</u> person who requests to be placed on a notification list shall elect to be notified either by electronic means or through a postal carrier. C. The agency may maintain additional lists for persons who have requested to be informed of specific regulatory issues, proposals, or actions. D. When <u>If</u> electronic mail is returned as undeliverable on multiple occasions at least 24 hours apart, <u>the agency may delete</u> that person may be deleted from the list. A single undeliverable message is insufficient cause to delete the person from the list. E. When <u>If</u> mail delivered by a postal carrier is returned as undeliverable on multiple occasions, <u>the agency may delete</u> that person may be deleted from the list. F. The agency may periodically request these <u>the</u> persons on the notification list to indicate their desire to either continue to be notified electronically, receive documents through a postal carrier, or be deleted from the list.</p> <p>INTENT: The intent is to make changes in style to conform to the <i>Style Manual</i>.</p> <p>RATIONALE: The rationale of the change is that the current language is not consistent with the <i>Style Manual</i>.</p>
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			<p>LIKELY IMPACT: The likely impact is that the section will be more readable.</p>
<p>12VAC5-40</p>		<p>12VAC5-11-40. Information to be sent to persons on the notification list. A. To persons electing to receive electronic notification or notification through a postal carrier as described in 12VAC5-11-30, the agency shall send the following information: 1. A notice of intended regulatory action (NOIRA). 2. A notice of the comment period on a proposed, a repropoed, or a fast-track regulation and hyperlinks to, or instructions on how to obtain, a copy of the regulation and any supporting documents. ...</p>	<p>CHANGE: 12VAC5-11-40. Information to be sent to persons on the notification list. A. To <u>The agency shall send, to persons electing to receive electronic notification or notification through a postal carrier as on the notification list described in 12VAC5-11-30, the agency shall send</u> the following information <u>if it is to be published in the Register:</u> 1. A notice of intended regulatory action (NOIRA); 2. A notice of the comment period on a proposed, a repropoed, or a fast-track regulation and hyperlinks to, or instructions on how to obtain, a copy of the regulation and any supporting documents; <u>and</u> ...</p> <p>INTENT: The intent of the change is to conform the section to the <i>Style Manual</i>.</p> <p>RATIONALE: The rationale is that the does not currently conform to the <i>Style Manual's</i> requirements.</p> <p>LIKELY IMPACT: The likely impact is that the section will be more readable.</p>
<p>12VAC5-11-50</p>		<p>12VAC5-11-50. Public comment. A. In considering any nonemergency, nonexempt regulatory action, the agency shall afford interested persons an opportunity to submit data, views, and arguments, either orally or in writing, to the agency. Such opportunity to comment shall include an online public comment forum on the Town Hall. 1. To any requesting person, the agency shall provide copies of the statement of basis, purpose, substance, and issues; the economic impact analysis of the proposed or fast-track regulatory</p>	<p>CHANGE: 12VAC5-11-50. Public comment. A. In considering any a <u>a</u> nonemergency, nonexempt regulatory action, the agency shall afford <u>an</u> interested persons <u>person</u> an opportunity to submit data, views, and arguments, either orally or in writing, to the agency. Such <u>The</u> opportunity to comment shall include an online public comment forum on the Town Hall. B. <u>An interested person may be accompanied by counsel or another representative when providing public comment to the agency.</u></p>

