

**State of Board of Health
Agenda
December 12, 2019 – 9:00 a.m.
Perimeter Center – Boardroom 2**

Call to Order and Welcome	Faye Prichard, Chair
Pledge of Allegiance	Linda Hines
Introductions	Ms. Prichard
Review of Agenda	Joseph Hilbert Deputy Commissioner for Governmental and Regulatory Affairs
Approval of September 5, 2019 Minutes	Ms. Prichard
Commissioner’s Report	M. Norman Oliver, MD, MA State Health Commissioner
Regulatory Action Update	Mr. Hilbert
Break	
Public Comment Period	
<u>Regulatory Action Items</u>	
Regulations of Licensure of Nursing Facilities 12VAC5-371 (Final Amendments)	Rebekah Allen, JD Senior Policy Analyst Office of Licensure and Certification
Regulations of Licensure of Hospitals 12VAC5-440 (Fast Track Amendments)	Kim Beazley Deputy Director Office of Licensure and Certification
Regulations of Licensure of Hospice 12VAC5-391 (Fast Track Amendments)	Ms. Allen
Food Regulations 12VAC5-421 (Fast Track Amendments)	Julie Henderson, Director for Food and General Environmental Services Office of Environmental Health Services
Break	
<u>Working Lunch/Action Item</u>	
Board of Health Annual Report/ Plan for Well-Being Update	Laurie Forlano, DO, MPH Deputy Commissioner for Population Health

Member Reports

Other Business

Adjourn



COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448

RICHMOND, VA 23218

M. Norman Oliver, MD, MA
STATE HEALTH COMMISSIONER

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

MEMORANDUM

DATE: November 13, 2019

TO: Virginia State Board of Health

FROM: Robert A. K. Payne, JD, Director, Office of Licensure and Certification

SUBJECT: Final Action – Regulations for the Licensure of Nursing Facilities

Enclosed for your review is the Final Action for the Regulations for the Licensure of Nursing Facilities (12VAC5-371).

This regulatory action is in response to a Petition for Rulemaking. The action will bring 12VAC5-371 into conformity with the provisions of Va. Code § 32.1-127.001, which states that “Notwithstanding any law or regulation to the contrary, the Board of Health shall promulgate regulations...for the licensure of...nursing homes that shall include minimum standards for the design and construction of...nursing homes [and] certified nursing facilities consistent with the current edition of the Guidelines for Design and Construction of Hospital and Health Care Facilities issued by the American Institute of Architects Academy of Architecture for Health [now the Facility Guidelines Institute].” The latest edition is the 2018 edition of the *Guidelines for Design and Construction of Residential Health, Care, and Support Facilities*.

The regulation currently states that the Virginia Uniform Statewide Building Code takes precedence over the Guidelines for Design and Construction of Hospital and Health Care Facilities. The edition of the Guidelines currently listed in the regulation is outdated. This provision does not conform to the requirements of Va. Code § 32.1-127.001.

The Board of Health is requested to approve the Final Action. Should the Board of Health approve the action, it 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 final adoption and public comment period will begin. The amendment will become effective after the close of the final adoption and public comment period.



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Final Regulation Agency Background Document

Agency name	Virginia Board of Health
Virginia Administrative Code (VAC) citation(s)	12 VAC 5-371
Regulation title(s)	Regulations for the Licensure of Nursing Facilities
Action title	Amend regulations to revise construction standards for nursing facilities
Date this document prepared	May 30, 2019

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

Brief Summary

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

This regulatory action is in response to a Petition for Rulemaking. The action will bring 12VAC5-371 into conformity with the provisions of Va. Code § 32.1-127.001, which states that “Notwithstanding any law or regulation to the contrary, the Board of Health shall promulgate regulations...for the licensure of...nursing homes that shall include minimum standards for the design and construction of...nursing homes [and] certified nursing facilities consistent with the current edition of the Guidelines for Design and Construction of Hospital and Health Care Facilities issued by the American Institute of Architects Academy of Architecture for Health.” The American Institute of Architects Academy of Architecture for Health is now the Facility Guidelines Institute. The latest edition is the 2018 edition of the *Guidelines for Design and Construction of Residential Health, Care, and Support Facilities*.

The regulation currently states that the Virginia Uniform Statewide Building Code takes precedence over the Guidelines for Design and Construction of Hospital and Health Care Facilities. The edition of the

Guidelines currently listed in the regulation is outdated. This provision does not conform to the requirements of Va. Code § 32.1-127.001.

The Virginia Board of Health plans to amend section 12VAC5-371-410 pertaining to building and construction codes for nursing facilities. The purpose of the amendment is to update the references to the guidelines and specify the sections with which nursing facilities will be required to comply. It will also remove the language giving precedence to the Virginia Uniform Statewide Building Code.

Acronyms and Definitions

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

Board – Virginia Board of Health
Code – Code of Virginia
FGI – Facility Guidelines Institute
Guidelines- *Guidelines for Design and Construction of Residential Health, Care, and Support Facilities.*

Statement of Final Agency Action

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

Mandate and Impetus

Please list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding the mandate for this regulatory change, and any other impetus that specifically prompted its initiation. If there are no changes to previously-reported information, include a specific statement to that effect.

The impetus is a Petition for Rulemaking and to conform the 12VAC5-371 to the Code of Virginia. Since the last stage, the FGI has published a 2018 edition of the Guidelines.

Legal Basis

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

The Board is promulgating this regulation under the authority of Va. Code § 32.1-12, which states, in relevant part, that “[t]he Board may make, adopt, promulgate and enforce such regulations and provide for reasonable variances and exemptions therefrom 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” and Va. Code § 32.1-127, which states, in relevant part, that, “[t]he regulations promulgated by the board...[s]hall include minimum standards for (i) the construction and maintenance of hospitals, nursing

homes and certified nursing facilities to ensure the environmental protection and the life safety of its patients, employees, and the public; (ii) the operation, staffing and equipping of hospitals, nursing homes and certified nursing facilities; (iii) qualifications and training of staff of hospitals, nursing homes and certified nursing facilities, except those professionals licensed or certified by the Department of Health Professions; (iv) conditions under which a hospital or nursing home may provide medical and nursing services to patients in their places of residence; and (v) policies related to infection prevention, disaster preparedness, and facility security of hospitals, nursing homes, and certified nursing facilities.”

Purpose

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

This regulatory action is in response to a Petition for Rulemaking. The action will bring the regulation into conformity with the provisions of Va. Code § 32.1-127.001, which states that “Notwithstanding any law or regulation to the contrary, the Board of Health shall promulgate regulations...for the licensure of...nursing homes that shall include minimum standards for the design and construction of...nursing homes[and] certified nursing facilities consistent with the current edition of the Guidelines for Design and Construction of Hospital and Health Care Facilities issued by the American Institute of Architects Academy of Architecture for Health [now FGI].” The regulations currently state that the Virginia Uniform Statewide Building Code takes precedence over the Guidelines and the edition of the Guidelines listed in the regulation is outdated. This regulatory provision is contrary to the requirements of Va. Code § 32.1-127.001.

Substance

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

VDH intends to amend section 410 of 12 VAC 5-371 to specify that nursing facilities shall be designed and constructed consistent with Parts 1 and 2 and section 3.1 of Part 3 of the 2018 edition of the Guidelines, and remove language which states the Virginia Uniform Statewide Building Code takes precedence over the Guidelines, thus bringing the regulation into compliance with the Code.

Issues

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

The primary advantages of the proposed regulatory action to the public are increased facility and construction safety protections in new nursing facilities. The primary disadvantage to the public associated with the proposed action is the increased cost some facilities may incur to construct their facility to comply with the regulations. This increased cost may be passed on to the patient. VDH does not foresee any additional disadvantages to the public. The primary advantage to the agency and the Commonwealth is the promotion of public health and safety. There are no disadvantages associated with the proposed regulations in relation to the agency or the Commonwealth.

Requirements More Restrictive than Federal

Please list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any requirement of the regulatory change which is more restrictive than applicable federal requirements. If there are no changes to previously-reported information, include a specific statement to that effect.

There is no change in the information reported in the previous stage.

Agencies, Localities, and Other Entities Particularly Affected

Please list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any other state agencies, localities, or other entities that are particularly affected by the regulatory change. If there are no changes to previously-reported information, include a specific statement to that effect.

There is no change in the information reported in the *Localities Particularly Affected* or *Economic Impact* sections of the Agency Background Document from the previous stage.

Public Comment

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

The Board received no public comments on this action.

Detail of Changes Made Since the Previous Stage

*Please list all changes that made to the text since the previous stage was published in the Virginia Register of Regulations and the rationale for the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. *Please put an asterisk next to any substantive changes.*

Current chapter-section number	New chapter-section number, if applicable	New requirement from previous stage	Updated new requirement since previous stage	Change, intent, rationale, and likely impact of updated requirements
12VAC5-371-410			A. All construction of new buildings and additions, renovations or , alterations, <u>or repairs</u> of existing buildings for occupancy as a nursing facility shall conform to state and local	This change updates the reference to Parts 1 and 2 and section 3.1 of the 2018 <i>Guidelines for</i>

			<p>codes, zoning and building ordinances, and the <u>Virginia Uniform Statewide Building Code (13VAC5-63)</u>.</p> <p>In addition, nursing facilities shall be designed and constructed according to Part consistent with Parts 1 and 2 and [sections section] 4.1—4 through 4.2—8 3.1 [and 3.2] of Part 4 3 of the 2010 [2014 2018] Guidelines for Design and Construction of <u>Residential Health, Care, and Support Facilities of the Facility Guidelines Institute (formerly of the American Institute of Architects)</u>. However, the requirements of the Uniform Statewide Building Code and local zoning and building ordinances shall take precedence pursuant to <u>§ 32.1-127.001 of the Code of Virginia</u>.</p> <p>B. Architectural drawings and specifications for all new construction or for additions, alterations or renovations to any existing building, shall be dated, stamped with licensure professional seal, and signed by the architect. The architect shall certify that the drawings and specifications were prepared to conform to building code requirements <u>the Virginia Uniform Statewide Building Code and be consistent with Parts 1 and 2 and [sections section 3.1 and 3.2] of Part 3 of the [2014 2018] Guidelines for Design and Construction of Residential Health, Care, and Support Facilities of the Facility Guidelines Institute. [The certification shall be forwarded to the OLC.]</u></p>	<p><i>Design and Construction of Residential Health, Care, and Support Facilities</i>, which was published after the Proposed Stage.</p> <p>This change removes a requirement that was included in the proposed stage. The requirement is no longer necessary.</p>
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<p>DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-371)</p>			<p>Guidelines for Design and Construction of <u>Residential Health, Care, and Support Facilities</u>, [2014 2018] <u>Edition</u>, Facilities Guideline Facility Guidelines Institute (formerly of the American Institute of Architects Academy of Architecture), 2010 Edition, http://www.fgiguideines.org</p>	<p>This change updates the reference to the 2018 <i>Guidelines</i>.</p>
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1 **Project 3898 - Proposed**

2 **DEPARTMENT OF HEALTH**

3 **Amend regulations to revise construction standards for nursing facilities**

4
5 **Part V**

6 **Physical Environment**

7 **12VAC5-371-410. Architectural drawings and specifications.**

8 A. All construction of new buildings and additions, renovations ~~or~~, alterations, or repairs of
9 existing buildings for occupancy as a nursing facility shall conform to state and local codes, zoning
10 and building ordinances, and the Virginia Uniform Statewide Building Code (13VAC5-63).

11 In addition, nursing facilities shall be designed and constructed ~~according to Part consistent~~
12 ~~with Parts 1 and 2 and [sections section] 4.1—1 through 4.2—8 3.1 [and 3.2] of Part 4 3 of the~~
13 ~~2010 [2014 2018] Guidelines for Design and Construction of Residential Health, Care, and~~
14 ~~Support Facilities of the Facilities Facility Guidelines Institute (formerly of the American Institute~~
15 ~~of Architects). However, the requirements of the Uniform Statewide Building Code and local~~
16 ~~zoning and building ordinances shall take precedence pursuant to § 32.1-127.001 of the Code of~~
17 Virginia.

18 B. Architectural drawings and specifications for all new construction or for additions,
19 alterations or renovations to any existing building, shall be dated, stamped with licensure
20 professional seal, and signed by the architect. The architect shall certify that the drawings and
21 specifications were prepared to conform to ~~building code requirements~~ the Virginia Uniform
22 Statewide Building Code and be consistent with Parts 1 and 2 and [sections section] 3.1 [and 3.2]
23 of Part 3 of the [2014 2018] Guidelines for Design and Construction of Residential Health, Care,
24 and Support Facilities of the Facility Guidelines Institute. [The certification shall be forwarded to
25 the OLC.]

26 C. Additional approval may include a Certificate of Public Need.

27 D. Upon completion of the construction, the nursing facility shall maintain a complete set of
28 legible "as built" drawings showing all construction, fixed equipment, and mechanical and
29 electrical systems, as installed or built.

30 **12VAC5-371-420. [Building inspection and classification. (Repealed.)]**

31 [All buildings shall be inspected and approved as required by the appropriate building
32 regulatory entity. Approval shall be a Certificate of Use and Occupancy indicating the building is
33 classified for its proposed licensed purpose.]

34 **DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-371)**

35 Guidelines for Design and Construction of Residential Health, Care, and Support Facilities,
36 [2014 2018] Edition, Facilities Guideline Facility Guidelines Institute (formerly of the American
37 Institute of Architects Academy of Architecture), 2010 Edition, <http://www.fgiguilines.org>

38 Guidelines for Preventing Health Care-Associated Pneumonia, 2003, MMWR 53 (RR03),
39 Advisory Committee on Immunization Practices, Centers for Disease Control and Prevention

40 Prevention and Control of Influenza, MMWR 53 (RR06), Advisory Committee on Immunization
41 Practices, Centers for Disease Control and Prevention



COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448
RICHMOND, VA 23218

M. Norman Oliver, MD, MA
STATE HEALTH COMMISSIONER

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

MEMORANDUM

DATE: October 8, 2019

TO: Virginia State Board of Health

FROM: Kimberly Beazley
Deputy Director, Office of Licensure and Certification

SUBJECT: Fast Track Action – Regulations for the Licensure of Hospitals in Virginia
(12VAC5-410) – Perinatal Anxiety

Enclosed for your review is a Fast-Track action to conform the Regulations for Licensure of Hospitals in Virginia (12VAC5-410) to Chapter 433 of the 2019 Acts of Assembly.

Ch. 433 of the 2019 Acts of Assembly amended and reenacted Va. Code § 32.1-134.01 to add perinatal anxiety to the list of information hospitals are required to make available to maternity patients, the father of the infant, and other relevant family members or caretakers prior to such patients' release. The existing list of information from that statutory section is not currently included in the hospital regulations and this action is being used to conform to the requirements of Va. Code § 32.1-134.01. This action is also being used to correct a spelling error in 12VAC5-410-441.

The Board of Health is requested to 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.



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Fast-Track Regulation Agency Background Document

Agency name	Virginia Board of Health
Virginia Administrative Code (VAC) citation(s)	12 VAC5-410-10 <i>et seq.</i>
Regulation title(s)	Regulations for the Licensure of Hospitals in Virginia
Action title	Amend Regulations to Conform to Ch. 433 of the 2019 Acts of Assembly
Date this document prepared	August 28, 2019

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

Brief Summary

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

Ch. 433 of the 2019 Acts of Assembly amended and reenacted Va. Code § 32.1-134.01 to add perinatal anxiety to the list of information hospitals are required to make available to maternity patients, the father of the infant, and other relevant family members or caretakers prior to such patients' discharge. The existing list of information from that Code section is not currently included in the hospital regulations and the Board is using this action to conform to the requirements of Va. Code § 32.1-134.01. The Board is also using this action to correct a spelling error in 12VAC5-410-441.

Acronyms and Definitions

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

“Board” means the Virginia State Board of Health.

Statement of Final Agency Action

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

Section to be completed following approval.

Mandate and Impetus

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

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

Ch. 433 of the 2019 Acts of Assembly amended and reenacted Va. Code § 32.1-134.01 to add perinatal anxiety to the list of information hospitals are required to make available to maternity patients, the father of the infant, and other relevant family members or caretakers prior to such patients' discharge. The existing list of information from that Code section is not currently included in the hospital regulations.

As the rulemaking is being utilized to conform to the statute and no new requirements are being developed, it is expected to be noncontroversial.

Legal Basis

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

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

Purpose

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

This regulation is being amended due to the changes to Va. Code § 32.1-143.01. The Board is required by Va. Code § 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. The goal of the regulatory change is to conform the regulations to the statute. It is intended to increase maternity patients' knowledge and awareness of certain information that protects the health, safety, and welfare of new mothers and their infants.

Substance

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

12VAC5-410-441: A new subdivision is added to require the provision of information pursuant to Va. Code § 32.1-134.01.

Issues

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

This action is being used to conform the regulations to existing requirements in the statute. The advantage to the public and the Commonwealth is that the regulations are in compliance with legislative changes enacted by the 2019 General Assembly. There are no disadvantages to the public, the agency, or the Commonwealth.

Requirements More Restrictive than Federal

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

There are no requirements in this proposal that exceed applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

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

Other State Agencies Particularly Affected

No other state agency is particularly affected.

Localities Particularly Affected

No locality is particularly affected.

Other Entities Particularly Affected

The 106 licensed inpatient hospitals and 63 outpatient surgical hospitals will be required to comply with the provision.

Economic Impact

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

Impact on State Agencies

<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.	Licensed inpatient hospitals and licensed outpatient surgical hospitals.
Agency's best estimate of the number of such entities that will be affected. Please include an	106 inpatient hospitals and 63 outpatient surgical hospitals. Three of the outpatient surgical

<p>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>hospitals are estimated to meet the definition of "small business"</p>
<p>All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Please be specific and include all costs including, but not limited to:</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>As all licensed hospitals are required to comply with the Code of Virginia, there are no projected costs for compliance with the regulatory change.</p>
<p>Benefits the regulatory change is designed to produce.</p>	<p>The regulatory change is designed to conform the regulations to the Code of Virginia.</p>

Alternatives

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

There are no viable alternatives to conform the regulations to the statutes. As the requirement to provide information on perinatal anxiety is already present in statute, there are no additional costs for small businesses associated with compliance with the regulation.

Regulatory Flexibility Analysis

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

The Board is required to regulate the licensure of hospitals consistent with the provisions of Article 1 (Va. Code § 32.1-127 *et seq.*) of Chapter 5, Title 32.1 of the Code of Virginia. Initiation of this regulatory action is the least burdensome method to conform the Regulations for the Licensure of Hospitals in Virginia (12VAC5-410) to the statute.

Public Participation

If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, 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.

Detail of Changes

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

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

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

For changes to existing regulation(s), please use the following chart:

Current section number	Current requirement	Change, intent, rationale, and likely impact of new requirements
441	<p>12VAC5-410-441. Obstetric service requirements; medical direction; physician consultation and coverage; nurse staffing and coverage; policies and procedures.</p> <p>A. he governing body shall appoint a physician as medical director of the organized obstetric service who meets the qualifications specified in the medical staff bylaws.</p> <p>1. If the medical director is not a board certified obstetrician or board eligible in obstetrics, the hospital shall have a written agreement with one or more board-certified or board-eligible obstetricians to provide consultation on a 24-hour basis. Consultation may be by telephone.</p> <p>2. The duties and responsibilities of the medical director of obstetric services shall include but not be limited to:</p> <p style="padding-left: 40px;">a. The general supervision of the quality of care provided patients admitted to the service;</p>	<p>Change: The Board is proposing the following change:</p> <p>12VAC5-410-441. Obstetric service requirements; medical direction; physician consultation and coverage; nurse staffing and coverage; policies and procedures.</p> <p>A. he The governing body shall appoint a physician as medical director of the organized obstetric service who meets the qualifications specified in the medical staff bylaws.</p> <p>1. If the medical director is not a board certified obstetrician or board eligible in obstetrics, the hospital shall have a written agreement with one or more board-certified or board-eligible obstetricians to provide consultation on a 24-hour basis. Consultation may be by telephone.</p> <p>2. The duties and responsibilities of the medical director of obstetric</p>