		<p>action; and the agency's response to public comments received.</p> <p>2. The agency may begin crafting a regulatory action prior to or during any opportunities it provides to the public to submit comments.</p> <p>B. The agency shall accept public comments in writing after the publication of a regulatory action in the Virginia Register as follows:</p> <ol style="list-style-type: none"> 1. For a minimum of 30 calendar days following the publication of the notice of intended regulatory action (NOIRA). 2. For a minimum of 60 calendar days following the publication of a proposed regulation. 3. For a minimum of 30 calendar days following the publication of a repropoed regulation. 4. For a minimum of 30 calendar days following the publication of a final adopted regulation. 5. For a minimum of 30 calendar days following the publication of a fast-track regulation. 6. For a minimum of 21 calendar days following the publication of a notice of periodic review. 7. Not later than 21 calendar days following the publication of a petition for rulemaking. <p>C. The agency may determine if any of the comment periods listed in subsection B of this section shall be extended.</p> <p>D. If the Governor finds that one or more changes with substantial impact have been made to a proposed regulation, he may require the agency to provide an additional 30 calendar days to solicit additional public comment on the changes in accordance with § 2.2-4013 C of the Code of Virginia.</p> <p>E. The agency shall send a draft of the agency's summary description of public comment to all public commenters on the proposed regulation at least five days before final adoption of the regulation pursuant to § 2.2-4012 E of the Code of Virginia.</p>	<p>4. To <u>C. The agency shall provide, to any requesting person, the agency shall provide</u> copies of the statement of basis, purpose, substance, and issues; the economic impact analysis of the proposed or fast-track regulatory action; and the agency's response to public comments received.</p> <p>2. D. The agency may begin crafting a regulatory action prior to before or during any opportunities an opportunity it provides to the public to submit comments.</p> <p>B. E. The agency shall accept public comments in writing after the publication of a regulatory action in the Virginia Register as follows:</p> <ol style="list-style-type: none"> 1. For a minimum of 30 calendar days following the publication of the notice of intended regulatory action (NOIRA). 2. For a minimum of 60 calendar days following the publication of a proposed regulation. 3. For a minimum of 30 calendar days following the publication of a repropoed regulation. 4. For a minimum of 30 calendar days following the publication of a final adopted regulation. 5. For a minimum of 30 calendar days following the publication of a fast-track regulation. 6. For a minimum of 21 calendar days following the publication of a notice of periodic review. 7. Not later than 21 calendar days following the publication of a petition for rulemaking. <p>G. E. The agency may determine if any of the extend a comment periods period listed in subsection B of this section shall be extended <u>at its discretion.</u></p>
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			<p>D. G. If the Governor finds that one or more changes with substantial impact have been made to a proposed regulation, he may require the agency to provide an additional 30 calendar days to solicit additional public comment on the changes in accordance with § 2.2-4013 C of the Code of Virginia.</p> <p>E. H. The agency shall send a draft of the agency's summary description of public comment to all public commenters on the proposed regulation at least five days before final adoption of the regulation pursuant to § 2.2-4012 E of the Code of Virginia.</p> <p>INTENT: The intent of the change is to clarify a person's right to be accompanied and represented by counsel while providing public comment and conform the section to the <i>Style Manual</i>.</p> <p>RATIONALE: Ch 795 of the 2012 Acts of Assembly granted a person the right to be accompanied and represented by counsel or another representative and the Guidelines have not been revised since then. The rationale for the style changes is the same as mentioned in earlier sections.</p> <p>LIKELY IMPACT: The likely impact is that persons wishing to provide public comment to the Board may be more aware of their right to representation when providing public comment and more people may choose to exercise that right.</p>
12VAC5-11-60		<p>12VAC5-11-60. Petition for rulemaking.</p> <p>A. As provided in § 2.2-4007 of the Code of Virginia, any person may petition the agency to consider a regulatory action.</p> <p>B. A petition shall include but is not limited to the following information:</p> <ol style="list-style-type: none"> 1. The petitioner's name and contact information; 2. The substance and purpose of the rulemaking that is requested, including 	<p>CHANGE: 12VAC5-11-60. Petition for rulemaking.</p> <p>A. As provided in Pursuant to § 2.2-4007 of the Code of Virginia, <u>any a</u> person may petition the <u>agency board</u> to consider a regulatory action.</p> <p>B. A petition shall include but is not limited to the following information:</p> <ol style="list-style-type: none"> 1. The petitioner's name and contact information;

		<p>reference to any applicable Virginia Administrative Code sections; and</p> <p>3. Reference to the legal authority of the agency to take the action requested.</p> <p>C. The agency shall receive, consider and respond to a petition pursuant to § 2.2-4007 and shall have the sole authority to dispose of the petition.</p> <p>D. The petition shall be posted on the Town Hall and published in the Virginia Register.</p> <p>E. Nothing in this chapter shall prohibit the agency from receiving information or from proceeding on its own motion for rulemaking.</p>	<p>2. The substance and purpose of the rulemaking <u>action</u> that is requested, including reference to any applicable Virginia Administrative Code sections; and</p> <p>3. Reference to the legal authority of the agency <u>board</u> to take the action requested.</p> <p>C. The agency shall receive, consider and respond to a petition pursuant to § 2.2-4007 and shall have the sole authority to dispose of the petition.</p> <p>D. The petition shall be posted on the Town Hall and published in the Virginia Register.</p> <p>E. Nothing in this chapter shall prohibit the agency from receiving information or from proceeding on its own motion for rulemaking.</p> <p>INTENT: The intent is to conform the Guidelines to the <i>Style Manual</i>.</p> <p>RATIONALE: The rationale for the style changes is the same as mentioned in earlier sections.</p> <p>LIKELY IMPACT: The likely impact is that the section will be more readable.</p>
<p>12VAC5-11-70</p>		<p>12VAC5-11-70. Appointment of regulatory advisory panel.</p> <p>A. The agency may appoint a regulatory advisory panel (RAP) to provide professional specialization or technical assistance when the agency determines that such expertise is necessary to address a specific regulatory issue or action or when individuals indicate an interest in working with the agency on a specific regulatory issue or action.</p> <p>B. Any person may request the appointment of a RAP and request to participate in its activities. The agency shall determine when a RAP shall be appointed and the composition of the RAP.</p> <p>C. A RAP may be dissolved by the agency if:</p>	<p>CHANGE: 12VAC5-11-70. Appointment of regulatory advisory panel.</p> <p>A. The agency may appoint a regulatory advisory panel (RAP) to provide professional, specialization <u>specialized</u>, or technical assistance when if the agency determines that such expertise <u>the assistance</u> is necessary to address a specific regulatory issue or action or when individuals indicate an interest in working with the agency on a specific regulatory issue or action.</p> <p>B. Any <u>A</u> person may request the appointment of a RAP and request to participate in its activities. The agency shall determine when if a RAP shall be appointed and the composition of the RAP.</p>

		<p>1. The proposed text of the regulation is posted on the Town Hall, published in the Virginia Register, or such other time as the agency determines is appropriate; or</p> <p>2. The agency determines that the regulatory action is either exempt or excluded from the requirements of the Administrative Process Act.</p>	<p>C. The agency may dissolve a RAP <u>may be dissolved by the agency</u> if:</p> <p>1. The proposed text of the regulation is posted on the Town Hall, published in the Virginia Register, or such other <u>at another</u> time as the agency determines is appropriate; or</p> <p>2. The agency determines that the regulatory action is either exempt or excluded from the requirements of the Administrative Process Act.</p> <p>INTENT: The intent is to make the section more readable, conform to the <i>Style Manual</i>.</p> <p>RATIONALE: The rationale for the style changes is the same as mentioned in earlier sections.</p> <p>LIKELY IMPACT: The likely impact is that the regulations will be more readable.</p>
<p>12VAC5-11-90</p>		<p>12VAC5-11-90. Meetings.</p> <p>Notice of any open meeting, including meetings of a RAP or NRP, shall be posted on the Virginia Regulatory Town Hall and Commonwealth Calendar at least seven working days prior to the date of the meeting. The exception to this requirement is any meeting held in accordance with § 2.2-3707 D of the Code of Virginia allowing for contemporaneous notice to be provided to participants and the public.</p>	<p>CHANGE: 12VAC5-11-90. Meetings.</p> <p>Notice <u>A. The agency shall post notice of any an</u> open meeting, including meetings <u>a meeting</u> of a RAP or NRP, shall be posted on the Virginia Regulatory Town Hall and Commonwealth Calendar at least seven working days prior to <u>before</u> the date of the meeting.</p> <p>B. The agency may provide contemporaneous notice for a special, emergency, or continued <u>The exception to this requirement is any meeting held in accordance with § 2.2-3707 D of the Code of Virginia allowing for contemporaneous notice to be provided to participants and the public.</u></p> <p><u>C. The agency may hold a closed meeting for the purposes listed in § 2.2-3711 of the Code of Virginia pursuant to the requirements of § 2.2-3712 of the Code of Virginia.</u></p> <p><u>D. The agency may conduct a meeting through electronic</u></p>