<p>b. The establishment of criteria for admission to the service;</p> <p>c. The adherence to standards of professional practices and policies and procedures adopted by the medical staff and governing body;</p> <p>d. The development of recommendations to the medical staff on standards of professional practice and staff privileges;</p> <p>e. The identification of clinical conditions and medical or surgical procedures that require physician consultation; and</p> <p>f. Arranging conferences, at least quarterly, to review obstetrical surgical procedures, complications and infant and maternal mortality and morbidity. Infant mortality and morbidity shall be discussed jointly between the obstetric and newborn service staffs.</p> <p>B. A physician with obstetrical privileges capable of arriving on-site within 30 minutes of notification shall be on a 24-hour on-call duty roster.</p> <p>C. A physician with obstetrical privileges shall be accessible for patient treatment within 10 minutes during the administration of an oxytocic agent to an antepartum patient.</p> <p>D. A physician or a certified nurse-midwife, under the supervision of a physician with obstetrical privileges, shall be in attendance for each delivery. Physician supervision of the nurse-midwife shall be in compliance with the regulations of the Boards of Nursing and Medicine.</p> <p>E. A physician shall be in attendance during all high-risk deliveries. High-risk deliveries shall be defined by the obstetric service medical staff.</p> <p>F. A physician or a nurse skilled in neonatal cardiopulmonary resuscitation (CPR) shall be available in the hospital at all times.</p> <p>G. A current roster of physicians, with a delineation of their obstetrical, newborn, pediatric, medical and surgical staff privileges, shall be posted at each nurses' station in the obstetric suite and in the emergency room.</p> <p>H. A copy of the 24-hour on-call duty schedule, including the list of on-call consulting</p>	<p>services shall include but not be limited to:</p> <p>a. The general supervision of the quality of care provided patients admitted to the service;</p> <p>b. The establishment of criteria for admission to the service;</p> <p>c. The adherence to standards of professional practices and policies and procedures adopted by the medical staff and governing body;</p> <p>d. The development of recommendations to the medical staff on standards of professional practice and staff privileges;</p> <p>e. The identification of clinical conditions and medical or surgical procedures that require physician consultation; and</p> <p>f. Arranging conferences, at least quarterly, to review obstetrical surgical procedures, complications and infant and maternal mortality and morbidity. Infant mortality and morbidity shall be discussed jointly between the obstetric and newborn service staffs.</p> <p>B. A physician with obstetrical privileges capable of arriving on-site within 30 minutes of notification shall be on a 24-hour on-call duty roster.</p> <p>C. A physician with obstetrical privileges shall be accessible for patient treatment within 10 minutes during the administration of an oxytocic agent to an antepartum patient.</p> <p>D. A physician or a certified nurse-midwife, under the supervision of a physician with obstetrical privileges, shall be in attendance for each delivery. Physician supervision of the nurse-midwife shall be in compliance with the regulations of the Boards of Nursing and Medicine.</p> <p>E. A physician shall be in attendance during all high-risk deliveries. High-risk deliveries shall be defined by the obstetric service medical staff.</p> <p>F. A physician or a nurse skilled in neonatal cardiopulmonary resuscitation (CPR) shall be available in the hospital at all times.</p>
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<p>physicians, shall be posted at each nurses' station in the obstetric suite and in the emergency room.</p> <p>I. An occupied unit of the obstetrics service shall be supervised by a registered nurse 24 hours a day.</p> <p>J. If the postpartum unit is organized as a separate nursing unit, staffing shall be based on a formula of one nursing personnel for every six to eight obstetric patients. Staffing shall include at least one registered nurse for the unit for each duty shift.</p> <p>K. If the postpartum and general care newborn units are organized as combined rooming-in or modified rooming-in units, staffing shall be based on a formula of one nursing personnel for every four mother-baby units. The rooming-in units shall be staffed at all times with no less than two nursing personnel each shift. At least one of the two nursing personnel on each shift shall be a registered nurse.</p> <p>L. A registered nurse shall be in attendance at all deliveries. The nurse shall be available on-site to monitor the mother's general condition and that of the fetus during labor, at least one hour after delivery, and longer if complications occur.</p> <p>M. Nurse staffing of the labor and delivery unit shall be scheduled to ensure that the total number of nursing personnel available on each shift is equal to one half of the average number of deliveries in the hospital during a 24-hour period.</p> <p>N. At least one of the personnel assigned to each shift on the obstetrics unit shall be a registered nurse. At no time when the unit is occupied shall the nursing staff on any shift be less than two staff members.</p> <p>O. Patients placed under analgesia or anesthesia during labor or delivery shall be under continuous observation by a registered nurse or a licensed practical nurse for at least one hour after delivery.</p> <p>P. To ensure adequate nursing staff for labor, delivery, and postpartum units during busy or crisis periods, duty schedules shall be developed in accordance with the following nurse/patient ratios:</p>	<p>G. A current roster of physicians, with a delineation of their obstetrical, newborn, pediatric, medical and surgical staff privileges, shall be posted at each nurses' station in the obstetric suite and in the emergency room.</p> <p>H. A copy of the 24-hour on-call duty schedule, including the list of on-call consulting physicians, shall be posted at each nurses' station in the obstetric suite and in the emergency room.</p> <p>I. An occupied unit of the obstetrics service shall be supervised by a registered nurse 24 hours a day.</p> <p>J. If the postpartum unit is organized as a separate nursing unit, staffing shall be based on a formula of one nursing personnel for every six to eight obstetric patients. Staffing shall include at least one registered nurse for the unit for each duty shift.</p> <p>K. If the postpartum and general care newborn units are organized as combined rooming-in or modified rooming-in units, staffing shall be based on a formula of one nursing personnel for every four mother-baby units. The rooming-in units shall be staffed at all times with no less than two nursing personnel each shift. At least one of the two nursing personnel on each shift shall be a registered nurse.</p> <p>L. A registered nurse shall be in attendance at all deliveries. The nurse shall be available on-site to monitor the mother's general condition and that of the fetus during labor, at least one hour after delivery, and longer if complications occur.</p> <p>M. Nurse staffing of the labor and delivery unit shall be scheduled to ensure that the total number of nursing personnel available on each shift is equal to one half of the average number of deliveries in the hospital during a 24-hour period.</p> <p>N. At least one of the personnel assigned to each shift on the obstetrics unit shall be a registered nurse. At no time when the unit is occupied shall the nursing staff on any shift be less than two staff members.</p> <p>O. Patients placed under analgesia or anesthesia during labor or delivery shall be under continuous observation by a registered nurse or a licensed practical nurse for at least one hour after delivery.</p> <p>P. To ensure adequate nursing staff for labor, delivery, and postpartum units during</p>
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<p>1. 1:1 to 2 Antepartum testing</p> <p>2. 1:2 Laboring patients</p> <p>3. 1:1 Patients in second stage of labor</p> <p>4. 1:1 Ill patients with complications</p> <p>5. 1:2 Oxytocin induction or augmentation of labor</p> <p>6. 1:2 Coverage of epidural anesthesia</p> <p>7. 1:1 Circulation for cesarean delivery</p> <p>8. 1:6 to 8 Antepartum/postpartum patients without complications</p> <p>9. 1:2 Postoperative recovery</p> <p>10. 1:3 Patients with complications, but in stable condition</p> <p>11. 1:4 Mother-newborn care</p> <p>Q. Student nurses, licensed practical nurses and nursing aides who assist in the nursing care of obstetric patients shall be under the supervision of a registered nurse.</p> <p>R. At least one registered nurse trained in obstetric and neonatal care shall be assigned to the care of mothers and infants at all times.</p> <p>S. At least one member of the nursing staff on each shift who is skilled in cardiopulmonary resuscitation of the newborn must be immediately available to the delivery suite.</p> <p>T. All nursing personnel assigned to the obstetric service shall have orientation to the obstetrical unit.</p> <p>U. The governing body shall adopt written policies and procedures for the management of obstetric patients approved by the medical and nursing staff assigned to the service.</p> <p>1. The policies and procedures shall include, but not be limited to, the following:</p> <p style="padding-left: 40px;">a. Criteria for the identification and referral of high-risk obstetric patients;</p> <p style="padding-left: 40px;">b. The types of birthing alternatives, if offered, by the hospital;</p> <p style="padding-left: 40px;">c. The monitoring of patients during antepartum, labor, delivery, recovery and</p>	<p>busy or crisis periods, duty schedules shall be developed in accordance with the following nurse/patient ratios:</p> <p>1. 1:1 to 2 Antepartum testing</p> <p>2. 1:2 Laboring patients</p> <p>3. 1:1 Patients in second stage of labor</p> <p>4. 1:1 Ill patients with complications</p> <p>5. 1:2 Oxytocin induction or augmentation of labor</p> <p>6. 1:2 Coverage of epidural anesthesia</p> <p>7. 1:1 Circulation for cesarean delivery</p> <p>8. 1:6 to 8 Antepartum/postpartum patients without complications</p> <p>9. 1:2 Postoperative recovery</p> <p>10. 1:3 Patients with complications, but in stable condition</p> <p>11. 1:4 Mother-newborn care</p> <p>Q. Student nurses, licensed practical nurses and nursing aides who assist in the nursing care of obstetric patients shall be under the supervision of a registered nurse.</p> <p>R. At least one registered nurse trained in obstetric and neonatal care shall be assigned to the care of mothers and infants at all times.</p> <p>S. At least one member of the nursing staff on each shift who is skilled in cardiopulmonary resuscitation of the newborn must be immediately available to the delivery suite.</p> <p>T. All nursing personnel assigned to the obstetric service shall have orientation to the obstetrical unit.</p> <p>U. The governing body shall adopt written policies and procedures for the management of obstetric patients approved by the medical and nursing staff assigned to the service.</p> <p>1. The policies and procedures shall include, but not be limited to, the following:</p> <p style="padding-left: 40px;">a. Criteria for the identification and referral of high-risk obstetric patients;</p> <p style="padding-left: 40px;">b. The types of birthing alternatives, if offered, by the hospital;</p> <p style="padding-left: 40px;">c. The monitoring of patients during antepartum, labor, delivery, recovery and</p>
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	<p>postpartum periods with or without the use of electronic equipment;</p> <p>d. The use of equipment and personnel required for high-risk deliveries, including multiple births;</p> <p>e. The presence of family members or chosen companions during labor, delivery, recovery, and postpartum periods;</p> <p>f. The reporting, to the Department of Health, of all congenital defects;</p> <p>g. The care of patients during labor and delivery to include the administration of Rh O(D) immunoglobulin to Rh negative mothers who have met eligibility criteria. Administration of RH O(D) immunoglobulin shall be documented in the patient's medical record;</p> <p>h. The provision of family planning information, to each obstetric patient at time of discharge, in accordance with § 32.1-134 of the Code of Virginia;</p> <p>i. The use of specially trained paramedical and nursing personnel by the obstetrics and newborn service units;</p> <p>j. A protocol for hospital personnel to use to assist them in obtaining public health, nutrition, genetic and social services for patients who need those services;</p> <p>k. The use of anesthesia with obstetric patients;</p> <p>l. The use of radiological and electronic services, including safety precautions, for obstetric patients;</p> <p>m. The management of mothers who utilize breast milk with their newborns. Breast milk shall be collected in aseptic containers, dated, stored under refrigeration and consumed or disposed of within 24 48 hours of collection if the breast milk has not been frozen. This policy pertains to breast milk collected while in the hospital or at home for hospital use;</p> <p>n. Staff capability to perform cesarean sections within 30 minutes of notice;</p>	<p>postpartum periods with or without the use of electronic equipment;</p> <p>d. The use of equipment and personnel required for high-risk deliveries, including multiple births;</p> <p>e. The presence of family members or chosen companions during labor, delivery, recovery, and postpartum periods;</p> <p>f. The reporting, to the Department of Health, of all congenital defects;</p> <p>g. The care of patients during labor and delivery to include the administration of Rh O(D) immunoglobulin to Rh negative mothers who have met eligibility criteria. Administration of RH O(D) immunoglobulin shall be documented in the patient's medical record;</p> <p>h. The provision of family planning information, to each obstetric patient at time of discharge, in accordance with § 32.1-134 of the Code of Virginia;</p> <p>i. The use of specially trained paramedical and nursing personnel by the obstetrics and newborn service units;</p> <p>j. A protocol for hospital personnel to use to assist them in obtaining public health, nutrition, genetic and social services for patients who need those services;</p> <p>k. The use of anesthesia with obstetric patients;</p> <p>l. The use of radiological and electronic services, including safety precautions, for obstetric patients;</p> <p>m. The management of mothers who utilize breast milk with their newborns. Breast milk shall be collected in aseptic containers, dated, stored under refrigeration and consumed or disposed of within 24 48 hours of collection if the breast milk has not been frozen. This policy pertains to</p>
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<p>o. Emergency resuscitation procedures for mothers and infants;</p> <p>p. The treatment of volume shock in mothers;</p> <p>q. Training of hospital staff in discharge planning for identified substance abusing, postpartum women and their infants; and</p> <p>r. Written discharge planning for identified substance abusing, postpartum women and their infants. The discharge plans shall include appropriate referral sources available in the community or locality for mother and infants such as:</p> <p>(1) Substance abuse treatment services; and</p> <p>(2) Comprehensive early intervention services for infants and toddlers with disabilities and their families pursuant to Part H of the Individuals with Disabilities Education Act, 20 USC § 1471 et seq.</p> <p>(3) The discharge planning process shall be coordinated by a health care professional and shall include, to the extent possible:</p> <p>(a) The father of the infant; and</p> <p>(b) Any family members who may participate in the follow-up care of the mother or infant.</p> <p>The discharge plan shall be discussed with the mother and documented in the medical record.</p> <p>2. The obstetric service shall adopt written policies and procedures for the use of the labor, delivery and recovery rooms (LDR)/Labor, delivery, recovery and postpartum rooms (LDRP) that include, but are not limited to the following:</p> <p>a. The philosophy, goals and objectives for the use of the LDR/LDRP rooms;</p> <p>b. Criteria for patient eligibility to use the LDR/LDRP rooms;</p>	<p>breast milk collected while in the hospital or at home for hospital use;</p> <p>n. Staff capability to perform cesarean sections within 30 minutes of notice;</p> <p>o. Emergency resuscitation procedures for mothers and infants;</p> <p>p. The treatment of volume shock in mothers;</p> <p>q. Training of hospital staff in discharge planning for identified substance abusing, postpartum women and their infants; and</p> <p>r. Written discharge planning for identified substance abusing, postpartum women and their infants. The discharge plans shall include appropriate referral sources available in the community or locality for mother and infants such as:</p> <p>(1) Substance abuse treatment services; and</p> <p>(2) Comprehensive early intervention services for infants and toddlers with disabilities and their families pursuant to Part H of the Individuals with Disabilities Education Act, 20 USC § 1471 et seq.</p> <p>(3) The discharge planning process shall be coordinated by a health care professional and shall include, to the extent possible:</p> <p>(a) The father of the infant; and</p> <p>(b) Any family members who may participate in the follow-up care of the mother or infant.</p> <p>The discharge plan shall be discussed with the mother and documented in the medical record. ; <u>and</u></p> <p><u>s. The provision of information pursuant to § 32.1-134.01 of the Code of Virginia about the incidence of postpartum blues, perinatal depression, and perinatal anxiety; information to increase awareness of shaken baby syndrome and the dangers of shaking infants; and</u></p>
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	<p>c. Identification of high-risk conditions which disqualify patients from use of the LDR/LDRP rooms;</p> <p>d. Patient care in LDR/LDRP rooms, including but not limited to, the following:</p> <p>(1) Defining vital signs, the intervals at which they shall be taken, and requirements for documentation; and</p> <p>(2) Observing, monitoring, and assessing the patient by a registered nurse, certified nurse midwife, or physician;</p> <p>e. The types of analgesia and anesthesia to be used in LDR/LDRP rooms;</p> <p>f. Specifications of conditions of labor or delivery requiring transfer of the patient from LDR/LDRP rooms to the delivery room;</p> <p>g. Specification of conditions requiring the transfer of the mother to the postpartum unit or the newborn to the nursery;</p> <p>h. Criteria for early or routine discharge of the mother and newborn;</p> <p>i. The completion of medical records;</p> <p>j. The presence of family members or chosen companions in the delivery room or operating room in the event that the patient is transferred to the delivery room or operating room;</p> <p>k. The number of visitors allowed in the LDR/LDRP room, and their relationship to the mother; and</p> <p>l. Infection control, including, but not limited to, gowning and attire to be worn by persons in the LDR/LDRP room, upon leaving it, and upon returning.</p>	<p><u>information about safe sleep environments for infants that is consistent with current information from the American Academy of Pediatrics.</u></p> <p>2. The obstetric service shall adopt written policies and procedures for the use of the labor, delivery and recovery rooms (LDR)/Labor, delivery, recovery and postpartum rooms (LDRP) that include, but are not limited to the following:</p> <p>a. The philosophy, goals and objectives for the use of the LDR/LDRP rooms;</p> <p>b. Criteria for patient eligibility to use the LDR/LDRP rooms;</p> <p>c. Identification of high-risk conditions which disqualify patients from use of the LDR/LDRP rooms;</p> <p>d. Patient care in LDR/LDRP rooms, including but not limited to, the following:</p> <p>(1) Defining vital signs, the intervals at which they shall be taken, and requirements for documentation; and</p> <p>(2) Observing, monitoring, and assessing the patient by a registered nurse, certified nurse midwife, or physician;</p> <p>e. The types of analgesia and anesthesia to be used in LDR/LDRP rooms;</p> <p>f. Specifications of conditions of labor or delivery requiring transfer of the patient from LDR/LDRP rooms to the delivery room;</p> <p>g. Specification of conditions requiring the transfer of the mother to the postpartum unit or the newborn to the nursery;</p> <p>h. Criteria for early or routine discharge of the mother and newborn;</p> <p>i. The completion of medical records;</p> <p>j. The presence of family members or chosen companions in the delivery room or operating</p>
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		<p>room in the event that the patient is transferred to the delivery room or operating room;</p> <p>k. The number of visitors allowed in the LDR/LDRP room, and their relationship to the mother; and</p> <p>l. Infection control, including, but not limited to, gowning and attire to be worn by persons in the LDR/LDRP room, upon leaving it, and upon returning.</p> <p>Intent: The intent of the change is to require hospitals to provide certain information to maternity patients before discharging them. The change also corrects a spelling error.</p> <p>Rationale: The provision is being included to conform the regulations to the Code, as amended by Chapter 433 of the 2019 Acts of Assembly.</p> <p>Likely Impact: Hospitals providing care to maternity patients will be aware of and will comply with the requirement to provide the required information to the patients. Maternity patients will be more likely to receive information about a number of public health concerns for new mothers.</p>
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1 Project 6145 - none

2 DEPARTMENT OF HEALTH

3 Amend Regulations to Conform to Chapter 433 of the 2019 Acts of Assembly

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5 **12VAC5-410-441. Obstetric service requirements; medical direction; physician**
6 **consultation and coverage; nurse staffing and coverage; policies and procedures.**

7 A. ~~he~~ The governing body shall appoint a physician as medical director of the organized
8 obstetric service who meets the qualifications specified in the medical staff bylaws.

9 1. If the medical director is not a board certified obstetrician or board eligible in
10 obstetrics, the hospital shall have a written agreement with one or more board-certified
11 or board-eligible obstetricians to provide consultation on a 24-hour basis. Consultation
12 may be by telephone.

13 2. The duties and responsibilities of the medical director of obstetric services shall
14 include but not be limited to:

15 a. The general supervision of the quality of care provided patients admitted to the
16 service;

17 b. The establishment of criteria for admission to the service;

18 c. The adherence to standards of professional practices and policies and
19 procedures adopted by the medical staff and governing body;

20 d. The development of recommendations to the medical staff on standards of
21 professional practice and staff privileges;

22 e. The identification of clinical conditions and medical or surgical procedures that
23 require physician consultation; and

24 f. Arranging conferences, at least quarterly, to review obstetrical surgical
25 procedures, complications and infant and maternal mortality and morbidity. Infant
26 mortality and morbidity shall be discussed jointly between the obstetric and
27 newborn service staffs.

28 B. A physician with obstetrical privileges capable of arriving on-site within 30 minutes of
29 notification shall be on a 24-hour on-call duty roster.

30 C. A physician with obstetrical privileges shall be accessible for patient treatment within
31 10 minutes during the administration of an oxytocic agent to an antepartum patient.

32 D. A physician or a certified nurse-midwife, under the supervision of a physician with
33 obstetrical privileges, shall be in attendance for each delivery. Physician supervision of the
34 nurse-midwife shall be in compliance with the regulations of the Boards of Nursing and
35 Medicine.

36 E. A physician shall be in attendance during all high-risk deliveries. High-risk deliveries
37 shall be defined by the obstetric service medical staff.

38 F. A physician or a nurse skilled in neonatal cardiopulmonary resuscitation (CPR) shall be
39 available in the hospital at all times.

40 G. A current roster of physicians, with a delineation of their obstetrical, newborn, pediatric,
41 medical and surgical staff privileges, shall be posted at each nurses' station in the obstetric
42 suite and in the emergency room.

43 H. A copy of the 24-hour on-call duty schedule, including the list of on-call consulting
44 physicians, shall be posted at each nurses' station in the obstetric suite and in the emergency
45 room.

46 I. An occupied unit of the obstetrics service shall be supervised by a registered nurse 24
47 hours a day.

48 J. If the postpartum unit is organized as a separate nursing unit, staffing shall be based
49 on a formula of one nursing personnel for every six to eight obstetric patients. Staffing shall
50 include at least one registered nurse for the unit for each duty shift.

51 K. If the postpartum and general care newborn units are organized as combined rooming-
52 in or modified rooming-in units, staffing shall be based on a formula of one nursing personnel
53 for every four mother-baby units. The rooming-in units shall be staffed at all times with no less
54 than two nursing personnel each shift. At least one of the two nursing personnel on each shift
55 shall be a registered nurse.

56 L. A registered nurse shall be in attendance at all deliveries. The nurse shall be available
57 on-site to monitor the mother's general condition and that of the fetus during labor, at least
58 one hour after delivery, and longer if complications occur.

59 M. Nurse staffing of the labor and delivery unit shall be scheduled to ensure that the total
60 number of nursing personnel available on each shift is equal to one half of the average number
61 of deliveries in the hospital during a 24-hour period.

62 N. At least one of the personnel assigned to each shift on the obstetrics unit shall be a
63 registered nurse. At no time when the unit is occupied shall the nursing staff on any shift be
64 less than two staff members.

65 O. Patients placed under analgesia or anesthesia during labor or delivery shall be under
66 continuous observation by a registered nurse or a licensed practical nurse for at least one
67 hour after delivery.

68 P. To ensure adequate nursing staff for labor, delivery, and postpartum units during busy
69 or crisis periods, duty schedules shall be developed in accordance with the following
70 nurse/patient ratios:

- 71 1. 1:1 to 2 Antepartum testing
- 72 2. 1:2 Laboring patients
- 73 3. 1:1 Patients in second stage of labor
- 74 4. 1:1 Ill patients with complications
- 75 5. 1:2 Oxytocin induction or augmentation of labor
- 76 6. 1:2 Coverage of epidural anesthesia
- 77 7. 1:1 Circulation for cesarean delivery
- 78 8. 1:6 to 8 Antepartum/postpartum patients without complications
- 79 9. 1:2 Postoperative recovery
- 80 10. 1:3 Patients with complications, but in stable condition
- 81 11. 1:4 Mother-newborn care

82 Q. Student nurses, licensed practical nurses and nursing aides who assist in the nursing
83 care of obstetric patients shall be under the supervision of a registered nurse.

84 R. At least one registered nurse trained in obstetric and neonatal care shall be assigned
85 to the care of mothers and infants at all times.

86 S. At least one member of the nursing staff on each shift who is skilled in cardiopulmonary
87 resuscitation of the newborn must be immediately available to the delivery suite.

88 T. All nursing personnel assigned to the obstetric service shall have orientation to the
89 obstetrical unit.

90 U. The governing body shall adopt written policies and procedures for the management of
91 obstetric patients approved by the medical and nursing staff assigned to the service.

92 1. The policies and procedures shall include, but not be limited to, the following:

93 a. Criteria for the identification and referral of high-risk obstetric patients;

94 b. The types of birthing alternatives, if offered, by the hospital;

95 c. The monitoring of patients during antepartum, labor, delivery, recovery and
96 postpartum periods with or without the use of electronic equipment;

97 d. The use of equipment and personnel required for high-risk deliveries, including
98 multiple births;

99 e. The presence of family members or chosen companions during labor, delivery,
100 recovery, and postpartum periods;

101 f. The reporting, to the Department of Health, of all congenital defects;

102 g. The care of patients during labor and delivery to include the administration of
103 Rh O(D) immunoglobulin to Rh negative mothers who have met eligibility criteria.
104 Administration of RH O(D) immunoglobulin shall be documented in the patient's
105 medical record;

106 h. The provision of family planning information, to each obstetric patient at time of
107 discharge, in accordance with § 32.1-134 of the Code of Virginia;

108 i. The use of specially trained paramedical and nursing personnel by the obstetrics
109 and newborn service units;

110 j. A protocol for hospital personnel to use to assist them in obtaining public health,
111 nutrition, genetic and social services for patients who need those services;

112 k. The use of anesthesia with obstetric patients;

113 l. The use of radiological and electronic services, including safety precautions, for
114 obstetric patients;

115 m. The management of mothers who utilize breast milk with their newborns. Breast
116 milk shall be collected in aseptic containers, dated, stored under refrigeration and
117 consumed or disposed of within 24 48 hours of collection if the breast milk has not
118 been frozen. This policy pertains to breast milk collected while in the hospital or at
119 home for hospital use;

120 n. Staff capability to perform cesarean sections within 30 minutes of notice;

121 o. Emergency resuscitation procedures for mothers and infants;

122 p. The treatment of volume shock in mothers;

123 q. Training of hospital staff in discharge planning for identified substance abusing,
124 postpartum women and their infants; and

125 r. Written discharge planning for identified substance abusing, postpartum women
126 and their infants. The discharge plans shall include appropriate referral sources
127 available in the community or locality for mother and infants such as:

128 (1) Substance abuse treatment services; and

129 (2) Comprehensive early intervention services for infants and toddlers with
130 disabilities and their families pursuant to Part H of the Individuals with Disabilities
131 Education Act, 20 USC § 1471 et seq.

132 (3) The discharge planning process shall be coordinated by a health care
133 professional and shall include, to the extent possible:

134 (a) The father of the infant; and

135 (b) Any family members who may participate in the follow-up care of the mother or
136 infant.

137 The discharge plan shall be discussed with the mother and documented in the
138 medical record; and

139 s. The provision of information pursuant to § 32.1-134.01 of the Code of Virginia
140 about the incidence of postpartum blues, perinatal depression, and perinatal
141 anxiety; information to increase awareness of shaken baby syndrome and the
142 dangers of shaking infants; and information about safe sleep environments for
143 infants that is consistent with current information from the American Academy of
144 Pediatrics.

145 2. The obstetric service shall adopt written policies and procedures for the use of the
146 labor, delivery and recovery rooms (LDR)/Labor, delivery, recovery and postpartum
147 rooms (LDRP) that include, but are not limited to the following:

148 a. The philosophy, goals and objectives for the use of the LDR/LDRP rooms;

149 b. Criteria for patient eligibility to use the LDR/LDRP rooms;

150 c. Identification of high-risk conditions which disqualify patients from use of the
151 LDR/LDRP rooms;

152 d. Patient care in LDR/LDRP rooms, including but not limited to, the following;

153 (1) Defining vital signs, the intervals at which they shall be taken, and requirements
154 for documentation; and

155 (2) Observing, monitoring, and assessing the patient by a registered nurse,
156 certified nurse midwife, or physician;

157 e. The types of analgesia and anesthesia to be used in LDR/LDRP rooms;

158 f. Specifications of conditions of labor or delivery requiring transfer of the patient
159 from LDR/LDRP rooms to the delivery room;

160 g. Specification of conditions requiring the transfer of the mother to the postpartum
161 unit or the newborn to the nursery;

162 h. Criteria for early or routine discharge of the mother and newborn;

163 i. The completion of medical records;

164 j. The presence of family members or chosen companions in the delivery room or
165 operating room in the event that the patient is transferred to the delivery room or
166 operating room;

167 k. The number of visitors allowed in the LDR/LDRP room, and their relationship to
168 the mother; and

169 l. Infection control, including, but not limited to, gowning and attire to be worn by
170 persons in the LDR/LDRP room, upon leaving it, and upon returning.



COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448

RICHMOND, VA 23218

M. NORMAN OLIVER, MD, MA
STATE HEALTH COMMISSIONER

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

MEMORANDUM

DATE: October 10, 2019

TO: Virginia State Board of Health

FROM: Kimberly Beazley
Deputy Director, Office of Licensure and Certification

SUBJECT: Fast Track Action – Regulations for the Licensure of Hospice (12VAC5-391-10
et seq.)

Enclosed for your review is a Fast Track action for the Regulations for the Licensure of Hospice (12VAC5-391-10 *et seq.*) to implement the findings of a periodic review.

In response to public comment received on the notice of periodic review, the action will repeal subsection B of 12VAC5-391-330, which requires hospice medical directors to have admitting privileges at local hospitals and nursing homes. Additionally, the action will update out-of-date references to Board of Nursing regulations, Department of Health Professions' sections of the Code of Virginia, and the current edition of the *Guidelines for Design and Construction of Residential Health, Care, and Support Facilities*. Further, section 380 currently references a training curriculum for personal care aides from the Department of Medical Assistance Services that is no longer in use. This action will change that reference to update the training options for volunteer home attendants. The action also updates the Documents Incorporated by Reference to reflect updated references in the regulatory text.

The Board of Health is requested to approve the Fast Track Amendments. Should the Board of Health approve the Fast Track Action the proposed amendments will be submitted to the Office of the Attorney General to begin the Executive Branch review process, as specified by the Administrative Process Act. Following Executive Branch review and approval, the fast track amendments 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 amendments will become effective.



townhall.virginia.gov

Fast-Track Regulation Agency Background Document

Agency name	Virginia Board of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-391-10 <i>et seq.</i>
Regulation title(s)	Regulations for the Licensure of Hospice
Action title	Amend Regulation Following Periodic Review
Date this document prepared	October 10, 2019

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

Brief Summary

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

The Virginia Board of Health recently concluded a periodic review of 12VAC5-391, in which it decided to amend the regulation. Part of the amendments contemplated include a repeal of 12VAC5-391-330(B). This subsection currently requires that a hospice's medical director have admitting privileges at one or more hospitals or nursing homes that provide inpatient service to the hospice's patients. This repeal will remove the admitting privileges requirement. A reference to an outdated Personal Care Aide Training Curriculum is also replaced by a new training option for hospice program volunteers. This action will also bring current several out-of-date references and associated Documents Incorporated by Reference in the regulations.

Acronyms and Definitions

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

“Agency” means the Virginia Department of Health.

“Board” means the Virginia Board of Health.

“FGI” means the Facility Guidelines Institute.

Statement of Final Agency Action

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

Mandate and Impetus

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

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

The Board is mandated by Va. Code § 2.2-4007.1(D) and Executive Order 14 to conduct a periodic review of its regulations. The most recent periodic review prompted the Board to amend this regulation. Based on public comments and the opinion of subject matter experts within the agency, the Board has decided to repeal subsection B of 12VAC5-391-330. The rulemaking is expected to be noncontroversial because all public comments received during periodic review supported the repeal of subsection B of 12VAC5-391-330 and the agency’s subject matter experts believe that repeal would not jeopardize the protection of public health, safety, and welfare. Further, the additional updates to the regulations do not alter the intent of the regulations or the requirements placed on regulated entities.

Legal Basis

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

Va, Code § 32.1-12 gives the Board the responsibility to make, adopt, promulgate, and enforce such regulations as may be necessary to carry out the provisions of Title 32.1 of the Code of Virginia. Va. Code § 32.1-162.5 requires the Board to adopt regulations governing the activities and services provided by hospices as may be necessary to protect the public health, safety and welfare, including requirements for (i) the qualifications and supervision of licensed and nonlicensed personnel; (ii) the standards for the care, treatment, health, safety, welfare, and comfort of patients and their families served by the program; (iii) the management, operation, staffing and equipping of the hospice program or hospice facility; (iv) clinical and business records kept by the hospice or hospice facility; (v) procedures for the review of utilization and quality of care; and (vi) minimum standards for design and construction.

Purpose

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

This regulation is being amended due to public comments and the professional opinions of subject matter experts within the agency. The Board is required by the General Assembly to promulgate regulations for the licensure of hospice in order to protect the health, safety, and welfare of citizens utilizing hospices. This regulatory change removes the requirement that the medical director of a hospice have admitting privileges at one or more hospitals and nursing facilities that provide inpatient service to the hospice's patients. Public comment indicated that this requirement was difficult for hospices to meet and disqualified candidates that would otherwise have been suitable. Subject matter experts within the agency agreed that this requirement was burdensome to hospices and did not improve protection of the public health, safety, and welfare. The regulatory change is also intended to update outdated references to other documents or VAC sections.

Substance

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

The Board has repealed subsection B of 12VAC5-391-330.

12VAC5-391-340: Updates the reference to Board of Nursing regulation sections.

12VAC5-391-350: Updates the requirements for personal care aide training.

12VAC5-391-380: Updates the reference to Dept. of Health Professions Code sections.

12VAC5-391-440: Updates the reference to the current edition of the *Guidelines for Design and Construction of Residential Health, Care, and Support Facilities*.

DIBRs: Updates the documents incorporated by reference regarding design and construction and removes a document regarding personal care aide training no longer referenced in the regulation.

Issues

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

The primary advantages are to hospices and their administrators, who will face less burdensome requirements in employing a medical director. Subject matter experts within the agency have determined that there are no disadvantages to repealing the requirement that hospice medical directors have admitting privileges at hospitals or nursing homes. Further, more up-to-date regulations will ensure that the industry is regulated accurately and efficiently, and will reduce confusion among regulated entities. There are no primary advantages or disadvantages to the agency or to the Commonwealth.

Requirements More Restrictive than Federal

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

There are no requirements in this proposal that exceed applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

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

No other state agency or locality is particularly affected by this proposed regulatory change.

Hospices and hospice administrators will be particularly affected by this proposed regulatory change.

Economic Impact

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

Impact on State Agencies

<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.	Hospices will face fewer requirements for qualification of medical directors.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: 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 approximately 133 licensed hospice agencies in Virginia. An estimated 18 of those are independently owned and operated. No hospice has more than 500 full-time employees.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Please be specific and include all costs including, but not limited to: 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 anticipated costs associated with this regulatory change.
Benefits the regulatory change is designed to produce.	This regulatory change is designed to make the employing of qualified medical directors less burdensome.

Alternatives

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

Repeal of 12VAC5-391-330(B) is the least burdensome way to remove the admitting privileges requirement.

Regulatory Flexibility Analysis

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

requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the regulatory change.

There are no alternative regulatory methods. The Board is required by the General Assembly to regulate hospices. This regulatory action removes a requirement that hospice medical directors have admitting privileges to a hospital or nursing home, thus allowing for more flexibility in choosing hospice medical directors. It also updates outdated references contained within the regulations.

Public Participation

If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, 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.

Detail of Changes

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

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

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

For changes to existing regulation(s), please use the following chart:

Current section number	New section number, if applicable	Current requirement	Change, intent, rationale, and likely impact of new requirements
330	N/A	<p>12VAC5-391-330. Medical direction.</p> <p>A. There shall be a medical director, who shall be a physician licensed by the Virginia Board of Medicine, responsible for the overall direction and management of the medical component of care. The individual shall have training and experience in the psychological</p>	<p>Change: The Board is proposing the following change:</p> <p>12VAC5-391-330. Medical direction.</p> <p>A. There shall be a medical director, who shall be a physician licensed by the Virginia Board of Medicine, responsible for the overall direction and management of the medical component of care. The individual shall have training and experience in</p>

		<p>and medical needs of the terminally ill.</p> <p>B. The medical director shall have admitting privileges at one or more hospitals and nursing facilities that provide inpatient service to the hospice program's patients.</p> <p>C. The duties and responsibilities of the medical director shall include at least the following:</p> <ol style="list-style-type: none"> 1. Consulting with attending physicians regarding pain and symptom management; 2. Reviewing patient eligibility for hospice services according to the law and the hospice program's admission policies; 3. Acting as a medical resource to the IDG; 4. Coordinating with attending physicians to assure a continuum of medical care in cases of emergency or in the event the attending physician is unable to retain responsibility for the patient's care; 5. Acting as medical liaison with physicians in the community; and 6. Determining, in consultation with the patient's physician, when a patient can no longer remain at home and should be moved to a congregate living facility of the patient's choosing. 	<p>the psychological and medical needs of the terminally ill.</p> <p>B. The medical director shall have admitting privileges at one or more hospitals and nursing facilities that provide inpatient service to the hospice program's patients.</p> <p><u>C.B.</u> The duties and responsibilities of the medical director shall include at least the following:</p> <ol style="list-style-type: none"> 1. Consulting with attending physicians regarding pain and symptom management; 2. Reviewing patient eligibility for hospice services according to the law and the hospice program's admission policies; 3. Acting as a medical resource to the IDG; 4. Coordinating with attending physicians to assure a continuum of medical care in cases of emergency or in the event the attending physician is unable to retain responsibility for the patient's care; 5. Acting as medical liaison with physicians in the community; and 6. Determining, in consultation with the patient's physician, when a patient can no longer remain at home and should be moved to a congregate living facility of the patient's choosing. <p>Intent: This regulatory change is intended to make it easier for hospices to find suitable medical directors.</p> <p>Rationale: Public comments indicate that the requirement of subsection B makes it difficult for hospices to find qualified medical directors. Subject matter experts from the agency agree that repeal would not jeopardize the protection of public health, safety, and welfare. Taking this into account, the Board decided to repeal this requirement.</p>
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			<p>Likely impact: It will be easier for hospices to find qualified medical directors.</p>
<p>340</p>	<p>N/A</p>	<p>12VAC5-391-340. Nursing services. A. All nursing services shall be provided directly or under the supervision of a registered nurse, currently licensed by the Virginia Board of Nursing, who has education and experience in the needs of the terminally ill. Duties and responsibilities of the supervising nurse shall include:</p> <ol style="list-style-type: none"> 1. Assuring that nursing services delivered are provided according to established hospice program policies; 2. Assuring that nursing services are available 24 hours a day, 7 days a week and that licensed practical nurses and home attendants work under the direct supervision of a registered nurse; 3. Participating in the development and implementation of orientation and in-service training hospice programs for all levels of nursing staff employed by the hospice program; 4. Acting as nurse liaison with staff and other agencies, hospice programs and individuals that have contractual agreements to provide nursing services; 5. Participating in quality improvement reviews and evaluations of the nursing services provided; and 6. Directing or supervising the delivery of nursing services. <p>B. Nursing services shall include, but are not limited to:</p>	<p>Change: The Board is proposing the following change:</p> <p>12VAC5-391-340. Nursing services. A. All nursing services shall be provided directly or under the supervision of a registered nurse, currently licensed by the Virginia Board of Nursing, who has education and experience in the needs of the terminally ill. Duties and responsibilities of the supervising nurse shall include:</p> <ol style="list-style-type: none"> 1. Assuring that nursing services delivered are provided according to established hospice program policies; 2. Assuring that nursing services are available 24 hours a day, 7 days a week and that licensed practical nurses and home attendants work under the direct supervision of a registered nurse; 3. Participating in the development and implementation of orientation and in-service training hospice programs for all levels of nursing staff employed by the hospice program; 4. Acting as nurse liaison with staff and other agencies, hospice programs and individuals that have contractual agreements to provide nursing services; 5. Participating in quality improvement reviews and evaluations of the nursing services provided; and 6. Directing or supervising the delivery of nursing services. <p>B. Nursing services shall include, but are not limited to:</p> <ol style="list-style-type: none"> 1. Assessing a patient's needs and admission for service as appropriate;

		<ol style="list-style-type: none"> 1. Assessing a patient's needs and admission for service as appropriate; 2. Working with the IDG to develop a plan of care; 3. Implementing the plan of care; 4. Obtaining physician's orders when necessary; 5. Providing those services requiring substantial and specialized nursing skill; 6. Educating the patient and patient's family in the care of the patient, including pain management; 7. Evaluating the outcome of services; 8. Coordinating and communicating the patient's physical or medical condition to the IDG; 9. Preparing clinical notes; and 10. Supervising licensed practical nurses and home attendants providing delegated nursing services. <p>C. A registered nurse shall coordinate the implementation of each patient's plan of care.</p> <p>D. If nursing duties are delegated, the hospice program shall develop and implement an organizational plan pursuant to 18VAC90-20-420 through 18VAC90-20-460 of the Virginia Administrative Code.</p> <p>E. Licensed practical nurses shall be currently licensed by the Virginia Board of Nursing.</p>	<ol style="list-style-type: none"> 2. Working with the IDG to develop a plan of care; 3. Implementing the plan of care; 4. Obtaining physician's orders when necessary; 5. Providing those services requiring substantial and specialized nursing skill; 6. Educating the patient and patient's family in the care of the patient, including pain management; 7. Evaluating the outcome of services; 8. Coordinating and communicating the patient's physical or medical condition to the IDG; 9. Preparing clinical notes; and 10. Supervising licensed practical nurses and home attendants providing delegated nursing services. <p>C. A registered nurse shall coordinate the implementation of each patient's plan of care.</p> <p>D. If nursing duties are delegated, the hospice program shall develop and implement an organizational plan pursuant to 18VAC90-20-420 <u>18VAC90-19-240</u> through 18VAC90-20-460 <u>18VAC90-19-280</u> of the Virginia Administrative Code.</p> <p>E. Licensed practical nurses shall be currently licensed by the Virginia Board of Nursing.</p> <p>F. The services provided by a licensed practical nurse may include, but are not limited to:</p> <ol style="list-style-type: none"> 1. Delivering nursing services according to the hospice program's policies and standard nursing practices;
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		<p>F. The services provided by a licensed practical nurse may include, but are not limited to:</p> <ol style="list-style-type: none"> 1. Delivering nursing services according to the hospice program's policies and standard nursing practices; 2. Assisting the registered nurse in performing specialized procedures; 3. Assisting the patient with activities of daily living, including the teaching of self-care techniques; 4. Preparing equipment and supplies for treatment that requires adherence to sterile or aseptic techniques; and 5. Preparing clinical notes. 	<ol style="list-style-type: none"> 2. Assisting the registered nurse in performing specialized procedures; 3. Assisting the patient with activities of daily living, including the teaching of self-care techniques; 4. Preparing equipment and supplies for treatment that requires adherence to sterile or aseptic techniques; and 5. Preparing clinical notes. <p>Intent: The change updates the reference to the Board of Nursing's regulations regarding delegation of duties.</p> <p>Rationale: The sections of the Virginia Administrative Code currently cited in this section has been repealed and the respective requirements are now located elsewhere in the VAC.</p> <p>Likely Impact: The change will reduce confusion for regulated entities regarding the specific requirements for the delegation of nursing duties.</p>
350	N/A	<p>12VAC5-391-350. Home attendant services.</p> <p>A. Services of the home attendants may include, but are not limited to:</p> <ol style="list-style-type: none"> 1. Assisting patients with (i) activities of daily living; (ii) ambulation and prescribed exercise; (iii) other special duties with appropriate training and demonstrated competency; 2. Administration of normally self-administered drugs in a patient's private residence as allowed by § 54.1-3408 of the Virginia Drug Control Act (Chapter 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia); 3. Taking and recording vital signs as indicated in the plan of care; 	<p>Change: The Board is proposing the following change:</p> <p>12VAC5-391-350. Home attendant services.</p> <p>A. Services of the home attendants may include, but are not limited to:</p> <ol style="list-style-type: none"> 1. Assisting patients with (i) activities of daily living; (ii) ambulation and prescribed exercise; (iii) other special duties with appropriate training and demonstrated competency; 2. Administration of normally self-administered drugs in a patient's private residence as allowed by § 54.1-3408 of the Virginia Drug Control Act (Chapter 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia); 3. Taking and recording vital signs as indicated in the plan of care;

	<p>4. Measuring and recording fluid intake and output;</p> <p>5. Recording and reporting to the health care professional changes in the patient's physical condition, behavior or appearance;</p> <p>6. Documenting services and observations in the medical record; and</p> <p>7. Performing any other duties that the attendant is qualified to do by additional training and demonstrated competency, within state guidelines.</p> <p>B. Prior to the initial delivery of services, the home attendant shall receive specific written instructions for the patient's care from the appropriate health care professional responsible for the care.</p> <p>C. Home attendants shall work under the supervision of the appropriate health care professional responsible for the patient's care.</p> <p>D. The nurse responsible for supervising the home attendant shall make visits to the patient's home as frequently as necessary, but not less than every two weeks. The results of each visit shall be documented in the medical record.</p> <p>E. Relevant in-service education or training for home attendants shall consist of at least 12 hours annually. In-service training may be in conjunction with on-site supervision.</p> <p>F. Home attendants shall be able to speak, read and write English and shall meet one of the following qualifications:</p> <ol style="list-style-type: none"> 1. Have satisfactorily completed a nursing education hospice program 	<p>4. Measuring and recording fluid intake and output;</p> <p>5. Recording and reporting to the health care professional changes in the patient's physical condition, behavior or appearance;</p> <p>6. Documenting services and observations in the medical record; and</p> <p>7. Performing any other duties that the attendant is qualified to do by additional training and demonstrated competency, within state guidelines.</p> <p>B. Prior to the initial delivery of services, the home attendant shall receive specific written instructions for the patient's care from the appropriate health care professional responsible for the care.</p> <p>C. Home attendants shall work under the supervision of the appropriate health care professional responsible for the patient's care.</p> <p>D. The nurse responsible for supervising the home attendant shall make visits to the patient's home as frequently as necessary, but not less than every two weeks. The results of each visit shall be documented in the medical record.</p> <p>E. Relevant in-service education or training for home attendants shall consist of at least 12 hours annually. In-service training may be in conjunction with on-site supervision.</p> <p>F. Home attendants shall be able to speak, read and write English and shall meet one of the following qualifications <u>before providing services to the hospice program's patients</u>:</p> <ol style="list-style-type: none"> 1. Have satisfactorily completed a nursing education hospice program preparing for registered nurse licensure or practical nurse licensure;
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		<p>preparing for registered nurse licensure or practical nurse licensure;</p> <p>2. Have satisfactorily completed a nurse aide education hospice program approved by the Virginia Board of Nursing;</p> <p>3. Have certification as a nurse aide issued by the Virginia Board of Nursing;</p> <p>4. Be successfully enrolled in a nursing education hospice program preparing for registered nurse or practical nurse licensure and have currently completed at least one nursing course that includes clinical experience involving patient care;</p> <p>5. Have satisfactorily passed a competency evaluation that meets the criteria of 42 CFR 484.36 (b); or</p> <p>6. Have satisfactorily completed training using the "Personal Care Aide Training Curriculum," dated 2003, of the Department of Medical Assistance Services. However, the training is permissible for volunteers only.</p>	<p>2. Have satisfactorily completed a nurse aide education hospice program approved by the Virginia Board of Nursing;</p> <p>3. Have certification as a nurse aide issued by the Virginia Board of Nursing;</p> <p>4. Be successfully enrolled in a nursing education hospice program preparing for registered nurse or practical nurse licensure and have currently completed at least one nursing course that includes clinical experience involving patient care;</p> <p><u>or</u></p> <p>5. Have satisfactorily passed a competency evaluation that meets the criteria of 42 CFR 484.36 (b); or</p> <p>6. Have satisfactorily completed training using the "Personal Care Aide Training Curriculum," dated 2003, of the Department of Medical Assistance Services. However, the training is permissible for volunteers only.</p> <p><u>If the home attendant is a volunteer, the home attendant shall meet one of the qualifications listed in subdivisions 1 through 5 of this subsection or have satisfactorily completed training provided by a hospice program or other entity that meets the requirements of subsection G.</u></p> <p><u>G. Hospice programs may develop a 40-hour training program for volunteers. The program shall:</u></p> <p><u>1. Include education addressing:</u></p> <p><u>a. Goals of personal care;</u></p> <p><u>b. Prevention of skin breakdown;</u></p> <p><u>c. Physical and biological aspects of aging;</u></p> <p><u>d. Physical and emotional needs of older adults;</u></p> <p><u>e. Orientation to types of physical disabilities;</u></p>
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			<p><u>f. Personal care and rehabilitative services;</u></p> <p><u>g. Body mechanics;</u></p> <p><u>h. Home management;</u></p> <p><u>i. Safety and accident prevention in the home;</u></p> <p><u>j. Policies and procedures regarding accidents or injuries;</u></p> <p><u>k. Food, nutrition, and meal preparation;</u></p> <p><u>l. Special considerations in preparation of special diets;</u></p> <p><u>m. Care of the home and personal belongings; and</u></p> <p><u>n. Documentation requirements for Medicaid individuals.</u></p> <p><u>2. Be conducted by a registered nurse who meets the requirements in 18VAC90-26-30.</u></p> <p><u>3. Issue and maintain certificates of completion containing:</u></p> <p><u>a. The instructor's printed name and signature;</u></p> <p><u>b. The participant's printed name; and</u></p> <p><u>c. The date of completion of the program.</u></p> <p>Intent: The intent is to replace the reference to an outdated training manual. The change allows hospice programs to set up in-house training for volunteer home attendants, as long as it meets the requirements set forth here. The change also ensures that all home aides have completed their required training before seeing patients.</p> <p>Rationale: The reference to 2003 DMAS Personal Care Aide Training Curriculum is out of date and needs to be replaced by a current curriculum.</p>
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			<p>DMAS indicated that their requirements for personal care aide training existed within the CCC Plus Waiver Manual, on which this language is based.</p> <p>Likely Impact: Hospice programs will set up their own training for volunteer home attendants. Once a person has completed one of these trainings, they will meet the training requirement at any hospice program.</p>
380	N/A	<p>12VAC5-391-380. Dietary or nutritional counseling Dietary or nutritional counselors shall meet the requirements of 18VAC75-30 pursuant to Chapter 27.1 (§ 54.1-2730 et seq.) of Title 54.1 of the Code of Virginia and have at least two years experience in a health care food or nutrition delivery system.</p>	<p>Change: The Board is proposing the following change:</p> <p>12VAC5-391-380. Dietary or nutritional counseling Dietary or nutritional counselors shall meet the requirements of 18VAC75-30 pursuant to Chapter 27.1 (§ 54.1-2730 et seq.) of Title 54.1 of the Code of Virginia and have at least two years experience in a health care food or nutrition delivery system.</p> <p>Intent: The change removes a reference to a chapter of regulations that has been repealed.</p> <p>Rationale: The sections of the Code of Virginia already cited by the regulation contain the appropriate requirements. No regulations have been promulgated to replace 18VAC75, thus the Code reference is sufficient.</p> <p>Likely Impact: The change will reduce confusion for regulated entities regarding the specific requirements for dietary or nutritional counselors.</p>
440	N/A	<p>12VAC5-391-440. General facility requirements. A. All construction of new buildings and additions, renovations or alterations of existing buildings for occupancy as a hospice facility shall conform to state and local codes, zoning and building ordinances and the Uniform Statewide Building Code.</p> <p>In addition, hospice facilities shall be designed and constructed according to section 4.2 of Part 4</p>	<p>Change: The Board is proposing the following change:</p> <p>12VAC5-391-440. General facility requirements. A. All construction of new buildings and additions, renovations or alterations of existing buildings for occupancy as a hospice facility shall conform to state and local codes, zoning and building ordinances and the Uniform Statewide Building Code.</p> <p>In addition, hospice facilities shall be designed and constructed according to section 4.2 of Part 4 of the 2006 3.2</p>