			<p><u>communication means pursuant to §§ 2.2-3708.2 and 2.2-3708.3 of the Code of Virginia.</u></p> <p>INTENT: The intent of the change is to conform the text to the <i>Style Manual</i> and reference closed meetings and meetings conducted through electronic communications.</p> <p>RATIONALE: The rationale is that the text was not consistent with the <i>Style Manual</i> and that referencing the Code section related to alternate conduct of meetings within the Guidelines would make the information easier to find for the public.</p> <p>LIKELY IMPACT: The likely impact is that the section will be more readable and will clarify meeting-related statutory requirements.</p>
<p>12VAC5-11-110</p>		<p>12VAC5-11-110. Periodic review of regulations. A. The agency shall conduct a periodic review of its regulations consistent with:</p> <ol style="list-style-type: none"> 1. An executive order issued by the Governor pursuant to § 2.2-4017 of the Administrative Process Act to receive comment on all existing regulations as to their effectiveness, efficiency, necessity, clarity, and cost of compliance; and 2. The requirements in § 2.2-4007.1 of the Administrative Process Act regarding regulatory flexibility for small businesses. <p>B. A periodic review may be conducted separately or in conjunction with other regulatory actions.</p> <p>C. Notice of a periodic review shall be posted on the Town Hall and published in the Virginia Register.</p>	<p>CHANGE: 12VAC5-11-110. Periodic review of regulations.</p> <p>A. The agency shall conduct a periodic review of its regulations consistent with:</p> <ol style="list-style-type: none"> 1. An executive order issued by the Governor pursuant to § 2.2-4017 of the Administrative Process Act to receive comment on all existing regulations as to <u>regarding</u> their effectiveness, efficiency, necessity, clarity, and cost of compliance; and 2. The requirements in § 2.2-4007.1 of the Administrative Process Act regarding regulatory flexibility for small businesses. <p>B. A <u>The agency may conduct a</u> periodic review may be conducted separately or in conjunction with other <u>another regulatory actions</u> <u>action</u>.</p> <p>C. Notice <u>The agency shall post a</u> notice of a periodic review shall be posted on the Town Hall and published <u>submit the notice to the Registrar for publication in the Virginia Register.</u></p> <p>INTENT: The intent is to conform to the <i>Style Manual</i>.</p>

			<p>RATIONALE: The rationale for the style changes is the same as mentioned in earlier sections.</p> <p>LIKELY IMPACT: The likely impact is that the regulations will be more readable.</p>
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1 **Project 7166 - NOIRA**

2 **Department of Health**

3 **Amend Public Participation Guidelines Following Periodic Review**

4 Chapter 11

5 Public Participation Guidelines

6 Part I

7 Purpose and Definitions

8 **12VAC5-11-10. Purpose.**

9 A. The purpose of this chapter is to promote transparency and public involvement in the
10 development, amendment or repeal of the regulations of the State Board of Health.

11 B. This chapter does not apply to regulations, guidelines, or other documents exempted or
12 excluded from the provisions of the Administrative Process Act (§ 2.2-4000 et seq. of the Code of
13 Virginia).

14 **Statutory Authority**

15 §§ 2.2-4007.02 and 32.1-12 of the Code of Virginia.

16 **Historical Notes**

17 Derived from Virginia Register Volume 25, Issue 4, eff. January 1, 2009.

18 **12VAC5-11-20. Definitions.**

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

21 "Administrative Process Act" means Chapter 40 (§ 2.2-4000 et seq.) of Title 2.2 of the Code
22 of Virginia.

23 "Agency" means the State Board of Health, which is the unit of state government empowered
24 by the agency's basic law to make regulations or decide cases. Actions specified in this chapter
25 may be fulfilled by state employees as delegated by the agency.

26 "Basic law" means provisions in the Code of Virginia that delineate the basic authority and
27 responsibilities of an agency or public body.

28 "Closed meeting" means a meeting from which the public is excluded.

29 "Commonwealth Calendar" means the electronic calendar for official government meetings
30 open to the public as required by § 2.2-3707 C of the Virginia Freedom of Information Act (§ 2.2-
31 3700 et seq. of the Code of Virginia).

32 "Meeting" or "meetings" shall have the same meaning as in § 2.2-3701 of the Code of Virginia.

33 "Negotiated rulemaking panel" or "NRP" means an ad hoc advisory panel of interested parties
34 established by an agency to consider issues that are controversial with the assistance of a
35 facilitator or mediator, for the purpose of reaching a consensus in the development of a proposed
36 regulatory action.

37 "Notification list" means a list used to notify persons pursuant to this chapter. ~~Such a list, which~~
38 may include an electronic list maintained through the Virginia Regulatory Town Hall or other list
39 maintained by the agency.

40 "Open meeting" or "public meeting" means ~~any scheduled gathering of a unit of state~~
41 ~~government empowered by an agency's basic law to make regulations or decide cases, which is~~
42 ~~related to promulgating, amending or repealing a regulation~~ a meeting at which the public may be
43 present.