	<p>of the 2006 Guidelines for Design and Construction of Health Care Facilities of the American Institute of Architects. However, the requirements of the Uniform Statewide Building Code and local zoning and building ordinances shall take precedence.</p> <p>B. All buildings shall be inspected and approved as required by the appropriate regional state fire marshal's office or building and fire regulatory official. Approval shall be a Certificate of Use and Occupancy indicating the building is classified for its proposed licensed purpose.</p> <p>C. The facility must have space for private patient family visiting and accommodations for family members after a patient's death. Patients shall be allowed to receive guests, including small children, at any hour.</p> <p>D. Patient rooms shall not exceed two beds per room and must be at grade level or above, enclosed by four ceiling-high walls. Each room shall be equipped for adequate nursing care, the comfort and privacy of patients, and with a device for calling the staff member on duty.</p> <p>E. Designated guest rooms for family members or patient guests and beds for use by employees of the facility shall not be included in the bed capacity of a hospice facility provided such beds and locations are identified and used exclusively by staff, volunteers or patient guests.</p> <p>Employees shall not utilize patient rooms nor shall bedrooms for employees be used by patients.</p> <p>F. Waste storage shall be located in a separate area outside or easily accessible to the outside</p>	<p><u>of Part 3 of the 2018</u> Guidelines for Design and Construction of <u>Health Care Residential Health, Care, and Support Facilities of the American Institute of Architects. However, the requirements of the Uniform Statewide Building Code and local zoning and building ordinances shall take precedence. the Facility Guidelines Institute.</u></p> <p>B. All buildings shall be inspected and approved as required by the appropriate regional state fire marshal's office or building and fire regulatory official. Approval shall be a Certificate of Use and Occupancy indicating the building is classified for its proposed licensed purpose.</p> <p>C. The facility must have space for private patient family visiting and accommodations for family members after a patient's death. Patients shall be allowed to receive guests, including small children, at any hour.</p> <p>D. Patient rooms shall not exceed two beds per room and must be at grade level or above, enclosed by four ceiling-high walls. Each room shall be equipped for adequate nursing care, the comfort and privacy of patients, and with a device for calling the staff member on duty.</p> <p>E. Designated guest rooms for family members or patient guests and beds for use by employees of the facility shall not be included in the bed capacity of a hospice facility provided such beds and locations are identified and used exclusively by staff, volunteers or patient guests. Employees shall not utilize patient rooms nor shall bedrooms for employees be used by patients.</p> <p>F. Waste storage shall be located in a separate area outside or easily accessible to the outside for direct pickup or disposal. The use of an incinerator shall require permitting from the nearest regional permitting office for the Department of Environmental Quality.</p>
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	<p>for direct pickup or disposal. The use of an incinerator shall require permitting from the nearest regional permitting office for the Department of Environmental Quality.</p> <p>G. The facility shall provide or arrange for under written agreement, laboratory, x-ray, and other diagnostic services, as ordered by the patient's physician.</p> <p>H. There shall be a plan implemented to assure the continuation of essential patient support services in case of power outages, water shortage, or in the event of the absence from work of any portion of the workforce resulting from inclement weather or other causes.</p> <p>I. No part of a hospice facility may be rented, leased or used for any purpose other than the provision of hospice care at the facility.</p> <p>J. A separate and distinct entrance shall be provided if the program intends to administer and provide its community-based hospice care from the facility so that such traffic and noise shall be diverted away from patient care areas.</p> <p>K. The hospice facility shall maintain a complete set of legible "as built" drawings showing all construction, fixed equipment, and mechanical and electrical systems, as installed or built.</p>	<p>G. The facility shall provide or arrange for under written agreement, laboratory, x-ray, and other diagnostic services, as ordered by the patient's physician.</p> <p>H. There shall be a plan implemented to assure the continuation of essential patient support services in case of power outages, water shortage, or in the event of the absence from work of any portion of the workforce resulting from inclement weather or other causes.</p> <p>I. No part of a hospice facility may be rented, leased or used for any purpose other than the provision of hospice care at the facility.</p> <p>J. A separate and distinct entrance shall be provided if the program intends to administer and provide its community-based hospice care from the facility so that such traffic and noise shall be diverted away from patient care areas.</p> <p>K. The hospice facility shall maintain a complete set of legible "as built" drawings showing all construction, fixed equipment, and mechanical and electrical systems, as installed or built.</p> <p>Intent: The intent of the change is to update the reference to the appropriate guidelines for design and construction of hospice facilities.</p> <p>Rationale: Section 32.1-162.5 of the Code of Virginia requires the regulations for the licensure of hospice programs to include minimum standards for design and construction consistent with the current edition of the FGI guidelines. 1VAC7-10-140 (C) requires the incorporation of such references to indicate the specific version or edition of a text that is referenced within regulation.</p> <p>Likely Impact: The change will reduce confusion for regulated entities regarding the specific requirements for</p>
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			<p>the design and construction of hospice facilities.</p>
<p>DIBR</p>	<p>N/A</p>	<p>DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-391) Personal Care Aide Training Curriculum, 2003, Department of Medical Assistance Services.</p> <p>2006 Guidelines for Design and Construction of Health Care Facilities, The Facility Guidelines Institute, The American Institute of Architects Academy of Architecture for Health, 1-800-242-3837.</p>	<p>Change: The Board is proposing the following change:</p> <p>DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-391) Personal Care Aide Training Curriculum, 2003, Department of Medical Assistance Services.</p> <p>2006 Guidelines for Design and Construction of Health Care Facilities, The Facility Guidelines Institute, The American Institute of Architects Academy of Architecture for Health, 1-800-242-3837.</p> <p><u>2018 Guidelines for Design and Construction of Residential Health, Care, and Support Facilities, The Facility Guidelines Institute.</u></p> <p>Intent: The intent of the change is to update the reference to the appropriate guidelines for design and construction of hospice facilities and to delete a document that is no longer referenced in the regulation.</p> <p>Rationale: Section 32.1-162.5 of the Code of Virginia requires the regulations for the licensure of hospice programs to include minimum standards for design and construction consistent with the current edition of the FGI guidelines. 1VAC7-10-140 (C) requires the incorporation of such references to indicate the specific version or edition of a text that is referenced within regulation.</p> <p>Likely Impact: Hospice facilities will be designed and constructed according to the current version of the FGI guidelines.</p>

1 Project 6102 - none

2 DEPARTMENT OF HEALTH
3 Amend Regulation Following Periodic Review
4

5 **12VAC5-391-330. Medical direction.**

6 A. There shall be a medical director, who shall be a physician licensed by the Virginia Board
7 of Medicine, responsible for the overall direction and management of the medical component of
8 care. The individual shall have training and experience in the psychological and medical needs of
9 the terminally ill.

10 ~~B. The medical director shall have admitting privileges at one or more hospitals and nursing~~
11 ~~facilities that provide inpatient service to the hospice program's patients.~~

12 C. B. The duties and responsibilities of the medical director shall include at least the following:

- 13 1. Consulting with attending physicians regarding pain and symptom management;
- 14 2. Reviewing patient eligibility for hospice services according to the law and the hospice
- 15 program's admission policies;
- 16 3. Acting as a medical resource to the IDG;
- 17 4. Coordinating with attending physicians to assure a continuum of medical care in cases
- 18 of emergency or in the event the attending physician is unable to retain responsibility for
- 19 the patient's care;
- 20 5. Acting as medical liaison with physicians in the community; and
- 21 6. Determining, in consultation with the patient's physician, when a patient can no longer
- 22 remain at home and should be moved to a congregate living facility of the patient's
- 23 choosing.

24 **12VAC5-391-340. Nursing services.**

25 A. All nursing services shall be provided directly or under the supervision of a registered nurse,
26 currently licensed by the Virginia Board of Nursing, who has education and experience in the
27 needs of the terminally ill. Duties and responsibilities of the supervising nurse shall include:

- 28 1. Assuring that nursing services delivered are provided according to established hospice
- 29 program policies;
- 30 2. Assuring that nursing services are available 24 hours a day, 7 days a week and that
- 31 licensed practical nurses and home attendants work under the direct supervision of a
- 32 registered nurse;
- 33 3. Participating in the development and implementation of orientation and in-service
- 34 training hospice programs for all levels of nursing staff employed by the hospice program;
- 35 4. Acting as nurse liaison with staff and other agencies, hospice programs and individuals
- 36 that have contractual agreements to provide nursing services;
- 37 5. Participating in quality improvement reviews and evaluations of the nursing services
- 38 provided; and
- 39 6. Directing or supervising the delivery of nursing services.

40 B. Nursing services shall include, but are not limited to:

- 41 1. Assessing a patient's needs and admission for service as appropriate;
- 42 2. Working with the IDG to develop a plan of care;
- 43 3. Implementing the plan of care;
- 44 4. Obtaining physician's orders when necessary;

- 45 5. Providing those services requiring substantial and specialized nursing skill;
46 6. Educating the patient and patient's family in the care of the patient, including pain
47 management;
48 7. Evaluating the outcome of services;
49 8. Coordinating and communicating the patient's physical or medical condition to the IDG;
50 9. Preparing clinical notes; and
51 10. Supervising licensed practical nurses and home attendants providing delegated
52 nursing services.

53 C. A registered nurse shall coordinate the implementation of each patient's plan of care.

54 D. If nursing duties are delegated, the hospice program shall develop and implement an
55 organizational plan pursuant to ~~48VAC90-20-420~~ 18VAC90-19-240 through ~~48VAC90-20-460~~
56 18VAC90-19-280 of the Virginia Administrative Code.

57 E. Licensed practical nurses shall be currently licensed by the Virginia Board of Nursing.

58 F. The services provided by a licensed practical nurse may include, but are not limited to:

- 59 1. Delivering nursing services according to the hospice program's policies and standard
60 nursing practices;
61 2. Assisting the registered nurse in performing specialized procedures;
62 3. Assisting the patient with activities of daily living, including the teaching of self-care
63 techniques;
64 4. Preparing equipment and supplies for treatment that requires adherence to sterile or
65 aseptic techniques; and
66 5. Preparing clinical notes.

67 **12VAC5-391-350. Home attendant services.**

68 A. Services of the home attendants may include, but are not limited to:

- 69 1. Assisting patients with (i) activities of daily living; (ii) ambulation and prescribed
70 exercise; (iii) other special duties with appropriate training and demonstrated competency;
71 2. Administration of normally self-administered drugs in a patient's private residence as
72 allowed by § 54.1-3408 of the Virginia Drug Control Act (Chapter 34 (§ 54.1-3400 et seq.)
73 of Title 54.1 of the Code of Virginia);
74 3. Taking and recording vital signs as indicated in the plan of care;
75 4. Measuring and recording fluid intake and output;
76 5. Recording and reporting to the health care professional changes in the patient's physical
77 condition, behavior or appearance;
78 6. Documenting services and observations in the medical record; and
79 7. Performing any other duties that the attendant is qualified to do by additional training
80 and demonstrated competency, within state guidelines.

81 B. Prior to the initial delivery of services, the home attendant shall receive specific written
82 instructions for the patient's care from the appropriate health care professional responsible for the
83 care.

84 C. Home attendants shall work under the supervision of the appropriate health care
85 professional responsible for the patient's care.

86 D. The nurse responsible for supervising the home attendant shall make visits to the patient's
87 home as frequently as necessary, but not less than every two weeks. The results of each visit
88 shall be documented in the medical record.

89 E. Relevant in-service education or training for home attendants shall consist of at least 12
90 hours annually. In-service training may be in conjunction with on-site supervision.

91 F. Home attendants shall be able to speak, read and write English and shall meet one of the
92 following qualifications before providing services to the hospice program's patients:

93 1. Have satisfactorily completed a nursing education hospice program preparing for
94 registered nurse licensure or practical nurse licensure;

95 2. Have satisfactorily completed a nurse aide education hospice program approved by the
96 Virginia Board of Nursing;

97 3. Have certification as a nurse aide issued by the Virginia Board of Nursing;

98 4. Be successfully enrolled in a nursing education hospice program preparing for
99 registered nurse or practical nurse licensure and have currently completed at least one
100 nursing course that includes clinical experience involving patient care; or

101 5. Have satisfactorily passed a competency evaluation that meets the criteria of 42 CFR
102 484.36 (b); ~~or~~ .

103 ~~6. Have satisfactorily completed training using the "Personal Care Aide Training~~
104 ~~Curriculum," dated 2003, of the Department of Medical Assistance Services. However, the~~
105 ~~training is permissible for volunteers only.~~

106 If the home attendant is a volunteer, the home attendant shall meet one of the qualifications
107 listed in subdivisions 1 through 5 of this subsection or have satisfactorily completed training
108 provided by a hospice program or other entity that meets the requirements of subsection G.

109 G. Hospice programs may develop a 40-hour training program for volunteers. The program
110 shall:

111 1. Include education addressing:

112 a. Goals of personal care;

113 b. Prevention of skin breakdown;

114 c. Physical and biological aspects of aging;

115 d. Physical and emotional needs of older adults;

116 e. Orientation to types of physical disabilities;

117 f. Personal care and rehabilitative services;

118 g. Body mechanics;

119 h. Home management;

120 i. Safety and accident prevention in the home;

121 j. Policies and procedures regarding accidents or injuries;

122 k. Food, nutrition, and meal preparation;

123 l. Special considerations in preparation of special diets;

124 m. Care of the home and personal belongings; and

125 n. Documentation requirements for Medicaid individuals.

126 2. Be conducted by a registered nurse who meets the requirements in 18VAC90-26-30.

127 3. Issue and maintain certificates of completion containing:

128 a. The instructor's printed name and signature;

129 b. The participant's printed name; and

130 c. The date of completion of the program.

131 **12VAC5-391-380. Dietary or nutritional counseling**

132 Dietary or nutritional counselors shall meet the requirements of ~~48VAC75-30~~ pursuant to
133 Chapter 27.1 (§ 54.1-2730 et seq.) of Title 54.1 of the Code of Virginia and have at least two years
134 experience in a health care food or nutrition delivery system.

135 Part IV
136 Hospice Facilities

137 **12VAC5-391-440. General facility requirements.**

138 A. All construction of new buildings and additions, renovations or alterations of existing
139 buildings for occupancy as a hospice facility shall conform to state and local codes, zoning and
140 building ordinances and the Uniform Statewide Building Code.

141 In addition, hospice facilities shall be designed and constructed according to section 4.2 of
142 ~~Part 4 of the 2006~~ 3.2 of Part 3 of the 2018 Guidelines for Design and Construction of Health-Care
143 Residential Health, Care, and Support Facilities of the American Institute of Architects. However,
144 ~~the requirements of the Uniform Statewide Building Code and local zoning and building~~
145 ~~ordinances shall take precedence.~~ the Facility Guidelines Institute.

146 B. All buildings shall be inspected and approved as required by the appropriate regional state
147 fire marshal's office or building and fire regulatory official. Approval shall be a Certificate of Use
148 and Occupancy indicating the building is classified for its proposed licensed purpose.

149 C. The facility must have space for private patient family visiting and accommodations for
150 family members after a patient's death. Patients shall be allowed to receive guests, including small
151 children, at any hour.

152 D. Patient rooms shall not exceed two beds per room and must be at grade level or above,
153 enclosed by four ceiling-high walls. Each room shall be equipped for adequate nursing care, the
154 comfort and privacy of patients, and with a device for calling the staff member on duty.

155 E. Designated guest rooms for family members or patient guests and beds for use by
156 employees of the facility shall not be included in the bed capacity of a hospice facility provided
157 such beds and locations are identified and used exclusively by staff, volunteers or patient guests.

158 Employees shall not utilize patient rooms nor shall bedrooms for employees be used by
159 patients.

160 F. Waste storage shall be located in a separate area outside or easily accessible to the outside
161 for direct pickup or disposal. The use of an incinerator shall require permitting from the nearest
162 regional permitting office for the Department of Environmental Quality.

163 G. The facility shall provide or arrange for under written agreement, laboratory, x-ray, and
164 other diagnostic services, as ordered by the patient's physician.

165 H. There shall be a plan implemented to assure the continuation of essential patient support
166 services in case of power outages, water shortage, or in the event of the absence from work of
167 any portion of the workforce resulting from inclement weather or other causes.

168 I. No part of a hospice facility may be rented, leased or used for any purpose other than the
169 provision of hospice care at the facility.

170 J. A separate and distinct entrance shall be provided if the program intends to administer and
171 provide its community-based hospice care from the facility so that such traffic and noise shall be
172 diverted away from patient care areas.

173 K. The hospice facility shall maintain a complete set of legible "as built" drawings showing all
174 construction, fixed equipment, and mechanical and electrical systems, as installed or built.

175 DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-391)

176 [Personal Care Aide Training Curriculum, 2003, Department of Medical Assistance Services.](#)

177 ~~2006 Guidelines for Design and Construction of Health Care Facilities, The Facility Guidelines~~
178 ~~Institute, The American Institute of Architects Academy of Architecture for Health, 1-800-242-~~
179 ~~3837.~~

180 2018 Guidelines for Design and Construction of Residential Health, Care, and Support
181 Facilities, The Facility Guidelines Institute.

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COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448

RICHMOND, VA 23218

M. NORMAN OLIVER, MD, MA
STATE HEALTH COMMISSIONER

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

MEMORANDUM

DATE: November 15, 2019

TO: Virginia State Board of Health

FROM: Allen Knapp, Office of Environmental Health
Julie Henderson, Division of Food and General Services

SUBJECT: Amend Chapter 421 to Adopt 2017 FDA Food Code

The Food Regulations (12VAC5-421 et seq.) establish a regulatory scheme, which outlines the minimum sanitary standards for the operation of restaurants, herein after referred to as food establishments. In addition, the Food Regulations include standards for the operation and use of equipment, vector control, approved methods for the cooling and heating of food products, hygiene and health standards for employees engaged in food handling to prevent the transmission of communicable disease, and the process to obtain and maintain a permit to operate a food establishment.

The Board of Health (Board) adopted the current food regulations in 2016; that regulatory action incorporated the provisions of the 2013 Food and Drug Administration (FDA) Food Code. The proposed regulatory action before you is to amend the Food Regulations to incorporate provisions of the 2017 FDA Food Code. A brief summary of the substantive changes are as follows:

- Removal, addition, and revision of definitions;
- Language amended to require the person in charge to be a certified food protection manager;
- Language added to include standards for the use of bandages, finger cots, or finger stalls;
- Language added to require written procedures for the clean-up of vomiting and diarrheal events;
- Language added to require the separation of raw animal foods from fruits and vegetables in certain instances;
- Language amended to reflect new cooking time for raw animal foods;
- Removal of the Food Service Advisory Committee to reflect changes within the Food and Drug Administration; and
- Language added to include clarity to enforcement procedures when impounding food.

Upon approval by the Board, the proposed Fast Track action will be submitted to the Regulatory Town Hall to begin the Executive Review Process. Following approval by the Governor, it will be published in the Virginia Register of Regulations for a 30-day public comment period. The regulatory action will become effective 15-days after close of the public comment period.



townhall.virginia.gov

Fast-Track Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation(s)	12 VAC 5-421
Regulation title(s)	Food Regulations
Action title	Amend Chapter 421 to Adopt 2017 FDA Food Code
Date this document prepared	November 15, 2019

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

Brief Summary

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

The Food Regulations (12VAC5-421 et seq.) establish minimum sanitary standards for the operation of restaurants, herein after referred to as food establishments. Those standards include: (1) the safe and sanitary maintenance, storage, operation, and use of equipment; (2) the safe preparation, handling, protection, and preservation of food, including necessary refrigeration and heating methods; (3) procedures for vector and pest control; (4) requirements for toilet and cleansing facilities for employees and customers; (5) requirements for appropriate lighting and ventilation not otherwise provided for in the Uniform Statewide Building Code; (6) requirements for an approved water supply and sewage disposal system; (7) personal hygiene standards for employees, particularly those engaged in food handling; and (8) the appropriate use of precautions to prevent the transmission of communicable diseases.

The proposed regulatory action would amend the existing Food Regulations to incorporate, in part, the 2017 Food and Drug Administration (FDA) Food Code and the Supplement to the 2017 FDA Food Code Annex I. Additional amendments are intended to ensure clarity and uniform application.

Acronyms and Definitions

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

No acronyms or technical terms were identified that were not included in the “Definitions” section of the Food Regulations.

Statement of Final Agency Action

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

Mandate and Impetus

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

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

VDH is initiating this regulatory action: (1) to amend its regulations to comport the Food Regulations with the current FDA Food Code, and (2) to amend its regulations to ensure clarity and ensure uniform application.

The FDA Food Code, revised approximately every four years, serves as a model document to assist state and local agencies with regulatory authority over food safety by creating a regulatory scheme that reflects the most current science available to reduce the risk of food borne illnesses associated with food establishments. VDH has revised the Food Regulations to reflect updates to the FDA Food Code, which include updates to effective controls as a means to reduce the risk of foodborne illness that contribute to financial losses and have dire health consequences.

The 2010 and 2016 revision of the Food Regulations incorporated the 2009 and 2013 FDA Food Code, respectively. As the regulations have not undergone a cumulative review in nine years, a thorough review is necessary to ensure the regulations are necessary to protect the public health, safety, and welfare pursuant to the policies and principles enumerated in E.O. 14 (2018).

This regulatory action is best suited for the fast track process as it is expected to be non-controversial. The proposed changes will ensure the Food Regulations reflect changes made to the 2017 FDA Food Code, complements current Virginia law, and provide minimal burdens on regulants while protecting public health.

Legal Basis

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

Sections 35.1-11 and 14 of the Code of Virginia (Code) authorize and require the Board of Health (Board) to promulgate and enforce regulations governing restaurants in accordance with the provisions of Title 35.1 of the Code.

Section 35.1-14.C of the Code provides the legal basis for the promulgation and modification of this regulation when the Board elects to adopt any edition of the FDA Food Code, or any portion thereof. The authority to adopt the FDA Food Code is discretionary; the authority to regulate food establishments is not.

Purpose

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

The U.S. Centers for Disease Control and Prevention estimate that foodborne diseases cause approximately 48 million people to become ill, 128,000 hospitalizations, and 3,000 deaths in the United States each year. This translates into 1 in 6 Virginians who become ill.

The purpose of these regulations is to prevent foodborne illness by ensuring that foods prepared and served at food establishments in Virginia are safe, unadulterated, and prepared under sanitary conditions. This is accomplished by ensuring regulations reflect current science and technology regarding minimum sanitary standards for food establishments to protect the dining public. These standards include approved sources for foods used in food establishments, specifications for safe handling, storage, preparation and serving of food, personal hygiene of employees, precautions to prevent the transmission of diseases communicable through food, and the general sanitation of the facility. When followed, these minimum standards will protect the public's health, safety, and welfare.

In addition, amending the Food Regulations to conform to the 2017 FDA Food Code will ensure the regulation promotes uniformity in administration of the food safety program. The benefits of adopting and implementing uniform standards have shown to lead to higher compliance, consistent training of public health staff, and an increased shared responsibility of the food industry and the government in ensuring food provided to the consumer is safe and does not become a vehicle for a disease outbreak or for the transmission of communicable disease.

Substance

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

The proposed changes to the Food Regulations will revise the regulations to incorporate the 2017 FDA Food Code and the 2017 FDA Food Code Annex I, in part. The proposed changes also ensure that the regulations complement current Virginia law and provide minimal burdens on regulants while protecting public health.

Substantive changes include: (1) removal, addition, and revision of definitions, (2) language amended to require the person in charge to be a certified food protection manager, (3) language added to include standards for the use of bandages, finger cots, or finger stalls, (4) language added to require written procedures for the clean-up of vomiting and diarrheal events, (5) language added to require the separation of raw animal foods from fruits and vegetables in certain instances, (6) language amended to reflect new cooking time for raw animal foods, (7) removal of the Food Service Advisory Committee to reflect changes within the Food and Drug Administration, and (8) language added to provide clarity to enforcement procedures when impounding food.

Issues

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

The primary advantage of the regulations to the public is the establishment of modern science-based standards that support the prevention of foodborne illness risk factors and ensure the safety of food service within the Commonwealth. The revisions will also make the regulations more understandable and align them with best practices.

The primary advantage to the agency is that the regulations will be based on current food science and clarify ambiguous areas relating to enforcement and inspection standards. Staff who better understand the regulatory scheme of food safety provide enhanced communication to the public and regulant community on how to prevent food borne illness.

The primary advantage to the regulated community, particularly chains and franchises that operate in other states as well as in multiple jurisdictions across the Commonwealth that have adopted the current version of the FDA Food Code, will be more consistent regulatory application.

There are no known disadvantages to the public or the Commonwealth with the adoption of these regulations.

Requirements More Restrictive than Federal

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

There are no known requirements in the proposed regulations that would be more restrictive than those currently required in federal law.

Agencies, Localities, and Other Entities Particularly Affected

Please identify any other state agencies, localities, or other entities particularly affected by the regulatory change. "Particularly affected" are those that are likely to bear any identified disproportionate material

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

No state agencies will bear any identified disproportionate material impact not experienced by other agencies, localities, or entities.

Economic Impact

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

Impact on State Agencies

<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>The Board does not expect any changes to costs, savings, fees or revenues as a result of the proposed 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>The Board does not expect any cost savings by other state agencies as a result of the regulatory change.</p> <p>In addition, the Board does not expect any changes to costs, fees or revenues for other state agencies as a result of the regulatory change.</p>
<p><i>For all agencies:</i> Benefits the regulatory change is designed to produce.</p>	<p>Benefits include alignment with the 2017 FDA Food Code, which promotes uniformity of food safety standards, reflects the most current science and knowledge regarding food safety, and improvement of agency understanding of food safety expectations.</p>

Impact on Localities

<p>Projected costs, savings, fees or revenues resulting from the regulatory change.</p>	<p>There is no projected cost to localities.</p>
<p>Benefits the regulatory change is designed to produce.</p>	<p>Benefits include alignment with the 2017 FDA Food Code, which promotes uniformity of food safety standards, reflects the most current science and knowledge regarding food safety, and improvement of local health department staff understanding of regulation administration such as licensing, inspection, and enforcement.</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 pertain to food establishments operating in the Commonwealth.</p>
<p>Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that:</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>There are approximately 38,000 food establishments in the Commonwealth. Based on employing 500 or fewer employees, an estimated 95 to 100% of the total number of food establishments will fall into the small business category.</p>
<p>All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Please be specific and include all costs including, but not limited to:</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>The proposed amendments would require a certified food protection manager (CFPMs) on the premises of a food establishment at all times of operation. The current regulations require food establishments to employ a CFPM; however, they are not required to be onsite at all times of operation. Certification costs range from \$28.00 to \$100.00 per individual and requires renewal every five years. VDH anticipates any costs associated with this regulatory change to be minimal as current regulations, adopted July 2016, require food establishments to employ a CFPM.</p>
<p>Benefits the regulatory change is designed to produce.</p>	<p>Benefits include alignment with the 2017 FDA Food Code which promotes uniformity of food safety standards, reflects the most current science and knowledge regarding food safety, and improvement of consumer and regulant understanding of food safety expectations</p>

Alternatives

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

The alternative to this proposed regulatory action is not to incorporate the 2017 FDA Food Code and Supplement to the 2017 FDA Food Code. This option would result in a regulation that does not incorporate the latest science based principles and FDA-recommended requirements to address an evolving food industry. Congress has mandated, through the 2011 Food Safety Modernization Act, the establishment of a national food safety system that integrates federal, state, and local food protection agencies. One component of this integration process is the establishment of uniform regulations at all levels. Currently, most states and localities have adopted FDA's Food Code and continue to update their regulations as FDA releases newer versions. This ensures that states are enforcing the same science-based regulations that are focused on public health protection and is a significant step in the integration of all states into one singular national food safety system. Failure to incorporate the proposed amendments

to this regulation will result in VDH enforcing regulations that are out of step with the rest of the nation and with several localities within Virginia.

Regulatory Flexibility Analysis

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

VDH has assessed the requirements of the regulations and has not identified alternative methods of achieving the goals of this regulatory action.

Public Participation

If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, 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.

Detail of Changes

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

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

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

The following sections include amendments to replace “regulatory authority” with “department” for the purposes of clarity: 60, 70, 80, 100, 450,660, 725, 760, 830, 850, 860,870, 1300, 1700, 2090, 2100, 2110, 3360,3510,3520,3600,3610,3620, 3630,3640, 3680, 3700,3710,3720, 3730, 3740,3750, 3800,3810, 3815, 3820, 3830,3840, 3860, 3870,3880, 3890, 3900, 3910, 3920,3930, 3940, 3950, 4040, 4050, 4060

For changes to existing regulation(s), please use the following chart:

Current section number	New section number, if applicable	Current requirement	Change, intent, rationale, and likely impact of new requirements
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<p>12VAC5-421-10</p>		<p>Definitions</p>	<ul style="list-style-type: none"> • Agent of the commissioner- Strike definition for clarity of authority. • Approved water system- Amend definition to include regulatory citations for clarity. • Board- Strike definition, term defined in the Code of Virginia. • Catering operation- Amend definition to clarify term is only applicable to a permitted food establishment. • CIP- Amend definition to include “Clean in Place”, acronym previously did not include full spelling of term. • Commissioner- Strike definition, term defined in the Code of Virginia. • Confirmed disease outbreak- Amend definition to align with 2017 FDA Food Code definition of same term. • Delicatessen- Strike definition for clarity, term not used in regulations other than definitions section. • Department- Strike definition, term defined in the Code of Virginia • Disclosure- Amend definition to align with the 2017 FDA Food Code definition of the same term. • F- Strike definition as it is well understood in the regulated community to mean Fahrenheit. • Fish- Amend definition to correct grammatical error. • Food establishment- Amend definition to strike sections cited in the Code of Virginia, to remove regulatory exemptions not under the Board’s authority, and to add language from the 2017 FDA Food Code. • Game animal- Amend definition for clarity. • HACCP Plan- Amend definition to include “Hazard Analysis and Critical Control Point”, acronym previous did
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			<p>not include full spelling of term.</p> <ul style="list-style-type: none"> • Injected- Amend definition to align with the 2017 FDA Food Code definition of the same term. • Intact Meat- Add definition to align with the 2017 FDA Food Code definition of the same term. • Permit- Amend definition for clarity. • Pure Water- Amend definition to include regulatory citations for clarity. • Pushcart- Strike definition for clarity, term not used in regulations other than definitions section. • Ready-to-eat food- Amend definition to correct cross reference and improve definition structure for clarity. • Reservice- Amend definition to correct grammatical error. • Sanitization- Amend term to align with the 2017 FDA Food Code definition of the same term. • Sealed-Amend definition for clarity. • Shiga toxin-producing Escherichia coli- Amend definition to correct grammatical error. • Variance- Amend definition for clarity. • Vending machine- Amend definition to align with the 2017 FDA Food Code definition of the same term. • Waterworks- Amend definition for clarity and to align with the definition of a “waterworks” in 12VAC5-590.
12VAC5-421-30		Outlines the purpose of this chapter	Section amended for clarity; strikes “be connected to and use” as certain classifications of food establishments may be permitted without direct connections to water source (mobile food unit).
12VAC5-421-40		Outlines administration of regulations	Section amended for clarity.

12VAC5-421-55		Requires at least one employee to be a certified food protection manager	Section amended to require the person in charge to be a certified food protection manager. Requirement has a deferred enactment of two years from the effective date of the regulations. The Regulations were amended in 2016 to require food establishments to employ a certified food protection manager. The Board of Health provided exemptions to this requirement that took into consideration the extent to which food is prepared. This proposed amendment further clarifies the exemptions yet also requires that the person in charge holds certification. This is important as the person in charge has the authority to instruct staff and it is important that this person knows and can control the risk factors that impact the safety of the food served.
12VAC5-421-60		Outlines the standard of accreditation of certified food protection manager certification.	Requires the person in charge obtain food protection manager certification from an accredited program.
12VAC5-421-70		Identifies the responsibilities of the person in charge	Section amended for clarity, addition of regulatory citation.
12VAC5-421-80		Requires person in charge to require employees or applicants who have been offered employment to report to the person in charge their health and activities as they relate to diseases that are transmissible through food.	Amended to align with 2017 FDA Food Code, language added "...the last".
12VAC5-421-100		Identifies when exclusions or restrictions of food employees diagnosed with certain diseases can be removed by the person in charge	Insert missing superscript at 1.e (2).
12VAC5-421-180		Identifies acceptability for use of hand sanitizers and chemical hand sanitizing solutions.	Update edition of document incorporated by reference "Approved Drug Products with Therapeutic Equivalence Valuations" to 2019 version in line with industry standards; and amendments to conform with 2017 FDA Food Code.
12VAC5-421-190		Outlines standard for maintenance of fingernails	Section amended to conform with the Virginia Register of Regulations style requirements.

12VAC5-421-255		Requires facility to have procedures to clean up vomit or diarrheal events	Amends section to require written procedures regarding cleanup of vomit or diarrheal events, conforms to 2017 FDA Food Code.
12VAC5-421-260		Requires food served in food establishments be safe, unadulterated and honestly presented.	Amend superscript from “Pf” or priority foundation to “P” or priority to conform to the 2017 FDA Food Code.
12VAC5-421-270		Establishes criteria by which a food establishment may individually portion whole muscle, intact beef steaks in a food establishment	<ol style="list-style-type: none"> 1) Amending superscript at 12VAC5-421-270. E.3 (a) from “Pf” or priority foundation to “P” or priority to conform with the FDA Food Code. This change corrects a typographical error. 2) Amend 12VAC421-270.G to amend the term “shell eggs” to “eggs” to conform to the 2017 FDA Food Code. This change corrects a typographical error.
12VAC5-421-295		Establishes the standard by which food establishments may offer for sale or services treated juice.	Amend section as prepackage juice must meet the requirements of both subsection 1 and 2. Adding an “and” between the subsections provides clarity and conforms to the 2017 FDA Food Code.
12VAC5-421-300		Establishes the standard by which food establishments may offer for sale or service fish and molluscan shellfish	Amend subsection A (2) to Strike, “...by a regulatory agency of competent jurisdiction.” This amendment conforms this section to the 2017 FDA Food Code.
12VAC5-421-310		Requires that molluscan shellfish be obtained from an approved source.	Amends subsection A to recognize the most recent version of the U.S Department of Health and Human Services, Public Health Service, Food and Drug Administration, National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish.
12VAC5-421-340		Outlines the appropriate temperatures to receive food products	<ol style="list-style-type: none"> 1) Amends 12VAC5-421-340.C to amend the term “shell eggs” to “eggs” to conform to the FDA Food Code. This change corrects a typographical error. 2) Strike “t” from section D, typographical error.
12VAC5-421-350		Outlines the standards and allowance for the use of additives to food	Corrects federal citation, amends “40 CFR Part 185” to “40 CFR Part 180” and changes “allowed” to “specified”. These amendments correct a typographical error and conforms this section to the 2017 FDA Food Code.
12VAC5-421-400		Outlines packing and identification standards for shucked shellfish	Amends subsection A. 2 to conform with language from the National Shellfish Sanitation Program Guide.

12VAC5-421-410		Outlines the criteria of shellstock identification	Amends subsection A to recognize the most recent version of the U.S Department of Health and Human Services, Public Health Service, Food and Drug Administration, National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, which includes amending shellstock label language.
12VAC5-421-440		Outlines requirements to maintain shellstock identification	Amend section to include "...or shucked shellfish" to the list of food products that if removed from its tagged or labeled container, may not be commingled with other shellstock of shucked shellfish from another container or of different harvest dates or growing areas.
12VAC5-421-450		Outlines processes to prevent contamination from hands	Amend title of section to conform to 2017 FDA Food Code.
VAC12VAC5-421-470		Outlines the requirement for protecting food from cross-contamination during storage, preparation, holding and display.	Adds subsection A. 1(c) to require the protection of prewashed fruits and vegetables from cross contamination by separating them from raw animal foods during storage, preparation holding and display. This amendment conforms this subsection to the 2017 FDA Food Code.
12VAC5-421-540		Outlines the requirements of food contact equipment and utensil sanitation	Amends section to correct cross reference; strike 12VAC5-421-1870 and add 12VAC5-421-1860. Section 1870 was repealed.
12VAC5-421-700		Specifies the required cooking temperature and the length of time for raw animal foods	<ol style="list-style-type: none"> 1) Amends the section to add "intact meat" as a food product to be cooked at 145F or above for at least 15 seconds. 2) Amends 700.A.2 to increase cooking time from 15 to 17 seconds for certain raw animal foods. 3) Amends 700.A.3 to reduce cooking time from 15 seconds to less than one second for certain raw animal foods. 4) Amend charts under 700 B to reverse placement, Chart under B 1 moved to B2; Chart under B 2 moved to B 1. <p>All amendments conform this section to the 2017 FDA Food Code.</p>
12VAC5-421-720		Specifies the proper hot holding temperature for plant foods	Strike "Fruits and vegetables", insert "Plant foods", new term encompasses both fruits and vegetables; conforms to 2017 FDA Food Code.

12VAC5-421-730		Requires appropriate freezing of fish before the sale or service of ready-to eat raw, raw-marinated, partially cooked, or marinated- partially cooked fish (sushi) to destroy parasites	Amends section 730. B. This amendment corrects a typographical error where shucked abductor muscle was combined with molluscan shellfish as 700 B.1.; conforms to 2017 FDA Food Code.
12VAC5-421-740		Specifies record retention for raw, marinated, raw-marinated, partially cooked, or marinated- partially cooked fish	<ol style="list-style-type: none"> 1) Amends cross reference from 12 VAC5-421-730 B 3 to 12VAC5-421-730.4. 2) Strikes “marinated”, term unnecessary. This conforms with proposed changes to 12VAC 5-421-730.
12 VAC5-421-830		Specifies the proper temperature and time line to retain ready-to eat foods and methods to date mark and dispose of food	Amends cross references in section A and B to correct typographical errors. Subsections were incorrectly cited during previous amendment of regulations; conforms to 2017 FDA Food Code.
12VAC5-421-850		Specifies the methods of compliance and time allowances for utilization of time as a public health control	Amends superscript from “P” or Priority to “Pf” or priority foundation at 850.B2 and C.2.; conforms to 2017 FDA Food Code.
12VAC5-421-870		Outlines the requirements necessary to package foods using a reduced oxygen packaging method	Amended for clarity, to correct typographical errors and to conform to the 2017 FDA Food Code.
12VAC-421-900		Specifies requirements for food label information	Amended for clarity, to correct typographical errors and to conform changes to the 2017 FDA Food Code.
12VAC5-421-930		Specifies when a consumer advisory is require for consumption of raw or undercooked animal foods and required language in disclosures	Amended for clarity, to correct typographical errors and to conform to the 2017 FDA Food Code.
12VAC5-421-940		Specifies criteria to which food must be discarded or reconditioned	Amends for clarity, to correct typographical errors and to conform to the 2017 FDA Food Code.
12VAC5-421-950		Outlines prohibitions to services of certain pasteurized foods	Insert superscripts under 950 1.c and 3, Strikes CFR title language to remain consistent throughout the document when citing CFRs, and correction of typographical errors to conform with changes to the 2017 FDA Food Code. Subsections 6(4) amended to comply with Register Style Manual.
12VAC5-421-1180		Specifies scaling of food temperature measuring devices	Section amended to conform to the 2017 FDA Food Code.

12VAC5-421-1190		Specifies scaling of ambient air and water temperature measuring devices	Section amended to conform to the 2017 FDA Food Code.
12VAC5-421-1300		Requires a variance and a HACCP plan for food establishments to use molluscan shellfish life support system display tanks.	Amend cross reference regulations to correct citation.
12VAC5-421-1380		Specifies requirements of flow pressure devices in warewashing machines	Insert "and" between section A and B. Section amended to conform to the 2017 FDA Food Code.
12VAC5-421-1520		Specifies requirements of temperature measuring devices for manual and mechanical warewashing	Insert "priority foundation" superscripts to section A and B to conform to 2017 FDA Food Code.
12VAC5-421-1535		Specifies necessity of cleaning agents and sanitizers to clean equipment and utensils	Section amended to correct cross-reference, Change "Article 6" to "Article 7".
12VAC5-421-1550		Outlines standards of spacing and sealing of fixed equipment	Amend language in 1550.B to conform to 2017 FDA Food Code.
12VAC5-421-1620		Specifies limitations of use of warewashing sinks	Amend section to correct cross reference, strike "12VAC5-421-1880 et seq." and insert "12VAC5-421-1885 et.seq."
12VAC5-421-1700		Outlines the minimum concentration and temperature of chemical sanitation of manual and mechanical warewashing equipment	Amends section 1700.A to add reference to 40 CFR 180.2020 to conform to 2017 FDA Food Code.
12VAC5-421-1920		Specifies frequency to launder linens, cloth gloves, napkins and wiping cloths	Amended 1920.B, insert "poultry"; Amend 1920.C to Strike "napkins" to conform to 2017 FDA Food Code.
12VAC5-421-2090		Requires that nondrinking water is only used if approved and only for non-culinary purposes	Strike "irrigation". Amended language to conform to the 2017 FDA Food Code.
12VAC5-421-2100		Specifies sampling requirements of private wells.	Add "Pf" superscript to section 2100 to conform to the 2017 FDA Food Code and amend language to include timelines to report nitrate, coliform, and E. coli positive lab results to the department.
12VAC5-421-2270		Specifies circumstances for use of backflow prevention device with carbonator	Amend language, strike "approved", insert "provided" to conform to 2017 FDA Food Code.
12 VAC5-421-2330		Requires scheduling of inspection and services of water treatment devices or	Amend language to include timeline to retain service records and to require such records be available upon the request of the regulatory authority.

		backflow preventer as necessary	
12VAC5-421-2350		Requires plumbing systems to be repaired and maintained	Reformat section for clarity, and conformance to the 2017 FDA Food Code.
12VAC5-421-2570		Requires food establishments to utilize an approved sewage disposal system.	Amend 2570.B to remove reference to 12VAC5-640 as an approved sewage disposal system. Chapter 640 pertains to alternative discharge system for individual single-family dwellings. In addition, section amended to include sewage disposal systems allowed by law such as local ordinances. Current language is restrictive.
12VAC5-421-2720		Requires food establishments to cover waste handling receptacles	Section amended for clarity and conformance to the 2017 FDA Food Code.
12VAC5-421-2750		Requires cleaning and cleaning frequency of receptacles and waste handling units	Section amended to correct error in cross reference citation, strike "12VAC5-421-2550, insert "12VAC5-421-2540".
12VAC5-421-3040		Outlines restrictions of use of sinks for food preparation and utensil washing	Section amended to conform to 2017 FDA Food Code, specifically formatting.
12VAC5-421-3360		Outlines conditions of use of poisonous or toxic materials in food establishments	Section amended to conform to 2017 FDA Food Code.
12VAC5-421-3390		Outlines the criteria for the use of chemicals when washing fruits and vegetables	Section, including title, amended to conform to 2017 FDA Food Code.
12VAC5-421-3410		Establishes requirements for the use of drying agents used in conjunction with sanitation.	Section amended to correct error in referenced federal regulation, strike, "175", insert "174", conforms to 2017 FDA Food Code. Strike "generally recognized as safe", insert acronym GRAS.
12VAC5-421-3510		General provision of the applicability of this chapter as it pertains to public health protection	Section amended to conform to 2017 FDA Food Code.
12VAC5-421-3570		Outlines criteria for the submission of a variance	Section amended for clarity.
12VAC5-421-3580		Outlines the variance evaluation process by the commissioner	Section amended to correct error in cross referenced regulation, add "section C" to 12VAC5-421-3570.
12VAC5-421-3620		Outlines when a HACCP plan is required	Section amended for clarity.
12VAC5-421-3630		Outlines the content requirements of a HACCP	Section amended to conform to 2017 FDA Food Code.

12VAC5-421-3660		Establishes the requirements pertaining to obtaining and maintaining a food establishment permit	Language added to clarify expiration dates of permits, not to exceed twelve months from date of issuance.
12VAC5-421-3670		Outline the application procedure for a food establishment permit	Amends section to expand on general application procedures and the disposition of applications after one year.
12VAC5-421-3690		Outlines with the qualifications and responsibilities of applicants	Section amended for clarity.
12VAC5-421-3710		Establishes a requirement to submit plans for new, converted, or remodeled food establishments	Section amended to clarify cross reference and conformance to 2017 FDA Food Code.
12VAC5-421-3720		Establishes process to renew a permit or issue a new permit.	Amends section to include the requirement to notify the department of change of legal ownership of a food establishment.
12VAC5-421-3750		Establishes responsibilities for permit holders which includes reporting and operating requirements	Amends section to correct cross references, adds language to require food establishments to notify the public a copy of the most recent inspection report is available upon request, and conformance to the 2017 FDA Food Code.
12VAC5-421-3770		Outlines process of summary suspension of permit, include notification to permit holder	Amended for clarity and to adhere to current administrative process.
12VAC5-421-3780		Establishes when the director may revoke a permit.	Section amended for clarity.
12VAC5-421-3800		Establishes inspection frequency for food establishments	Section amended for clarity, additional cross reference added to conform to the 2017 FDA Food Code.
12VAC5-421-3815		Establishes standard for competency of environmental health specialists.	Section amended to comply with 1VAC7-10-140.D.
12VAC5-421-3830		Outlines process for staff to follow when access to a food establishment is denied.	Section amended to correct error in regulatory cross reference, Strike "12VAC5-421-3750.F" insert "12VAC5-421-3750.6" and amended for clarity.
12VAC5-421-3850		Outlines process of applying to circuit court to obtain inspection warrant if denied access to a food establishment	Strike "or his designee", commissioner's authority to elect a designee is in statute.
12VAC5-421-3860		Outlines the information required for an inspection form.	Amended to conform to current administrative practices, insert item "core" as these items are currently documented on inspection form.

12VAC5-421-3870		Establishes timeline food establishments must correct violations.	Amended to relocate language referencing timeline for temporary food establishments to correct violations to 12VAC5-421-3930. Section 3930 is titled, "Timely correction."
12VAC5-421-3910		Establishes operating process for food establishments when imminent health hazards are identified.	Amended to conform to the 2017 FDA Food Code; add language to outline terms in which a food establishment may operate with department approval after interruption of electric or water service.
12VAC5-421-3930		Establishes corrective action timeline for food establishments	Relocates language from 12VAC5-421-3870 regarding corrective action timeline for temporary food establishments.
12VAC5-421-3940		Requires verification and documentation of potential violations to be recorded on the inspection report and the agency's records.	Amended to conform to the 2017 FDA Food Code; add language to include correction of HACCP plan deviation.
12VAC5-421-3970		Outlines enforcement authority of the regulation	Amended for clarity, strike section already in the Code of Virginia section 35.1-2. Duplicative in regulation.
12VAC5-421-4020		Establishes requirement that food establishments comply with the Uniform Statewide Building Code	Section amended for consistency in terminology; strike "restaurant" insert "food establishments."
12VAC5-421-4035		Outlines operational requirements for facilities that otherwise are exempt from the requirement of a permit that choose to be regulated	Section repealed, strike allowance for optional regulatory authority.
12VAC5-421-4040		Establishes process of when to obtain medical information of food employees or conditional employees suspected of transmitting of being infected with an illness transmissible through food.	Section amended to comply with 2017 FDA Food Code, clarifies this section is applicable to "food employees" and "conditional employees" as defined.