44 "Person" means any individual, corporation, partnership, association, cooperative, limited
45 liability company, trust, joint venture, government, political subdivision, or any other legal or
46 commercial entity and any successor, representative, agent, agency, or instrumentality thereof.

47 ~~"Public hearing" means a scheduled time at which members or staff of the agency will meet~~
48 ~~for the purpose of receiving public comment on a regulatory action.~~

49 "Regulation" means any statement of general application having the force of law, affecting the
50 rights or conduct of any person, adopted by the agency in accordance with the authority conferred
51 on it by applicable laws.

52 "Regulatory action" means the promulgation, amendment, or repeal of a regulation by the
53 agency.

54 "Regulatory advisory panel" or "RAP" means a standing or ad hoc advisory panel of interested
55 parties established by the agency for the purpose of assisting in regulatory actions.

56 "Town Hall" means the Virginia Regulatory Town Hall, the website operated by the Virginia
57 Department of Planning and Budget at www.townhall.virginia.gov, which has online public
58 comment forums and displays information about regulatory meetings and regulatory actions under
59 consideration in Virginia and sends this information to registered public users.

60 "Virginia Register of Regulations" or "Register" means ~~the Virginia Register of Regulations,~~
61 ~~the publication that provides official legal notice of new, amended and repealed regulations of~~
62 ~~state agencies, which is published~~ issued under the provisions of Article 6 (§ 2.2-4031 et seq.) of
63 the Administrative Process Act.

64 **Statutory Authority**

65 §§ 2.2-4007.02 and 32.1-12 of the Code of Virginia.

66 **Historical Notes**

67 Derived from Virginia Register Volume 25, Issue 4, eff. January 1, 2009.

68 Part II

69 Notification of Interested Persons

70 **12VAC5-11-30. Notification list.**

71 A. The agency shall maintain a list of persons who have requested to be notified of a regulatory
72 ~~actions~~ action being pursued by the agency.

73 B. ~~Any~~ A person may request to be placed on a notification list by registering as a public user
74 on the Town Hall or by making a request to the agency. ~~Any~~ A person who requests to be placed
75 on a notification list shall elect to be notified either by electronic means or through a postal carrier.

76 C. The agency may maintain additional lists for persons who have requested to be informed
77 of specific regulatory issues, proposals, or actions.

78 D. ~~When~~ If electronic mail is returned as undeliverable on multiple occasions at least 24 hours
79 apart, the agency may delete that person ~~may be deleted~~ from the list. ~~A single undeliverable~~
80 ~~message is insufficient cause to delete the person from the list.~~

81 E. ~~When~~ If mail delivered by a postal carrier is returned as undeliverable on multiple
82 occasions, the agency may delete that person ~~may be deleted~~ from the list.

83 F. The agency may periodically request ~~those~~ the persons on the notification list to indicate
84 their desire to either continue to be notified electronically, receive documents through a postal
85 carrier, or be deleted from the list.

86 **Statutory Authority**

87 §§ 2.2-4007.02 and 32.1-12 of the Code of Virginia.

88 **Historical Notes**

89 Derived from Virginia Register Volume 25, Issue 4, eff. January 1, 2009.

90 **12VAC5-11-40. Information to be sent to persons on the notification list.**

91 A. ~~To~~ The agency shall send, to persons ~~electing to receive electronic notification or~~
92 ~~notification through a postal carrier as~~ on the notification list described in 12VAC5-11-30, ~~the~~
93 ~~agency shall send~~ the following information if it is to be published in the Register:

- 94 1. A notice of intended regulatory action (NOIRA);
95 2. A notice of the comment period on a proposed, a repropoed, or a fast-track regulation
96 and hyperlinks to, or instructions on how to obtain, a copy of the regulation and any
97 supporting documents; and
98 3. A notice soliciting comment on a final regulation when the regulatory process has been
99 extended pursuant to § 2.2-4007.06 or 2.2-4013 C of the Code of Virginia.

100 B. The failure of any person to receive any notice or copies of any documents shall not affect
101 the validity of any regulation or regulatory action.

102 **Statutory Authority**

103 §§ 2.2-4007.02 and 32.1-12 of the Code of Virginia.