If an existing regulation or regulations (or parts thereof) are being repealed and replaced by one or more new regulations, please use the following chart:

Current chapter-section number	New chapter-section number, if applicable	Current requirement	Change, intent, rationale, and likely impact of new requirements
12VAC5-421-3550		Establishes the Food Service Advisory Committee (FSAC) which provides policy and program advise to the Commissioner	Section is repealed. Established in the regulations in 2002, the FSAC was modeled after the FDA Food Advisory Committee. To date the committee has never convened and the FDA Food

			Advisory Committee was terminated in December of 2017. The Food Protection Task Force (FPTF), a multifaceted group consisting of government agencies, industry, and academia, was established under a FDA grant to address food safety and defense in the Commonwealth. In light of the establishment of the FPTF, the FSAC is duplicative. Action does not create a new requirement.
12VAC5-421-3560		Outlines exemptions to the regulations	Section repealed, exemptions exist in the Code of Virginia under sections 35.1-25 and 26. Duplicative in regulation. Action does not create a new requirement.
12VAC5-421-3960	12VAC5-421-3961 to 12VAC5-421-3966	Outlines process when impounding food	Section repealed and replaced with language to clarify process of impounding food, requiring notification of due process rights to food establishment, and documentation. Action does not create a new requirement for the regulant population.
12VAC5-421-4010		Outlines penalties, injunctions, civil penalties and charges for violations to this chapter.	Section repealed, exists in Code of Virginia Section 35.1-14. Duplicative in regulation. Action does not create a new requirement.
12VAC5-421-4035		Outlines operational requirements for facilities that otherwise are exempt from the requirement of a permit that choose to be regulated	Section repealed, strike allowance for food establishments who would otherwise be exempt from permitting from voluntarily obtaining a permit.

If a new regulation is being promulgated, that is not replacing an existing regulation, please use this chart:

New chapter-section number	New requirements	Other regulations and law that apply	Intent and likely impact of new requirements
12VAC5-421-235	Outlines the permissible use of bandages, finger cots, or finger stalls	N/A	Section added to conform to 2017 FDA Food Code. Intended to reduce the likelihood of disease transmission through a permeable bandage and that it does not become a physical contaminate by the transfer of the finger cot or finger stall into the food.
12VAC5-421-2140	Specifies the types of approved source from which food establishments must obtain water.	N/A	This amendment allows for mobile food units and temporary food establishments to obtain water in a way other than a direct connection to a water main.

12VAC5-421-3595	Requires permit holders, who apply for a variance or HACCP Plan to comply with the approved variance and/or HACCP Plan.	N/A	Section added to conform to 2017 FDA Food Code. No impact foreseeable
12VAC5-421-3961	Requires staff, when impounding food products, to provide a written order outlining the reason for the impoundment	N/A	Section added to conform to 2017 FDA Food Code, expands on section 12VAC5-421-3960. No impact on regulated community.
12VAC5-421-3962	Outlines language required on impoundment/hold orders of food products	N/A	Section added to conform to 2017 FDA Food Code, expands on section 12VAC5-421-3960. No impact on regulated community.
12VAC5-421-3963	Outlines procedures for staff to properly label food under a hold order and label language	N/A	Section added to conform to 2017 FDA Food Code, expands on section 12VAC5-421-3960. No impact on regulated community.
12VAC5-421-3964	Requires permit holders not to move, use, or sell food under a hold order	N/A	Section added to conform to 2017 FDA Food Code, expands on section 12VAC5-421-3960. No impact on regulated community.
12VAC5-421-3965	Outlines process a permit holders may use to appeal a hold order to impound food and when staff shall release food under a hold order	N/A	Section added to conform to 2017 FDA Food Code, expands on section 12VAC5-421-3960. No impact on regulated community.
12VAC5-421-3966	Outlines when staff may order a permit holder to comply with regulations or destroy or denature food and due process rights of permit holder	N/A	Section added to conform to 2017 FDA Food Code, expands on section 12VAC5-421-3960. No impact on regulated community.

1 Project 5671 - none

2 DEPARTMENT OF HEALTH
3 CH 421 Amend Chapter 421 to Adopt 2017 FDA Food Code

4
5 Part I
6 Definitions, Purpose and Administration

7 12VAC5-421-10. Definitions.

8 A. Section 35.1-1 of the Code of Virginia provides definitions of the following terms and
9 phrases as used in this chapter.

10 "Board"

11 "Commissioner"

12 "Department"

13 B. For the purposes of implementing this chapter, the term "food establishment" as defined
14 herein is equivalent to the term "restaurant" as defined in 35.1-1 of the Code of Virginia.

15 C. The following words and terms when used in this chapter shall have the following meanings
16 unless the context clearly indicates otherwise.

17 "Accredited program" means a food protection manager certification program that has been
18 evaluated and listed by an accrediting agency as conforming to national standards that certify
19 individuals. "Accredited program" refers to the certification process and is a designation based
20 upon an independent evaluation of factors such as the sponsor's mission; organizational
21 structure; staff resources; revenue sources; policies; public information regarding program scope,
22 eligibility requirements, recertification, discipline and grievance procedures; and test development
23 and administration. "Accredited program" does not refer to training functions or educational
24 programs.

25 "Additive" means either a (i) "food additive" having the meaning stated in the Federal Food,
26 Drug, and Cosmetic Act, § 201(s) and 21 CFR 170.3(e)(1) or (ii) "color additive" having the
27 meaning stated in the Federal Food, Drug, and Cosmetic Act, § 201(t) and 21 CFR 70.3(f).

28 "Adulterated" has the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 402.

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

30 ~~"Agent of the commissioner" means the district or local health director, unless otherwise~~
31 ~~stipulated.~~

32 "Approved" means acceptable to the department based on a determination of conformity with
33 principles, practices, and generally recognized standards that protect public health.

34 "Approved water system" means a permitted waterworks constructed, maintained, and
35 operated pursuant to 12VAC5-590, Waterworks Regulations; or a private well constructed,
36 maintained, and operated pursuant to 12VAC5-630, Private Well Regulations.

37 "Asymptomatic" means without obvious symptoms; not showing or producing indications of a
38 disease or other medical condition, such as an individual infected with a pathogen but not
39 exhibiting or producing any signs or symptoms of vomiting, diarrhea, or jaundice. Asymptomatic
40 includes not showing symptoms because symptoms have resolved or subsided, or because
41 symptoms never manifested.

42 "a_w" means water activity that is a measure of the free moisture in a food, is the quotient of
43 the water vapor pressure of the substance divided by the vapor pressure of pure water at the
44 same temperature, and is indicated by the symbol a_w.

45 "Balut" means an embryo inside a fertile egg that has been incubated for a period sufficient
46 for the embryo to reach a specific stage of development after which it is removed from incubation
47 before hatching.

48 "Bed and breakfast operation" means a residential-type establishment that provides (i) two or
49 more rental accommodations for transient guests and food service to a maximum of 18 transient
50 guests on any single day for five or more days in any calendar year or (ii) at least one rental
51 accommodation for transient guests and food service to a maximum of 18 transient guests on any
52 single day for 30 or more days in any calendar year.

53 "Beverage" means a liquid for drinking, including water.

54 ~~"Board" means the State Board of Health.~~

55 "Bottled drinking water" means water that is sealed in bottles, packages, or other containers
56 and offered for sale for human consumption, including bottled mineral water.

57 "Building official" means a representative of the Department of Housing and Community
58 Development.

59 "Casing" means a tubular container for sausage products made of either natural or artificial
60 (synthetic) material.

61 "Catering operation" means a person who contracts with a client to prepare a specific menu
62 and amount of food in ~~an approved and a~~ permitted food establishment for service to the client's
63 guests or customers at a service location different from the permitted food establishment. Catering
64 may also include cooking or performing final preparation of food at the service location.

65 "Catering operation" does not include:

- 66 1. A private chef or cook who, as the employee of a consumer, prepares food solely in the
67 consumer's home.
- 68 2. Delivery service of food by an approved and permitted food establishment to an end
69 consumer.

70 "Certification number" means a unique combination of letters and numbers assigned by a
71 shellfish control authority to a molluscan shellfish dealer according to the provisions of the
72 National Shellfish Sanitation Program.

73 "CFR" means Code of Federal Regulations. Citations in this chapter to the CFR refer
74 sequentially to the title, part, and section number, such as 40 CFR 180.194 refers to Title 40, Part
75 180, Section 194.

76 "Clean in Place" or "CIP" means cleaned in place by the circulation or flowing by mechanical
77 means through a piping system of a detergent solution, water rinse, and sanitizing solution onto
78 or over equipment surfaces that require cleaning, such as the method used, in part, to clean and
79 sanitize a frozen dessert machine. CIP does not include the cleaning of equipment such as band
80 saws, slicers or mixers that are subjected to in-place manual cleaning without the use of a CIP
81 system.

82 "Commingle" means:

- 83 1. To combine shellstock harvested on different days or from different growing areas as
84 identified on the tag or label; or
- 85 2. To combine shucked shellfish from containers with different container codes or different
86 shucking dates.

87 "Comminuted" means reduced in size by methods including chopping, flaking, grinding, or
88 mincing. "Comminuted" includes (i) fish or meat products that are reduced in size and restructured
89 or reformulated such as gefilte fish, gyros, ground beef, and sausage and (ii) a mixture of two or
90 more types of meat that have been reduced in size and combined, such as sausages made from
91 two or more meats.

92 "Commissary" means a ~~eating establishment~~, food establishment, or any other place in
93 which food, food containers, or supplies are kept, handled, prepared, packaged, or stored for
94 distribution to satellite operations.

95 ~~"Commissioner" means the State Health Commissioner, his duly designated officer, or his~~
96 ~~agent.~~

97 "Commonwealth" means the Commonwealth of Virginia.

98 "Conditional employee" means a potential food employee to whom a job offer is made with
99 employment dependent upon responses to subsequent medical questions or examinations
100 designed to identify potential food employees who may be suffering from a disease that can be
101 transmitted through food and done in compliance with Title 1 of the Americans with Disabilities
102 Act of 1990.

103 "Confirmed disease outbreak" means a foodborne disease outbreak in which laboratory
104 analysis of appropriate specimens identifies a causative ~~organism or chemical~~ agent and
105 epidemiological analysis implicates the food as the source of the illness.

106 "Consumer" means a person who is a member of the public, takes possession of food, is not
107 functioning in the capacity of an operator of a food establishment or food processing plant, and
108 does not offer the food for resale.

109 "Core item" means a provision in this chapter that is not designated as a priority item or a
110 priority foundation item. Core item includes an item that usually relates to general sanitation,
111 operational controls, sanitation standard operating procedures (SSOPs), facilities or structures,
112 equipment design, or general maintenance.

113 "Corrosion-resistant materials" means a material that maintains acceptable surface
114 cleanability characteristics under prolonged influence of the food to be contacted, the normal use
115 of cleaning compounds and sanitizing solutions, and other conditions of the use environment.

116 "Counter-mounted equipment" means equipment that is not portable and is designed to be
117 mounted off the floor on a table, counter, or shelf.

118 "Critical control point" means a point or procedure in a specific food system where loss of
119 control may result in an unacceptable health risk.

120 "Critical limit" means the maximum or minimum value to which a physical, biological, or
121 chemical parameter must be controlled at a critical control point to minimize the risk that the
122 identified food safety hazard may occur.

123 "Cut leafy greens" means fresh leafy greens whose leaves have been cut, shredded, sliced,
124 chopped, or torn. The term "leafy greens" includes iceberg lettuce, romaine lettuce, leaf lettuce,
125 butter lettuce, baby leaf lettuce (i.e., immature lettuce or leafy greens), escarole, endive, spring
126 mix, spinach, cabbage, kale, arugula, and chard. The term "leafy greens" does not include herbs
127 such as cilantro or parsley.

128 "Dealer" means a person who is authorized by a shellfish control authority for the activities of
129 a shellstock shipper, shucker-packer, repacker, reshipper, or depuration processor of molluscan
130 shellfish according to the provisions of the National Shellfish Sanitation Program and is listed in
131 the U.S. Food and Drug Administration's Interstate Certified Shellfish Shippers List, updated
132 monthly (U.S. Food and Drug Administration).

133 ~~"Delicatessen" means a store where ready to eat products such as cooked meats, prepared~~
134 ~~salads, etc. are sold for off-premises consumption.~~

135 "Department" means the Virginia Department of Health.

136 "Director" means the district or local health director.

137 "Disclosure" means a written statement that clearly identifies the animal derived foods that
138 are, or can be ordered, raw, undercooked, or without otherwise being processed to eliminate

139 pathogens in their entirety, or items that contain an ingredient that is raw, undercooked, or without
140 otherwise being processed to eliminate pathogens.

141 "Dry storage area" means a room or area designated for the storage of packaged or
142 containerized bulk food that is not time/temperature control for safety food and dry goods such as
143 single-service items.

144 "Easily cleanable" means a characteristic of a surface that:

- 145 1. Allows effective removal of soil by normal cleaning methods;
- 146 2. Is dependent on the material, design, construction, and installation of the surface; and
- 147 3. Varies with the likelihood of the surface's role in introducing pathogenic or toxigenic
148 agents or other contaminants into food based on the surface's approved placement,
149 purpose, and use.

150 "Easily cleanable" includes a tiered application of the criteria that qualify the surface as easily
151 cleanable as specified above to different situations in which varying degrees of cleanability are
152 required such as:

- 153 1. The appropriateness of stainless steel for a food preparation surface as opposed to the
154 lack of need for stainless steel to be used for floors or for tables used for consumer dining;
155 or
- 156 2. The need for a different degree of cleanability for a utilitarian attachment or accessory
157 in the kitchen as opposed to a decorative attachment or accessory in the consumer dining
158 area.

159 "Easily movable" means:

- 160 1. Portable; mounted on casters, gliders, or rollers; or provided with a mechanical means
161 to safely tilt a unit of equipment for cleaning; and
- 162 2. Having no utility connection, a utility connection that disconnects quickly, or a flexible
163 utility connection line of sufficient length to allow the equipment to be moved for cleaning
164 of the equipment and adjacent area.

165 "Egg" means the shell egg of avian species such as chicken, duck, goose, guinea, quail, ratite,
166 or turkey. Egg does not include a balut; egg of the reptile species such as alligator; or an egg
167 product.

168 "Egg product" means all, or a portion of, the contents found inside eggs separated from the
169 shell and pasteurized in a food processing plant, with or without added ingredients, intended for
170 human consumption, such as dried, frozen, or liquid eggs. Egg product does not include food that
171 contains eggs only in a relatively small proportion such as cake mixes.

172 "Employee" means the permit holder, person in charge, food employee, person having
173 supervisory or management duties, person on the payroll, family member, volunteer, person
174 performing work under contractual agreement, or other person working in a food establishment.

175 "EPA" means the U.S. Environmental Protection Agency.

176 "Equipment" means an article that is used in the operation of a food establishment.
177 "Equipment" includes items such as a freezer, grinder, hood, ice maker, meat block, mixer, oven,
178 reach-in refrigerator, scale, sink, slicer, stove, table, temperature measuring device for ambient
179 air, vending machine, or warewashing machine. Equipment does not include apparatuses used
180 for handling or storing large quantities of packaged foods that are received from a supplier in a
181 cased or overwrapped lot, such as hand trucks, forklifts, dollies, pallets, racks, and skids.

182 "Exclude" means to prevent a person from working as an employee in a food establishment
183 or entering a food establishment as an employee.

184 ~~"°F" means degrees Fahrenheit.~~

185 "FDA" means the U.S. Food and Drug Administration.

186 "Fish" means fresh or saltwater finfish, crustaceans, and other forms of aquatic life (including
187 alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals)
188 other than birds or mammals, and all mollusks, if such animal life is intended for human
189 consumption and includes ~~any~~ an edible human food product derived in whole or in part from fish,
190 including fish that has been processed in any manner.

191 "Food" means (i) a raw, cooked, or processed edible substance, ice, beverage, or ingredient
192 used or intended for use or for sale in whole or in part for human consumption or (ii) chewing
193 gum.

194 "Foodborne disease outbreak" means the occurrence of two or more cases of a similar illness
195 resulting from the ingestion of a common food.

196 "Food-contact surface" means a surface of equipment or a utensil with which food normally
197 comes into contact, or a surface of equipment or a utensil from which food may drain, drip, or
198 splash into a food, or onto a surface normally in contact with food.

199 "Food employee" means an individual working with unpackaged food, food equipment or
200 utensils, or food-contact surfaces.

201 "Food establishment" means an operation that (i) stores, prepares, packages, serves, or
202 vends food directly to the consumer or otherwise provides food to the public for human
203 consumption, such as a restaurant, satellite or catered feeding location, catering operation if the
204 operation provides food directly to a consumer or to a conveyance used to transport people,
205 market, vending location, conveyance used to transport people, institution, or food bank, and (ii)
206 relinquishes possession of food to a consumer directly or indirectly through a delivery service,
207 such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is
208 provided by common carriers.

209 "Food establishment" includes (i) an element of the operation such as a transportation vehicle
210 or a central preparation facility that supplies a vending location or satellite feeding location unless
211 the vending or feeding location is permitted under this chapter; and (ii) an operation that is
212 conducted in a mobile, stationary, temporary, or permanent facility or location where consumption
213 is on or off the premises and regardless of whether there is a charge for the food; ~~and (iii) a facility~~
214 ~~that does not meet the exemption criteria identified in subdivision 6 of this definition or a facility~~
215 ~~that meets the exemption requirements but chooses to be regulated under this chapter.~~

216 For the purpose of implementing this chapter, the following places are also included in the
217 definition of a "food establishment" as defined in § 35.1-1 of the Code of Virginia:

218 ~~1. Any place where food is prepared for service to the public on or off the premises, or any~~
219 ~~place where food is served, including lunchrooms, short order places, cafeterias, coffee~~
220 ~~shops, cafes, taverns, delicatessens, dining accommodations of public or private clubs,~~
221 ~~kitchen facilities of hospitals and nursing homes, dining accommodations of public and~~
222 ~~private schools and colleges, and kitchen areas of local correctional facilities subject to~~
223 ~~standards adopted under § 53.1-68 of the Code of Virginia.~~

224 ~~2. Any place or operation that prepares or stores food for distribution to persons of the~~
225 ~~same business operation or of a related business operation for service to the public,~~
226 ~~including operations preparing or storing food for catering services, push cart operations,~~
227 ~~hotdog stands, and other mobile points of service.~~

228 ~~3. Mobile points of service to which food is distributed by a place or operation described~~
229 ~~in subdivision 2 of this definition, unless the point of service and of consumption is in a~~
230 ~~private residence.~~

231 "Food establishment" does not include:

- 232 1. An establishment that offers only prepackaged food that is not time/temperature control
233 for safety food;
- 234 2. A produce stand that only offers whole, uncut fresh fruits and vegetables; or
- 235 3. A food processing plant, including those that are located on the premises of a food
236 establishment;
- 237 4. A kitchen in a private home if only food that is not time/temperature control for safety
238 food is prepared for sale or service at a function such as a religious or charitable
239 organization's bake sale if allowed by law and if the consumer is informed by a clearly
240 visible placard at the sales or service location that the food is prepared in a kitchen that is
241 not subject to regulation and inspection by the regulatory authority;
- 242 5. An area where food that is prepared as specified in subdivision 4 of this definition is
243 sold or offered for human consumption;
- 244 6. A kitchen in a private home, such as, but not limited to, a family day-care provider or a
245 home for adults, serving 12 or fewer recipients;
- 246 7. A private home that receives catered or home-delivered food; or
- 247 8. Places manufacturing packaged or canned foods that are distributed to grocery stores
248 or other similar food retailers for sale to the public.

249 For the purpose of implementing this chapter, the following are also exempt from the definition
250 of a "food establishment" in this chapter, as defined in §§ 35.1-25 and 35.1-26 of the Code of
251 Virginia:

- 252 1. Boarding houses that do not accommodate transients;
- 253 2. Cafeterias operated by industrial plants for employees only;
- 254 3. Churches, fraternal, school and social organizations and volunteer fire departments and
255 rescue squads that hold dinners and bazaars not more than one time per week and not in
256 excess of two days duration at which food prepared in homes of members or in the kitchen
257 of the church or organization and is offered for sale to the public;
- 258 4. Grocery stores, including the delicatessen that is a part of a grocery store, selling
259 exclusively for off-premises consumption and places manufacturing or selling packaged
260 or canned goods;
- 261 5. Churches that serve meals for their members as a regular part of their religious
262 observance;
- 263 6. Convenience stores or gas stations that are subject to the State Board of Agriculture
264 and Consumer Services' Retail Food Establishment Regulations (2VAC5-585) or any
265 regulations subsequently adopted and that (i) have 15 or fewer seats at which food is
266 served to the public on the premises of the convenience store or gas station and (ii) are
267 not associated with a national or regional restaurant chain. Notwithstanding this
268 exemption, such convenience stores or gas stations shall remain responsible for collecting
269 any applicable local meals tax; and
- 270 7. Any bed and breakfast operation that prepares food for and offers food to guests,
271 regardless of the time the food is prepared and offered, if (i) the premises of the bed and
272 breakfast operation is a home that is owner occupied or owner-agent occupied, (ii) the
273 bed and breakfast operation prepares food for and offers food to transient guests of the
274 bed and breakfast only, (iii) the number of guests served by the bed and breakfast
275 operation does not exceed 18 on any single day, and (iv) guests for whom food is prepared
276 and to whom food is offered are informed by statements contained in published
277 advertisements, mailed brochures, and placards posted at the registration area that the

278 ~~food is prepared in a kitchen that is not licensed as a restaurant and is not subject to the~~
279 ~~regulations governing restaurants.~~

280 "Food processing plant" means a commercial operation that manufactures, packages, labels,
281 or stores food for human consumption and provides food for sale or distribution to other business
282 entities such as food processing plants or food establishments. Food processing plant does not
283 include a food establishment.

284 "Game animal" means an animal, the products of which are food, that is not classified as (i)
285 livestock, sheep, swine, goat, horse, mule, or other equine in 9 CFR 301.2; (ii) poultry; or (iii) fish.
286 "Game animal" includes mammals such as reindeer, elk, deer, antelope, water buffalo, bison,
287 rabbit, squirrel, opossum, raccoon, nutria, or muskrat and nonaquatic reptiles such as land
288 snakes. "Game animal" does not include ratites.

289 ~~"Game animal" includes mammals such as reindeer, elk, deer, antelope, water buffalo, bison,~~
290 ~~rabbit, squirrel, opossum, raccoon, nutria, or muskrat and nonaquatic reptiles such as land~~
291 ~~snakes.~~

292 ~~"Game animal" does not include ratites such as ostrich, emu, and rhea.~~

293 "General use pesticide" means a pesticide that is not classified by EPA for restricted use as
294 specified in 40 CFR 152.175.

295 "Grade A standards" means the requirements of the Grade "A" Pasteurized Milk Ordinance,
296 ~~2013~~ 2017 Revision (U.S. Food and Drug Administration), with which certain fluid and dry milk
297 and milk products comply.

298 "Hazard Analysis and Critical Control Point" or "HACCP Plan" means a written document that
299 delineates the formal procedures for following the Hazard Analysis Critical Control Point principles
300 developed by The National Advisory Committee on Microbiological Criteria for Foods.

301 "Handwashing sink" means a lavatory, a basin or vessel for washing, a wash basin, or a
302 plumbing fixture especially placed for use in personal hygiene and designed for the washing of
303 hands. Handwashing sink includes an automatic handwashing facility.

304 "Hazard" means a biological, chemical, or physical property that may cause an unacceptable
305 consumer health risk.

306 "Health practitioner" means a physician licensed to practice medicine, or if allowed by law, a
307 nurse practitioner, physician assistant, or similar medical professional.

308 "Hermetically sealed container" means a container that is designed and intended to be secure
309 against the entry of microorganisms and, in the case of low acid canned foods, to maintain the
310 commercial sterility of its contents after processing.

311 "Highly susceptible population" means persons who are more likely than other people in the
312 general population to experience foodborne disease because they are:

- 313 1. Immunocompromised, preschool age children, or older adults; and
314 2. Obtaining food at a facility that provides services such as custodial care, health care,
315 or assisted living, such as a child or adult day care center, kidney dialysis center, hospital
316 or nursing home, or nutritional or socialization services such as a senior center.

317 "Imminent health hazard" means a significant threat or danger to health that is considered to
318 exist when there is evidence sufficient to show that a product, practice, circumstance, or event
319 creates a situation that requires immediate correction or cessation of operation to prevent injury
320 based on the number of potential injuries, and the nature, severity, and duration of the anticipated
321 injury.

322 "Injected" means manipulating meat to which a solution has been introduced into its interior
323 by processes ~~such that are referred to~~ as "injecting," "pump marinating," or "stitch pumping."

324 "Intact Meat" means a cut of whole muscle(s) meat that has not undergone comminution,
325 injection, mechanical tenderization, or reconstruction.

326 "Juice" means the aqueous liquid expressed or extracted from one or more fruits or
327 vegetables, purées of the edible portions of one or more fruits or vegetables, or any concentrate
328 of such liquid or purée. Juice does not include, for purposes of HACCP, liquids, purées, or
329 concentrates that are not used as beverages or ingredients of beverages.

330 "Kitchenware" means food preparation and storage utensils.

331 "Law" means applicable local, state, and federal statutes, regulations, and ordinances.

332 "Linens" means fabric items such as cloth hampers, cloth napkins, table cloths, wiping cloths,
333 and work garments including cloth gloves.

334 "Major food allergen" means milk, egg, fish (such as bass, flounder, cod, and including
335 crustacean shellfish such as crab, lobster, or shrimp), tree nuts (such as almonds, pecans, or
336 walnuts), wheat, peanuts, and soybeans; or a food ingredient that contains protein derived from
337 one of these foods. Major food allergen does not include any highly refined oil derived from a
338 major food allergen in this definition and any ingredient derived from such highly refined oil or any
339 ingredient that is exempt under the petition or notification process specified in the Food Allergen
340 Labeling and Consumer Protection Act of 2004 (P.L. 108-282).

341 "Meat" means the flesh of animals used as food including the dressed flesh of cattle, swine,
342 sheep, or goats and other edible animals, except fish, poultry, and wild game animals as specified
343 under 12VAC5-421-330 A 2 and A 3.

344 "Mechanically tenderized" means manipulating meat with deep penetration by processes
345 which may be referred to as "blade tenderizing," "jaccarding," "pinning," "needling," or using
346 blades, pins, needles, or any mechanical device. "Mechanically tenderized" does not include
347 processes by which solutions are injected into meat.

348 "mg/L" means milligrams per liter, which is the metric equivalent of parts per million (ppm).

349 "Mobile food unit" means a food establishment mounted on wheels (excluding boats in the
350 water) readily moveable from place to place at all times during operation and shall include
351 pushcarts, trailers, trucks, or vans. The unit, all operations, and all equipment must be integral to
352 and be within or attached to the unit.

353 "Molluscan shellfish" means any edible species of fresh or frozen oysters, clams, mussels,
354 and scallops or edible portions thereof, except when the scallop product consists only of the
355 shucked adductor muscle.

356 "Noncontinuous cooking" means the cooking of food in a food establishment using a process
357 in which the initial heating of the food is intentionally halted so that it may be cooled and held for
358 complete cooking at a later time prior to sale or service. "Noncontinuous cooking" does not include
359 cooking procedures that only involve temporarily interrupting or slowing an otherwise continuous
360 cooking process.

361 "Occasional" means not more than one time per week, and not in excess of two days duration.

362 "Packaged" means bottled, canned, cartoned, bagged, or wrapped, whether packaged in a
363 food establishment or a food processing plant. Packaged does not include wrapped or placed in
364 a carry-out container to protect the food during service or delivery to the consumer, by a food
365 employee, upon consumer request.

366 "Permit" means a license issued by the ~~regulatory authority~~department that authorizes a
367 person to operate a food establishment.

368 "Permit holder" means ~~the entity~~person that is legally responsible for the operation of the food
369 establishment ~~such as the owner, the owner's agent, or other person,~~ and possesses a valid
370 permit to operate a food establishment.

371 "Person" means an association, a corporation, individual, partnership, other legal entity,
372 government, or governmental subdivision or agency.

373 "Person in charge" means the individual present at a food establishment who is responsible
374 for the operation at the time of inspection.

375 "Personal care items" means items or substances that may be poisonous, toxic, or a source
376 of contamination and are used to maintain or enhance a person's health, hygiene, or appearance.
377 Personal care items include items such as medicines; first aid supplies; and other items such as
378 cosmetics, and toiletries such as toothpaste and mouthwash.

379 "pH" means the symbol for the negative logarithm of the hydrogen ion concentration, which is
380 a measure of the degree of acidity or alkalinity of a solution. Values between 0 and 7.0 indicate
381 acidity and values between 7.0 and 14 indicate alkalinity. The value for pure distilled water is
382 7.0, which is considered neutral.

383 "Physical facilities" means the structure and interior surfaces of a food establishment including
384 accessories such as soap and towel dispensers and attachments such as light fixtures and
385 heating or air conditioning system vents.

386 "Plumbing fixture" means a receptacle or device that is permanently or temporarily connected
387 to the water distribution system of the premises and demands a supply of water from the system
388 or discharges used water, waste materials, or sewage directly or indirectly to the drainage system
389 of the premises.

390 "Plumbing system" means the water supply and distribution pipes; plumbing fixtures and traps;
391 soil, waste, and vent pipes; sanitary and storm sewers and building drains, including their
392 respective connections, devices, and appurtenances within the premises; and water-treating
393 equipment.

394 "Poisonous or toxic materials" means substances that are not intended for ingestion and are
395 included in four categories:

- 396 1. Cleaners and sanitizers, that include cleaning and sanitizing agents and agents such
397 as caustics, acids, drying agents, polishes, and other chemicals;
- 398 2. Pesticides, except sanitizers, that include substances such as insecticides and
399 rodenticides;
- 400 3. Substances necessary for the operation and maintenance of the establishment such as
401 nonfood grade lubricants, paints, and personal care items that may be deleterious to
402 health; and
- 403 4. Substances that are not necessary for the operation and maintenance of the
404 establishment and are on the premises for retail sale, such as petroleum products and
405 paints.

406 "Potable water" means water fit for human consumption that is obtained from an approved
407 water supply and that is (i) sanitary and normally free of minerals, organic substances, and toxic
408 agents in excess of reasonable amounts and (ii) adequate in quantity and quality for the minimum
409 health requirements of the persons served (see Article 2 (§ 32.1-167 et seq.) of Chapter 6 of Title
410 32.1 of the Code of Virginia). Potable water is traditionally known as drinking water and excludes
411 such nonpotable forms as "boiler water," "mop water," "rainwater," "wastewater," and "nondrinking
412 water."

413 "Poultry" means any domesticated bird (chickens, turkeys, ducks, geese, guineas, ratites, or
414 squabs), whether live or dead, as defined in 9 CFR 381.1, and any migratory waterfowl, game
415 bird, pheasant, partridge, quail, grouse, or pigeon whether live or dead, as defined in 9 CFR 362.1.

416 "Premises" means the physical facility, its contents, and the contiguous land or property under
417 the control of the permit holder; or the physical facility, its contents, and the land or property which

418 are under the control of the permit holder and may impact food establishment personnel, facilities,
419 or operations, if a food establishment is only one component of a larger operation such as a health
420 care facility, hotel, motel, school, recreational camp, or prison.

421 "Primal cut" means a basic major cut into which carcasses and sides of meat are separated,
422 such as a beef round, pork loin, lamb flank or veal breast.

423 "Priority foundation item" means a provision in this chapter whose application supports,
424 facilitates, or enables one or more priority items. "Priority foundation item" includes an item that
425 requires the purposeful incorporation of specific actions, equipment, or procedures by industry
426 management to attain control of risk factors that contribute to foodborne illness or injury such as
427 personnel training, infrastructure or necessary equipment, HACCP plans, documentation or
428 record keeping, and labeling and is denoted in this regulation with a superscript Pf^{Pf}.

429 "Priority item" means a provision in this chapter whose application contributes directly to the
430 elimination, prevention or reduction to an acceptable level of hazards associated with foodborne
431 illness or injury and there is no other provision that more directly controls the hazard. "Priority
432 item" includes items with a quantifiable measure to show control of hazards such as cooking,
433 reheating, cooling, and handwashing and is denoted in this chapter with a superscript P^P.

434 "Private well" means any water well constructed for a person on land that is owned or leased
435 by that person and is usually intended for household, groundwater source heat pump, agricultural
436 use, industrial use, or other nonpublic water well.

437 "Pure water" means potable water fit for human consumption that is (i) sanitary and normally
438 free of minerals, organic substances, and toxic agents in excess of reasonable amounts and (ii)
439 adequate in quantity and quality for the minimum health requirements of the persons served (see
440 §§ 32.1-167 and 32.1-176.1 of the Code of Virginia and 12VAC5-590, Waterworks Regulations
441 and ~~12VAC5-630-370~~, 12VAC5-630, Private Well Regulations. Potable water is traditionally
442 known as drinking water, and excludes such nonpotable forms as "boiler water," "mop water,"
443 "rainwater," "wastewater," and "nondrinking water."

444 ~~"Pushcart" means any wheeled vehicle or device other than a motor vehicle or trailer that may
445 be moved with or without the assistance of a motor and that does not require registration by the
446 department of motor vehicles.~~

447 "Ratite" means a flightless bird such as an emu, ostrich, or rhea.

448 "Ready-to-eat food" means food that:

- 449 1. Is in a form that is edible without additional preparation to achieve food safety, as
450 specified under 12VAC5-421-700 A, B, and C, 12VAC5-421-710 or 12VAC5-421-730;
- 451 2. Is a raw or partially cooked animal food and the consumer is advised as specified under
452 12VAC5-421- 700 D 1 and 3; or
- 453 3. Is prepared in accordance with a variance that is granted as specified under 12VAC5-
454 421-700 D 4; and
- 455 4. Ready-to-eat food may receive additional preparation for palatability or aesthetic,
456 epicurean, gastronomic, or culinary purposes.

457 "Ready-to-eat food" includes:

- 458 1. Raw animal food that is cooked as specified under 12VAC5-421-700, or 12VAC5-421-
459 710 or frozen as specified under 12VAC5-421-730;
- 460 2. Raw fruits and vegetables that are washed as specified under 12VAC5-421-510;
- 461 3. Fruits and vegetables that are cooked for hot holding as specified under 12VAC5-421-
462 720;

- 463 4. All time/temperature control for safety food that is cooked to the temperature and time
 464 required for the specific food under ~~12VAC5-421-700~~Part III, Article 4 (12VAC5-421-700
 465 et seq.) and cooled as specified in 12VAC5-421-800;
- 466 5. Plant food for which further washing, cooking, or other processing is not required for
 467 food safety, and from which rinds, peels, husks, or shells, if naturally present, are removed;
- 468 6. Substances derived from plants such as spices, seasonings, and sugar;
- 469 7. A bakery item such as bread, cakes, pies, fillings, or icing for which further cooking is
 470 not required for food safety;
- 471 8. The following products that are produced in accordance with USDA guidelines and that
 472 have received a lethality treatment for pathogens: dry, fermented sausages, such as dry
 473 salami or pepperoni; salt-cured meat and poultry products, such as prosciutto ham,
 474 country cured ham, and Parma ham; and dried meat and poultry products, such as jerky
 475 or beef sticks; and
- 476 9. Food manufactured ~~according to~~ as specified in 21 CFR Part 113.

477 "Reduced oxygen packaging" means the reduction of the amount of oxygen in a package by
 478 removing oxygen; displacing oxygen and replacing it with another gas or combination of gases;
 479 or otherwise controlling the oxygen content to a level below that normally found in the atmosphere
 480 (approximately 21% at sea level); and a process as specified in this definition that involves a food
 481 for which the hazards Clostridium botulinum or Listeria monocytogenes require control in the final
 482 packaged form. Reduced oxygen packaging includes:

- 483 1. Vacuum packaging, in which air is removed from a package of food and the package is
 484 hermetically sealed so that a vacuum remains inside the package;
- 485 2. Modified atmosphere packaging, in which the atmosphere of a package of food is
 486 modified so that its composition is different from air, but the atmosphere may change over
 487 time due to the permeability of the packaging material or the respiration of the food.
 488 Modified atmosphere packaging includes reduction in the proportion of oxygen, total
 489 replacement of oxygen, or an increase in the proportion of other gases such as carbon
 490 dioxide or nitrogen;
- 491 3. Controlled atmosphere packaging, in which the atmosphere of a package of food is
 492 modified so that until the package is opened, its composition is different from air, and
 493 continuous control of that atmosphere is maintained, such as by using oxygen scavengers
 494 or a combination of total replacement oxygen, nonrespiring food, and impermeable
 495 packaging material;
- 496 4. Cook chill packaging, in which cooked food is hot filled into impermeable bags that have
 497 the air expelled and are then sealed or crimped closed. The bagged food is rapidly chilled
 498 and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens; or
- 499 5. Sous vide packaging, in which raw or partially cooked food is vacuum packaged in an
 500 impermeable bag, cooked in the bag, rapidly chilled, and refrigerated at temperatures that
 501 inhibit the growth of psychrotrophic pathogens.

502 "Refuse" means solid waste not carried by water through ~~the~~ a sewage system.

503 "Regulatory authority" means the Virginia Department of Agriculture and Consumer Services,
 504 ~~the Virginia Department of Health~~department, or their authorized representative having
 505 jurisdiction over the food establishment.

506 "Reminder" means a written statement concerning the health risk of consuming animal foods
 507 raw, undercooked, or without otherwise being processed to eliminate pathogens.

508 "Reservice" "Re-service" means the transfer of food that is unused and returned by a
 509 consumer after being served or sold and in the possession of the consumer, to another person.

510 "Restrict" means to limit the activities of a food employee so that there is no risk of transmitting
511 a disease that is transmissible through food and the food employee does not work with exposed
512 food, clean equipment, utensils, linens, and unwrapped single-service or single-use articles.

513 "Restricted egg" means any check, dirty egg, incubator reject, inedible, leaker, or loss as
514 defined in 9 CFR Part 590.

515 "Restricted use pesticide" means a pesticide product that contains the active ingredients
516 specified in 40 CFR 152.175 and that is limited to use by or under the direct supervision of a
517 certified applicator.

518 "Risk" means the likelihood that an adverse health effect will occur within a population as a
519 result of a hazard in a food.

520 "Safe material" means an article manufactured from or composed of materials that ~~shall~~ may
521 not reasonably be expected to result, directly or indirectly, in their becoming a component or
522 otherwise affecting the characteristics of any food; an additive that is used as specified in § 409
523 of the Federal Food, Drug, and Cosmetic Act (21 USC § 348); or other materials that are not
524 additives and that are used in conformity with applicable regulations of the ~~Food and Drug~~
525 ~~Administration.~~ FDA.

526 "Sanitization" means the application of cumulative heat or chemicals on cleaned food-contact
527 surfaces that, when evaluated for efficacy, is sufficient to yield a reduction of five logs, which is
528 equal to a 99.999% reduction, of representative disease microorganisms of public health
529 importance.

530 "Sealed" means free of cracks or other openings that ~~permit~~ allow the entry or passage of
531 moisture.

532 "Service animal" means an animal such as a guide dog, signal dog, or other animal individually
533 trained to provide assistance to an individual with a disability.

534 "Servicing area" means an operating base location to which a mobile food establishment or
535 transportation vehicle returns regularly for such things as vehicle and equipment cleaning,
536 discharging liquid or solid wastes, refilling water tanks and ice bins, and boarding food.

537 "Sewage" means liquid waste containing animal or vegetable matter in suspension or solution
538 and may include liquids containing chemicals in solution. Sewage includes water-carried and non-
539 water-carried human excrement or kitchen, laundry, shower, bath, or lavatory waste separately
540 or together with such underground surface, storm, or other water and liquid industrial wastes as
541 may be present from residences, buildings, vehicles, industrial establishments, or other places.

542 "Shellfish control authority" means a state, federal, foreign, tribal or other government entity
543 legally responsible for administering a program that includes certification of molluscan shellfish
544 harvesters and dealers for interstate commerce such as the Virginia Department of Health
545 Division of Shellfish Sanitation.

546 "Shellstock" means raw, in-shell molluscan shellfish.

547 "Shiga toxin-producing Escherichia coli" or "STEC" means any E. coli capable of producing
548 Shiga toxins (also called verocytotoxins). STEC infections can be asymptomatic or may result in
549 a spectrum of illness ranging from mild nonbloody diarrhea, to hemorrhagic colitis (i.e., bloody
550 diarrhea) to hemolytic uremic syndrome (HUS), which is a type of kidney failure. Examples of
551 serotypes of STEC include E. coli 0157:H7, E. coli 0157:NM, E. coli 026:H11; ~~E. coli 0145:NM~~,
552 Coli 0145:NM, E. coli 0103:H2, and E. coli 0111:NM. STEC are sometimes referred to as VTEC
553 (verocytotoxigenic E. coli) or as EHEC (Enterohemorrhagic E. coli). EHEC are a subset of STEC
554 that can cause hemorrhagic colitis or HUS.

555 "Shucked shellfish" means molluscan shellfish that have one or both shells removed.

556 "Single-service articles" means tableware, carry-out utensils, and other items such as bags,
 557 containers, placemats, stirrers, straws, toothpicks, and wrappers that are designed and
 558 constructed for one time, one person use after which they are intended for discard.

559 "Single-use articles" means utensils and bulk food containers designed and constructed to be
 560 used once and discarded. Single-use articles includes items such as wax paper, butcher paper,
 561 plastic wrap, formed aluminum food containers, jars, plastic tubs or buckets, bread wrappers,
 562 pickle barrels, ketchup bottles, and number 10 cans which do not meet the materials, durability,
 563 strength and cleanability specifications contained in 12VAC5-421-960, 12VAC5-421-1080, and
 564 12VAC5-421-1100 for multiuse utensils.

565 "Slacking" means the process of moderating the temperature of a food such as allowing a
 566 food to gradually increase from a temperature of -10°F (-23°C) to 25°F (-4°C) in preparation for
 567 deep-fat frying or to facilitate even heat penetration during the cooking of previously block-frozen
 568 food such as shrimp.

569 "Smooth" means a food-contact surface having a surface free of pits and inclusions with a
 570 cleanability equal to or exceeding that of (100 grit) number three stainless steel; a non-food-
 571 contact surface of equipment having a surface equal to that of commercial grade hot-rolled steel
 572 free of visible scale; and a floor, wall, or ceiling having an even or level surface with no roughness
 573 or projections that render it difficult to clean.

574 "Substantial compliance" means equipment or structure design or construction; food
 575 preparation, handling, storage, transportation; or cleaning procedures that will not substantially
 576 affect health consideration or performance of the facility or the employees.

577 "Tableware" means eating, drinking, and serving utensils for table use such as flatware
 578 including forks, knives, and spoons; hollowware including bowls, cups, serving dishes, tumblers;
 579 and plates.

580 "Temperature measuring device" means a thermometer, thermocouple, thermistor, or other
 581 device that indicates the temperature of food, air, or water.

582 "Temporary food establishment" means a food establishment that operates for a period of no
 583 more than 14 consecutive days in conjunction with a single event or celebration.

584 "Time/temperature control for safety food" or "TCS food" means a food that requires
 585 time/temperature control for safety to limit pathogenic microorganism growth or toxin formation:

586 1. TCS food includes an animal food that is raw or heat treated; a plant food that is heat
 587 treated or consists of raw seed sprouts, cut melons, cut leafy greens, cut tomatoes, or
 588 mixtures of cut tomatoes that are not modified in a way so that they are unable to support
 589 pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not
 590 modified in a way so that they are unable to support pathogenic microorganism growth or
 591 toxin formation; and except as specified in subdivision 2 d of this definition, a food that
 592 because of the interaction of its A_w and pH values is designated as product assessment
 593 required (PA) in Table A or B of this definition:

Table A. Interaction of pH and A_w for control of spores in food heat treated to destroy vegetative cells and subsequently packaged.

A_w values	pH values		
	4.6 or less	>4.6 - 5.6	>5.6
≤ 0.92	non-TCS food*	non-TCS food	non-TCS food
>0.92 - 0.95	non-TCS food	non-TCS food	PA**

>0.95	non-TCS food	PA	PA
*TCS food means time/temperature control for safety food			
**PA means product assessment required			

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Table B. Interaction of pH and A_w for control of vegetative cells and spores in food not heat treated or heat treated but not packaged.

A _w values	pH values			
	< 4.2	4.2 - 4.6	> 4.6 - 5.0	> 5.0
<0.88	non-TCS food*	non-TCS food	non-TCS food	non-TCS food
0.88 - 0.90	non-TCS food	non-TCS food	non-TCS food	PA**
>0.90 - 0.92	non-TCS food	non-TCS food	PA	PA
>0.92	non-TCS food	PA	PA	PA
*TCS food means time/temperature control for safety food				
**PA means product assessment required				

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2. TCS food does not include:

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a. An air-cooled hard-boiled egg with shell intact, or an egg with shell intact that is not hard-boiled, but has been pasteurized to destroy all viable salmonellae;

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b. A food in an unopened hermetically sealed container that is commercially processed to achieve and maintain commercial sterility under conditions of nonrefrigerated storage and distribution;

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c. A food that because of its pH or A_w value, or interaction of A_w and pH values, is designated as a non-TCS food in Table A or B of this definition;

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d. A food that is designated as PA in Table A or B of this definition and has undergone a product assessment showing that the growth or toxin formation of pathogenic microorganisms that are reasonably likely to occur in that food is precluded due to:

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(1) Intrinsic factors including added or natural characteristics of the food such as preservatives, antimicrobials, humectants, acidulants, or nutrients;

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(2) Extrinsic factors including environmental or operational factors that affect the food such as packaging, modified atmosphere such as reduced oxygen packaging, shelf-life and use, or temperature range of storage and use; or

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(3) A combination of intrinsic and extrinsic factors; or

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e. A food that does not support the growth or toxin formation of pathogenic microorganisms in accordance with one of the subdivisions 2 a through 2 d of this definition even though the food may contain a pathogenic microorganism or chemical or physical contaminant at a level sufficient to cause illness or injury.

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"USDA" means the U.S. Department of Agriculture.

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"Utensil" means a food-contact implement or container used in the storage, preparation, transportation, dispensing, sale, or service of food, such as kitchenware or tableware that is multiuse, single service, or single use; gloves used in contact with food; temperature sensing

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620 probes of food temperature measuring devices and probe-type price or identification tags used in
621 contact with food.

622 "Variance" means a written document issued by the ~~regulatory authority~~department that
623 authorizes a modification or waiver of one or more requirements of this chapter if, in the opinion
624 of the ~~regulatory authority~~department, a health hazard or nuisance will not result from the
625 modification or waiver.

626 "Vending machine" means a self-service device that, upon insertion of a coin, paper currency,
627 token, card, ~~or~~ key, electronic transaction, or by optional manual operation, dispenses unit
628 servings of food in bulk or in packages without the necessity of replenishing the device between
629 each vending operation.

630 "Vending machine location" means the room, enclosure, space, or area where one or more
631 vending machines are installed and operated and includes the storage areas and areas on the
632 premises that are used to service and maintain the vending machines.

633 "Warewashing" means the cleaning and sanitizing of utensils and food-contact surfaces of
634 equipment.

635 "Waterworks" means a system that serves piped water for human consumption to at least 15
636 service connections or 25 or more individuals for at least 60 days out of the year. "Waterworks"
637 includes all structures, equipment and appurtenances used in the storage, collection, purification,
638 treatment, and distribution of ~~potable~~ pure water except the piping and fixtures inside the building
639 where such water is delivered (see Article 2 (§ 32.1-167 et seq.) of Chapter 6 of Title 32.1 of the
640 Code of Virginia).

641 "Whole-muscle, intact beef" means whole muscle beef that is not injected, mechanically
642 tenderized, reconstructed, or scored and marinated, from which beef steaks may be cut.

643 **12VAC5-421-30. Purpose.**

644 This chapter has been promulgated by the ~~State Board of Health~~board to specify the following
645 requirements to protect public health:

- 646 1. A procedure for obtaining a license (permit);
- 647 2. Criteria for assuring the safe preparation, handling, protection and/or temperature
648 control for food;
- 649 3. Criteria for the safe and sanitary maintenance, storage, operation and use of equipment;
- 650 4. Requirements that food establishments ~~be connected to, and use~~ utilize an approved
651 water supply and sewage disposal system;
- 652 5. Requirements for toilet and cleansing facilities for employees ~~and customers;~~;
- 653 6. Criteria for vector and pest control;
- 654 7. Requirements for the sanitary maintenance and use of food establishment's physical
655 plant;
- 656 8. Requirements for appropriate lighting and ventilation not otherwise provided for in the
657 Uniform Statewide Building Code; and
- 658 9. A classification system for food establishments.