104 **Historical Notes**

105 Derived from Virginia Register Volume 25, Issue 4, eff. January 1, 2009.

106 Part III

107 Public Participation Procedures

108 **12VAC5-11-50. Public comment.**

109 A. In considering ~~any a~~ nonemergency, nonexempt regulatory action, the agency shall afford
110 an interested persons person an opportunity to submit data, views, and arguments, either orally
111 or in writing, to the agency. ~~Such~~ The opportunity to comment shall include an online public
112 comment forum on the Town Hall.

113 B. An interested person may be accompanied by counsel or another representative when
114 providing public comment to the agency.

115 1. ~~To~~ C. The agency shall provide, to any requesting person, ~~the agency shall provide~~ copies
116 of the statement of basis, purpose, substance, and issues; the economic impact analysis of the
117 proposed or fast-track regulatory action; and the agency's response to public comments received.

118 2. D. The agency may begin crafting a regulatory action ~~prior to~~ before or during ~~any~~
119 ~~opportunities~~ an opportunity it provides to the public to submit comments.

120 ~~B.~~ E. The agency shall accept public comments in writing after the publication of a regulatory
121 action in the Virginia Register as follows:

- 122 1. For a minimum of 30 calendar days following the publication of the notice of intended
123 regulatory action (NOIRA).
124 2. For a minimum of 60 calendar days following the publication of a proposed regulation.
125 3. For a minimum of 30 calendar days following the publication of a repropoed regulation.

126 4. For a minimum of 30 calendar days following the publication of a final adopted
127 regulation.

128 5. For a minimum of 30 calendar days following the publication of a fast-track regulation.

129 6. For a minimum of 21 calendar days following the publication of a notice of periodic
130 review.

131 7. Not later than 21 calendar days following the publication of a petition for rulemaking.

132 ~~G. F.~~ The agency may ~~determine if any of the~~ extend a comment periods period listed in
133 ~~subsection B of this section shall be extended at its discretion.~~

134 ~~D. G.~~ If the Governor finds that one or more changes with substantial impact have been made
135 to a proposed regulation, he may require the agency to provide an additional 30 calendar days to
136 solicit additional public comment on the changes in accordance with § 2.2-4013 C of the Code of
137 Virginia.

138 ~~E. H.~~ The agency shall send a draft of the agency's summary description of public comment
139 to all public commenters on the proposed regulation at least five days before final adoption of the
140 regulation pursuant to § 2.2-4012 E of the Code of Virginia.

141 **Statutory Authority**

142 §§ 2.2-4007.02 and 32.1-12 of the Code of Virginia.

143 **Historical Notes**

144 Derived from Virginia Register Volume 25, Issue 4, eff. January 1, 2009.

145 **12VAC5-11-60. Petition for rulemaking.**

146 A. ~~As provided in~~ Pursuant to § 2.2-4007 of the Code of Virginia, ~~any~~ a person may petition
147 the agency to consider a regulatory action.

148 B. A petition shall include ~~but is not limited to~~ the following information:

- 149 1. The petitioner's name and contact information;
150 2. The substance and purpose of the ~~rulemaking~~ action that is requested, including
151 reference to any applicable Virginia Administrative Code sections; and
152 3. Reference to the legal authority of the agency to take the action requested.

153 C. The agency shall receive, consider and respond to a petition pursuant to § 2.2-4007 and
154 shall have the sole authority to dispose of the petition.

155 D. The petition shall be posted on the Town Hall and published in the Virginia Register.

156 E. Nothing in this chapter shall prohibit the agency from receiving information or from
157 proceeding on its own motion for rulemaking.

158 **Statutory Authority**

159 §§ 2.2-4007.02 and 32.1-12 of the Code of Virginia.

160 **Historical Notes**

161 Derived from Virginia Register Volume 25, Issue 4, eff. January 1, 2009.

162 **12VAC5-11-70. Appointment of regulatory advisory panel.**

163 A. The agency may appoint a regulatory advisory panel (RAP) to provide professional,
164 ~~specialization~~ specialized, or technical assistance ~~when~~ if the agency determines that ~~such~~
165 ~~expertise~~ the assistance is necessary to address a specific regulatory issue or action or when
166 individuals indicate an interest in working with the agency on a specific regulatory issue or action.

167 B. ~~Any~~ A person may request the appointment of a RAP and request to participate in its
168 activities. The agency shall determine ~~when~~ if a RAP shall be appointed and the composition of
169 the RAP.

- 170 C. ~~A The agency may dissolve a RAP may be dissolved by the agency if:~~
171 1. The proposed text of the regulation is posted on the Town Hall, published in the Virginia
172 Register, or ~~such other~~ at another time as the agency determines is appropriate; or
173 2. The agency determines that the regulatory action is either exempt or excluded from the
174 requirements of the Administrative Process Act.

175 **Statutory Authority**

176 §§ 2.2-4007.02 and 32.1-12 of the Code of Virginia.

177 **Historical Notes**

178 Derived from Virginia Register Volume 25, Issue 4, eff. January 1, 2009.

179 **12VAC5-11-90. Meetings.**

180 ~~Notice A. The agency shall post notice of any an~~ open meeting, including ~~meetings a meeting~~
181 of a RAP or NRP, ~~shall be posted~~ on the Virginia Regulatory Town Hall and Commonwealth
182 Calendar at least seven working days ~~prior to~~ before the date of the meeting.

183 B. The agency may give notice to the public contemporaneously with the notice provided to
184 the members of the agency conducting the meeting for a special, emergency, or continued ~~The~~
185 ~~exception to this requirement is any meeting held in accordance with § 2.2-3707 D of the Code of~~
186 ~~Virginia allowing for contemporaneous notice to be provided to participants and the public.~~

187 C. The agency may hold a closed meeting for the purposes listed in § 2.2-3711 of the Code
188 of Virginia pursuant to the requirements of § 2.2-3712 of the Code of Virginia.

189 D. The agency may conduct a meeting through electronic communication means pursuant to
190 §§ 2.2-3708.2 and 2.2-3708.3 of the Code of Virginia.

191 **Statutory Authority**

192 §§ 2.2-4007.02 and 32.1-12 of the Code of Virginia.

193 **Historical Notes**

194 Derived from Virginia Register Volume 25, Issue 4, eff. January 1, 2009.

195 **12VAC5-11-110. Periodic review of regulations.**

- 196 A. The agency shall conduct a periodic review of its regulations consistent with:
197 1. An executive order issued by the Governor pursuant to § 2.2-4017 of the Administrative
198 Process Act to receive comment on all existing regulations ~~as to~~ regarding their
199 effectiveness, efficiency, necessity, clarity, and cost of compliance; and
200 2. The requirements in § 2.2-4007.1 of the Administrative Process Act regarding regulatory
201 flexibility for small businesses.

202 B. ~~A The agency may conduct a periodic review may be conducted~~ separately or in
203 conjunction with ~~other another~~ regulatory actions action.

204 C. ~~Notice The agency shall post a notice of a periodic review shall be posted~~ on the Town Hall
205 and ~~published~~ submit the notice to the Registrar for publication in the Virginia Register.

206 **Statutory Authority**

207 §§ 2.2-4007.02 and 32.1-12 of the Code of Virginia.

208 **Historical Notes**

209 Derived from Virginia Register Volume 25, Issue 4, eff. January 1, 2009.



COMMONWEALTH of VIRGINIA
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The Honorable Faye O. Pritchard, Chair
Virginia State Board of Health
109 Governor Street
Richmond, VA 23219

May 6, 2022

Dear Chair Pritchard:

Section 32.1-111.11 of the Code of Virginia states that “The Board shall designate regional emergency medical services councils which shall be authorized to receive and disburse public funds. Each council shall be charged with the development and implementation of an efficient and effective regional emergency medical services delivery system. The Board shall review those agencies that were the designated regional emergency medical services councils. The Board shall, in accordance with the standards established in its regulations, review and may renew or deny applications for such designations every three years. In its discretion, the Board may establish conditions for renewal of such designations or may solicit applications for designation as a regional emergency medical services council.” In accordance with the Code section above, as well as 12 VAC 5-31-2340 (Section N) of the Virginia Emergency Medical Services Regulations governing Regional EMS Councils, the Virginia Office of EMS (OEMS) is providing the Board of Health with information and recommendations for entities who have applied for re-designation as a Regional EMS Council in Virginia.

Applications for designation as Regional EMS Councils were received by OEMS in October of 2021. Upon verification of completion of those applications, OEMS forwarded application information to Regional EMS Council designation site reviewers, to provide an objective evaluation of the information supplied by the applicant in the submitted materials, as well as conduct a review of the physical location of the applicant, and conduct interviews of the applicant organization’s staff, officers, and other system stakeholders.

The site review team consisted of the following individuals:

R. Jason Ferguson
Associate Vice President
Professional and Career Studies Professor
Central Virginia Community College
Member, State EMS Advisory Board
Board Member, Blue Ridge EMS Council

Brian Hricik
Deputy Chief EMS
Alexandria Fire Department
Past Member, State EMS Advisory Board
Board Member and Past President, Northern Virginia EMS Council

Larry A. Oliver
Deputy Chief, Frederick County Fire and Rescue Department
Volunteer District Chief, Front Royal Volunteer Fire and Rescue Department, Inc.
Past Member, State EMS Advisory Board
Vice President, Lord Fairfax EMS Council
Member, Training and Certification Committee Representing VAGEMSA

Wayne Berry
Office of EMS Program Representative, ret.
EMS Captain, Newport News Fire Department, ret.

Site reviews of all applicant entities were conducted between March 16 and April 20, 2022.

Based on the applications received, as well as the site reviewer reports, the OEMS recommends continued designation of Regional EMS Councils and in specified service areas as follows:

Blue Ridge EMS Council – Service area including the counties of Amherst, Appomattox, Bedford and Campbell, and the cities of Bedford and Lynchburg.

Central Shenandoah EMS Council – Service area including the counties of Augusta, Bath, Highland, Rockbridge and Rockingham, and the cities of Buena Vista, Harrisonburg, Lexington, Staunton and Waynesboro.

Lord Fairfax EMS Council – Service area including the counties of Clarke, Frederick, Page, Shenandoah, Warren, and the city of Winchester.

Northern Virginia EMS Council – Service area including the counties of Arlington, Fairfax, Loudoun, and Prince William; and the cities of Alexandria, Fairfax, Falls Church, Manassas, and Manassas Park.

Old Dominion EMS Alliance* – Service area including the counties of Amelia, Brunswick, Buckingham, Charles City, Charlotte, Chesterfield, Cumberland, Dinwiddie, Halifax, Hanover, Henrico, Goochland, Greensville, Lunenburg, Mecklenburg, New Kent, Nottoway, Powhatan, Prince Edward, Prince George, Surry, Sussex; the cities of Colonial Heights, Emporia, Hopewell, Petersburg, Richmond, and South Boston; and the towns of Ashland, Farmville and South Hill.

Peninsulas EMS Council – Service area including the counties of Essex, Gloucester, James City, King and Queen, King William, Lancaster; Mathews, Middlesex, Northumberland, Richmond, Westmoreland, York, and the cities of cities of Poquoson, Hampton, Newport News and Williamsburg.

Rappahannock EMS Council – Service area including the counties of Caroline, Culpeper, Fauquier, King George, Orange, Rappahannock, Spotsylvania, and Stafford; the town of Colonial Beach and the city of Fredericksburg.

Southwest Virginia EMS Council – Service area including the counties of Bland, Buchanan, Carroll, Dickenson, Grayson, Lee, Russell, Scott, Smyth, Tazewell, Washington, Wise and Wythe and the cities of Bristol, Galax, and Norton.

Thomas Jefferson EMS Council – Service area including the counties of Albemarle, Fluvanna, Greene, Louisa, Madison, Nelson, and the City of Charlottesville.

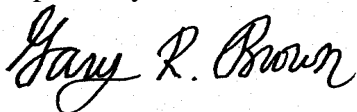
Tidewater EMS Council – Service area including the counties of Accomack, Isle of Wight, Northampton, and Southampton, and the cities of Chesapeake, Franklin, Norfolk, Portsmouth, Suffolk, and Virginia Beach.

Western Virginia EMS Council – Service area including the counties of Alleghany, Craig, Botetourt, Floyd, Franklin, Giles, Henry, Montgomery, Roanoke, Patrick, Pittsylvania, and Pulaski; and the cities of Covington, Danville, Martinsville, Radford, Roanoke, and Salem.

A map outlining the recommended service areas accompanies this cover. OEMS recommends a designation term of no less than three (3) years, commencing on July 1, 2022.

OEMS staff is prepared to answer any questions of the Board related to Regional EMS Council designation, and anticipates the Board approval of the recommendation as specified above.

Respectfully submitted,



Gary R. Brown, Director
Virginia Department of Health
Office of EMS

Designated Regional EMS Council Map 2022