659 **12VAC5-421-40. Administration of regulation.**

660 This chapter is administered by the following:

- 661 1. The ~~State Board of Health, hereinafter referred to as the board,~~board has responsibility
662 to promulgate, amend and repeal regulations necessary to protect the public health.
- 663 2. The ~~State Health Commissioner, hereinafter referred to as the commissioner,~~
664 commissioner is the chief executive officer of the ~~State Department of Health.~~department.

665 The commissioner has the authority to act within the scope of regulations promulgated by
666 the board and for the board when it is not in session.

667 3. ~~The district or local health director, hereinafter referred to as the director,~~director is
668 responsible for the permitting and inspection of food establishments located within the
669 director's district and for assuring compliance with this ~~part~~chapter. The director is the duly
670 designated officer or agent of the commissioner.

671 **12VAC5-421-55. Certified food protection manager.**

672 A. ~~At least one employee with supervisory and management responsibility and the authority~~
673 ~~to direct and control food preparation and service~~The person in charge shall be a certified food
674 protection manager, ~~demonstrating who has shown~~ proficiency of required knowledge and
675 information through passing a test that is part of an accredited program.

676 B. This section does not apply to food establishments that serve only ~~non-temperature non-~~
677 ~~time/temperature~~ control for safety food and food establishments ~~where food handling does not~~
678 ~~exceed reheating, cold holding, and hot holding of commercially processed and packaged ready-~~
679 ~~to-eat foods that store and prepare food only to the extent that they reheat or cold hold~~
680 commercially processed, fully cooked time/temperature control for safety foods. Food
681 establishments exempt from the certified food protection manager requirement may not cool
682 time/temperature control for safety foods.

683 C. For purposes of enforcement, this section will take effect on ~~July 1, 2018~~(insert two years
684 from the effective date of this regulation).

685 **12VAC5-421-60. Demonstration of knowledge.**

686 Based on the risks of foodborne illness inherent to the food operation, during inspections and
687 upon request the person in charge shall demonstrate to the ~~regulatory authority~~department
688 knowledge of foodborne disease prevention, and the requirements of this chapter. The person in
689 charge shall demonstrate this knowledge by:

- 690 1. Complying with this chapter by having no violations of priority items during the current
691 inspection;^{Pf}
- 692 2. Being a certified food protection manager who has shown proficiency of required
693 information through passing a test that is part of an accredited program;^{Pf} or
- 694 3. Responding correctly to the environmental health specialist's questions as they relate
695 to the specific food operation. The areas of operation may include:
 - 696 a. Describing the relationship between the prevention of foodborne disease and the
697 personal hygiene of a food employee;^{Pf}
 - 698 b. Explaining the responsibility of the person in charge for preventing the transmission
699 of foodborne disease by a food employee who has a disease or medical condition that
700 may cause foodborne disease;^{Pf}
 - 701 c. Describing the symptoms associated with the diseases that are transmissible
702 through food;^{Pf}
 - 703 d. Explaining the significance of the relationship between maintaining the time and
704 temperature of time/temperature control for safety food and the prevention of
705 foodborne illness;^{Pf}
 - 706 e. Explaining the hazards involved in the consumption of raw or undercooked meat,
707 poultry, eggs, and fish;^{Pf}
 - 708 f. Stating the required food temperatures and times for safe cooking of
709 time/temperature control for safety food including meat, poultry, eggs, and fish;^{Pf}
 - 710 g. Stating the required temperatures and times for the safe refrigerated storage, hot
711 holding, cooling, and reheating of time/temperature control for safety food;^{Pf}

- 712 h. Describing the relationship between the prevention of foodborne illness and the
713 management and control of the following:
- 714 (1) Cross contamination;^{Pf}
715 (2) Hand contact with ready-to-eat foods;^{Pf}
716 (3) Handwashing;^{Pf} and
717 (4) Maintaining the food establishment in a clean condition and in good repair;^{Pf}
- 718 i. Describing the foods identified as major food allergens and the symptoms that a
719 major food allergen could cause in a sensitive individual who has an allergic reaction;^{Pf}
- 720 j. Explaining the relationship between food safety and providing equipment that is:
- 721 (1) Sufficient in number and capacity;^{Pf} and
722 (2) Properly designed, constructed, located, installed, operated, maintained, and
723 cleaned;^{Pf}
- 724 k. Explaining correct procedures for cleaning and sanitizing utensils and food-contact
725 surfaces of equipment;^{Pf}
- 726 l. Identifying the source of water used and measures taken to ensure that the water
727 supply remains protected from contamination such as providing protection from
728 backflow and precluding the creation of cross connections;^{Pf}
- 729 m. Identifying poisonous or toxic materials in the food establishment and the
730 procedures necessary to ensure that they are safely stored, dispensed, used, and
731 disposed of according to law;^{Pf}
- 732 n. Identifying critical control points in the operation from purchasing through sale or
733 service that when not controlled may contribute to the transmission of foodborne
734 illness and explaining steps taken to ensure that the points are controlled in
735 accordance with the requirements of this chapter;^{Pf}
- 736 o. Explaining the details of how the person in charge and food employees comply with
737 a HACCP plan if such a plan is required by the law, this chapter, or a voluntary an
738 agreement between the regulatory authority department and the food establishment;^{Pf}
- 739 p. Explaining the responsibilities, rights, and authorities assigned by this chapter to
740 the:
- 741 (1) Food employee;^{Pf}
742 (2) Conditional employee;^{Pf}
743 (3) Person in charge;^{Pf} and
744 (4) Regulatory authority department;^{Pf} and
- 745 q. Explaining how the person in charge, food employees, and conditional employees
746 comply with reporting responsibilities and the exclusion or restriction of food
747 employees.^{Pf}

748 **12VAC5-421-70. Duties of person in charge.**

749 The person in charge shall ensure that:

- 750 1. Food establishment operations are not conducted in a private home or in a room used
751 as living or sleeping quarters as specified under 12VAC5-421-2990;^{Pf}
- 752 2. Persons unnecessary to the food establishment operation are not allowed in the food
753 preparation, food storage, or warewashing areas, except that brief visits and tours may be
754 authorized by the person in charge if steps are taken to ensure that exposed food; clean
755 equipment, utensils, and linens; and unwrapped single-service and single-use articles are
756 protected from contamination;^{Pf}

- 757 3. Employees and other persons such as delivery and maintenance persons and pesticide
758 applicators entering the food preparation, food storage, and warewashing areas comply
759 with this chapter;^{Pf}
- 760 4. Employees are effectively cleaning their hands, by routinely monitoring the employees'
761 handwashing;^{Pf}
- 762 5. Employees are visibly observing foods as they are received to determine that they are
763 from approved sources, delivered at the required temperatures, protected from
764 contamination, unadulterated, and accurately presented, by routinely monitoring the
765 employees' observations and periodically evaluating foods upon their receipt;^{Pf}
- 766 6. Employees are verifying that foods delivered to the food establishment during non-
767 operating hours are from approved sources and are placed into appropriate storage
768 locations such that they are maintained at the required temperatures, protected from
769 contamination, unadulterated, and accurately presented;^{Pf}
- 770 7. Employees are properly cooking time/temperature control for safety food, being
771 particularly careful in cooking those foods known to cause severe foodborne illness and
772 death, such as eggs and comminuted meats, through daily oversight of the employees'
773 routine monitoring of the cooking temperatures using appropriate temperature measuring
774 devices properly scaled and calibrated as specified under 12VAC5-421-1180 and
775 12VAC5-421-1730 B;^{Pf}
- 776 8. Employees are using proper methods to rapidly cool time/temperature control for safety
777 food that is not held hot or is not for consumption within four hours, through daily oversight
778 of the employees' routine monitoring of food temperatures during cooling;^{Pf}
- 779 9. Employees are properly maintaining the temperatures of time/temperature control for
780 safety food during hot and cold holding through daily oversight of the employees routine
781 monitoring of food temperatures;^{Pf}
- 782 10. Consumers who order raw or partially cooked ready-to-eat foods of animal origin are
783 informed as specified under 12VAC5-421-930 that the food is not cooked sufficiently to
784 ensure its safety;^{Pf}
- 785 11. Employees are properly sanitizing cleaned multiuse equipment and utensils before
786 they are reused, through routine monitoring of solution temperature and exposure time for
787 hot water sanitizing, and chemical concentration, pH, temperature, and exposure time for
788 chemical sanitizing;^{Pf}
- 789 12. Consumers are notified that clean tableware is to be used when they return to self-
790 service areas such as salad bars and buffets as specified in 12VAC5-421-590;^{Pf}
- 791 13. Except when approval is obtained from the ~~regulatory authority~~ department as
792 specified in 12VAC5-421-450 E, employees are preventing cross-contamination of ready-
793 to-eat food with bare hands by properly using suitable utensils such as deli tissue,
794 spatulas, tongs, single-use gloves, or dispensing equipment;^{Pf}
- 795 14. Employees are properly trained in food safety, including food allergy awareness, as it
796 relates to their assigned duties;^{Pf}
- 797 15. Food employees and conditional employees are informed in a verifiable manner of
798 their responsibility to report in accordance with law, to the person in charge, information
799 about their health and activities as they relate to diseases that are transmissible through
800 food, as specified under 12VAC5-421-80;^{Pf} and
- 801 16. Written procedures and plans, where specified by this chapter and as developed by
802 the food establishment, are maintained and implemented as required.^{Pf}

Article 2
Employee Health

803
804
805 **12VAC5-421-80. Responsibility of permit holder, person in charge, and conditional**
806 **employees.**

807 A. The permit holder shall require food employees and conditional employees to report to the
808 person in charge information about their health and activities as they relate to diseases that are
809 transmissible through food. A food employee or conditional employee shall report the information
810 in a manner that allows the person in charge to reduce the risk of foodborne disease transmission,
811 including providing necessary additional information, such as the date of onset of symptoms and
812 an illness, or of a diagnosis without symptoms, if the food employee or conditional employee:

- 813 1. Has any of the following symptoms:
- 814 a. Vomiting;^P
 - 815 b. Diarrhea;^P
 - 816 c. Jaundice;^P
 - 817 d. Sore throat with fever;^P or
 - 818 e. A lesion containing pus such as a boil or infected wound that is open or draining
819 and is:
 - 820 (1) On the hands or wrists, unless an impermeable cover such as a finger cot or stall
821 protects the lesion and a single-use glove is worn over the impermeable cover;^P
 - 822 (2) On exposed portions of the arms, unless the lesion is protected by an impermeable
823 cover;^P or
 - 824 (3) On other parts of the body, unless the lesion is covered by a dry, durable, tight-
825 fitting bandage;^P
- 826 2. Has an illness diagnosed by a health practitioner due to:
- 827 a. Norovirus;^P
 - 828 b. Hepatitis A virus;^P
 - 829 c. Shigella spp.;^P
 - 830 d. Shiga toxin-producing Escherichia coli; ^P
 - 831 e. Typhoid fever (caused by Salmonella typhi);^P or
 - 832 f. Salmonella (nontyphoidal);^P
- 833 3. Had ~~typhoid~~ Typhoid fever, diagnosed by a health practitioner, within the past three
834 months, without having received antibiotic therapy, as determined by a health
835 practitioner;^P
- 836 4. Has been exposed to, or is the suspected source of, a confirmed disease outbreak,
837 because the food employee or conditional employee consumed or prepared food
838 implicated in the outbreak, or consumed food at an event prepared by a person who is
839 infected or ill with:
- 840 a. Norovirus within the past 48 hours of the last exposure; ^P
 - 841 b. Shiga toxin-producing Escherichia coli, or Shigella spp. within the past three days
842 of the last exposure;^P
 - 843 c. Typhoid fever (caused by Salmonella typhi) within the past 14 days of the last
844 exposure;^P or
 - 845 d. Hepatitis A virus within the past 30 days of the last exposure;^P or
- 846 5. Has been exposed by attending or working in a setting where there is a confirmed
847 disease outbreak, or living in the same household as, and has knowledge about an

848 individual who works or attends a setting where there is a confirmed disease outbreak, or
849 living in the same household as, and has knowledge about, ~~and~~ an individual diagnosed
850 with an illness caused by:

- 851 a. Norovirus within the past 48 hours of the last exposure;^P
- 852 b. Shiga toxin-producing Escherichia coli or Shigella spp. within the past three days of
853 the last exposure;^P
- 854 c. Typhoid fever (caused by Salmonella typhi) within the past 14 days of the last
855 exposure;^P or
- 856 d. Hepatitis A virus within the past 30 days of the last exposure.^P

857 B. The person in charge shall notify the ~~regulatory authority~~ department when a food employee
858 is:

- 859 1. Jaundiced;^{Pf} or
- 860 2. Diagnosed with an illness due to a pathogen as specified under subdivisions A 2 a
861 through f of this section.^{Pf}

862 C. The person in charge shall ensure that a conditional employee:

- 863 1. Who exhibits or reports a symptom, or who reports a diagnosed illness as specified
864 under subdivisions A 1, 2, and 3 of this section, is prohibited from becoming a food
865 employee until the conditional employee meets the criteria for the specific symptoms or
866 diagnosed illness as specified under 12VAC5-421-100;^P and
- 867 2. Who will work as a food employee in a food establishment that serves a highly
868 susceptible population and reports a history of exposure as specified under subdivisions
869 A 4 and 5 of this section, is prohibited from becoming a food employee until the conditional
870 employee meets the criteria specified under subdivision 10 of 12VAC5-421-100.^P

871 D. The person in charge shall ensure that a food employee who exhibits or reports a symptom,
872 or who reports a diagnosed illness or history of exposure as specified under subdivisions A 1
873 through 5 of this section is:

- 874 1. Excluded as specified under subdivisions 1, 2, and 3 of 12VAC5-421-90, and
875 subdivisions 4 a, 5 a, 6 a, 7, or 8 a of 12VAC5-421-90 and in compliance with the
876 provisions specified under subdivisions 1 through 8 of 12VAC5-421-100;^P or
- 877 2. Restricted as specified under subdivision 4 b, 5 b, 6 b, or 8 b of 12VAC5-421-90, or
878 subdivision 9 or 10 of 12VAC5-421-90 and in compliance with the provisions specified
879 under subdivisions 4 through 10 of 12VAC5-421-100.^P

880 E. A food employee or conditional employee shall report to the person in charge the
881 information as specified under subsection A of this section.^{Pf}

882 F. A food employee shall:

- 883 1. Comply with an exclusion as specified under subdivisions 1, 2, and 3 of 12VAC5-421-
884 90 and subdivision 4 a, 5 a, 6 a, 7, or 8 a of 12VAC5-421-90 and with the provisions
885 specified under subdivisions 1 through 8 of 12VAC5-421-100;^P or
- 886 2. Comply with a restriction as specified under subdivisions 4 b, 5 b, 6 b, 7, or 8 b of
887 12VAC5-421-90, or subdivision 8, 9, or 10 of 12VAC5-421-90 and comply with the
888 provisions specified under subdivisions 4 through 10 of 12VAC5-421-100.^P

889 **12VAC5-421-90. Exclusions and restrictions.**

890 The person in charge shall exclude or restrict a food employee from a food establishment in
891 accordance with the following:

- 892 1. Except when the symptom is from a noninfectious condition, exclude a food employee
893 if the food employee is:

- 894 a. Symptomatic with vomiting or diarrhea;^P or
- 895 b. Symptomatic with vomiting or diarrhea and diagnosed with an infection from
- 896 Norovirus, Shigella spp., Salmonella (nontyphoidal), or Shiga toxin-producing
- 897 Escherichia coli.^P
- 898 2. Exclude a food employee who is:
- 899 a. Jaundiced and the onset of jaundice occurred within the last seven calendar days,
- 900 unless the food employee provides to the person in charge written medical
- 901 documentation from a health practitioner specifying that the jaundice is not caused by
- 902 Hepatitis A virus or other fecal-orally transmitted infection;^P
- 903 b. Diagnosed with an infection from Hepatitis A virus within 14 calendar days from the
- 904 onset of any illness symptoms, or within seven calendar days of the onset of jaundice;^P
- 905 or
- 906 c. Diagnosed with an infection from Hepatitis A virus without developing symptoms.^P
- 907 3. Exclude a food employee who is diagnosed with ~~typhoid~~ Typhoid fever, or reports having
- 908 had ~~typhoid~~ Typhoid fever within the past three months as specified in 12VAC5-421-80 A
- 909 3.^P
- 910 4. If a food employee is diagnosed with an infection from Norovirus and is asymptomatic:
- 911 a. Exclude the food employee who works in a food establishment serving a highly
- 912 susceptible population;^P or
- 913 b. Restrict the food employee who works in a food establishment not serving a highly
- 914 susceptible population.^P
- 915 5. If a food employee is diagnosed with an infection from Shigella spp. and is
- 916 asymptomatic:
- 917 a. Exclude the food employee who works in a food establishment serving a highly
- 918 susceptible population;^P or
- 919 b. Restrict the food employee who works in a food establishment not serving a highly
- 920 susceptible population.^P
- 921 6. If a food employee is diagnosed with an infection from Shiga toxin-producing
- 922 Escherichia coli, and is asymptomatic:
- 923 a. Exclude the food employee who works in a food establishment serving a highly
- 924 susceptible population;^P or
- 925 b. Restrict the food employee who works in a food establishment not serving a highly
- 926 susceptible population.^P
- 927 7. If a food employee is diagnosed with an infection from Salmonella (nontyphoidal) and
- 928 is asymptomatic, restrict the food employee who works in a food establishment:
- 929 a. Serving a highly susceptible population,^P or
- 930 b. Not serving a highly susceptible population.^P
- 931 8. If a food employee is ill with symptoms of acute onset of sore throat with fever:
- 932 a. Exclude the food employee who works in a food establishment serving a highly
- 933 susceptible population;^P or
- 934 b. Restrict the food employee who works in a food establishment not serving a highly
- 935 susceptible population.^P
- 936 9. If a food employee is infected with a skin lesion containing pus such as a boil or infected
- 937 wound that is open or draining and not properly covered as specified under 12VAC5-421-
- 938 80 A 1 e, restrict the food employee.^P

939 10. If a food employee is exposed to a foodborne pathogen as specified under 12VAC5-
940 421-80 A 4 or 5, restrict the food employee who works in a food establishment serving a
941 highly susceptible population.^P

942 **12VAC5-421-100. Removal, adjustment, or retention of exclusions and restrictions.**

943 The person in charge shall adhere to the following conditions when removing, adjusting, or
944 retaining the exclusion or restriction of a food employee:

945 1. Except when a food employee is diagnosed with ~~typhoid~~Typhoid fever or an infection
946 from Hepatitis A virus:

947 a. Reinstatement a food employee who was excluded as specified under subdivision 1 a of
948 12VAC5-421-90 if the food employee:

949 (1) Is asymptomatic for at least 24 hours;^P or

950 (2) Provides to the person in charge written medical documentation from a health
951 practitioner that states the symptom is from a noninfectious condition.^P

952 b. If a food employee was diagnosed with an infection from Norovirus and excluded
953 as specified under subdivision 1 b of 12VAC5-421-90:

954 (1) Restrict the food employee, who is asymptomatic for at least 24 hours and works
955 in a food establishment not serving a highly susceptible population until the conditions
956 for reinstatement as specified in subdivision 4 a or b of this section are met;^P or

957 (2) Retain the exclusion for the food employee, who is asymptomatic for at least 24
958 hours and works in a food establishment that serves a highly susceptible population,
959 until the conditions for reinstatement as specified in subdivision 4 a or b of this section
960 are met.^P

961 c. If a food employee was diagnosed with an infection from Shigella spp. and excluded
962 as specified under subdivision 1 b of 12VAC5-421-90:

963 (1) Restrict the food employee, who is asymptomatic, for at least 24 hours and works
964 in a food establishment not serving a highly susceptible population, until the conditions
965 for reinstatement as specified in subdivision 5 a or b of this section are met;^P or

966 (2) Retain the exclusion for the food employee, who is asymptomatic for at least 24
967 hours and works in a food establishment that serves a highly susceptible population,
968 until the conditions for reinstatement as specified in subdivision 5 a or b, or 5 a and 1
969 c (1) of this section are met.^P

970 d. If a food employee was diagnosed with an infection from Shiga toxin-producing
971 Escherichia coli and excluded as specified under subdivision 1 b of 12VAC5-421-90:

972 (1) Restrict the food employee, who is asymptomatic for at least 24 hours and works
973 in a food establishment not serving a highly susceptible population, until the conditions
974 for reinstatement as specified in subdivision 6 a or b of this section are met;^P or

975 (2) Retain the exclusion for the food employee, who is asymptomatic for at least 24
976 hours and works in a food establishment that serves a highly susceptible population,
977 until the conditions for reinstatement as specified in subdivision 6 a or b are met.^P

978 e. If a food employee was diagnosed with an infection from Salmonella (nontyphoidal)
979 and excluded as specified under subdivision 1 b of 12VAC5-421-90:

980 (1) Restrict the food employee who is asymptomatic for at least 30 days until conditions
981 for reinstatement as specified under subdivision 7 a or 7 b of this section are met;^P or

982 (2) Retain the exclusion for the food employee who is symptomatic, until conditions for
983 reinstatement as specified under subdivision 7 a or 7 b of this section are met.^E

- 984 2. Reinstatement a food employee who was excluded as specified under subdivision 2 of
985 12VAC5-421-90 if the person in charge obtains approval from the ~~regulatory~~
986 ~~authority~~department and one of the following conditions is met:
- 987 a. The food employee has been jaundiced for more than seven calendar days;^P
 - 988 b. The anicteric food employee has been symptomatic with symptoms other than
989 jaundice for more than 14 calendar days;^P or
 - 990 c. The food employee provides to the person in charge written medical documentation
991 from a health practitioner stating that the food employee is free of a Hepatitis A virus
992 infection.^P
- 993 3. Reinstatement a food employee who was excluded as specified under subdivision 3 of
994 12VAC5-421-90 if:
- 995 a. The person in charge obtains approval from the ~~regulatory authority~~department;^P
996 and
 - 997 b. The food employee provides to the person in charge written medical documentation
998 from a health practitioner that states the employee is free from ~~typhoid~~Typhoid fever.^P
- 999 4. Reinstatement a food employee who was excluded as specified under subdivision 1 b or 4
1000 a of 12VAC5-421-90, who was restricted under subdivision 4 b of 12VAC5-421-90 if the
1001 person in charge obtains approval from the ~~regulatory authority~~department and one of the
1002 following conditions is met:
- 1003 a. The excluded or restricted food employee provides to the person in charge written
1004 medical documentation from a health practitioner stating that the food employee is free
1005 of a Norovirus infection;^P
 - 1006 b. The food employee was excluded or restricted after symptoms of vomiting or
1007 diarrhea resolved, and more than 48 hours have passed since the food employee
1008 became symptomatic;^P or
 - 1009 c. The food employee was excluded or restricted and did not develop symptoms and
1010 more than 48 hours have passed since the food employee was diagnosed.^P
- 1011 5. Reinstatement a food employee who was excluded as specified under subdivision 1 b or 5
1012 a of 12VAC5-421-90 or who was restricted under subdivision 5 b of 12VAC5-421-90 if the
1013 person in charge obtains approval from the ~~regulatory authority~~department and one of the
1014 following conditions is met:
- 1015 a. The excluded or restricted food employee provides to the person in charge written
1016 medical documentation from a health practitioner stating that the food employee is free
1017 of a Shigella spp. infection based on test results showing two consecutive negative
1018 stool specimen cultures that are taken:
 - 1019 (1) Not earlier than 48 hours after discontinuance of antibiotics,^P and
 - 1020 (2) At least 24 hours apart;^P
 - 1021 b. The food employee was excluded or restricted after symptoms of vomiting or
1022 diarrhea resolved, and more than seven calendar days have passed since the food
1023 employee became asymptomatic;^P or
 - 1024 c. The food employee was excluded or restricted and did not develop symptoms and
1025 more than seven calendar days have passed since the food employee was
1026 diagnosed.^P
- 1027 6. Reinstatement a food employee who was excluded or restricted as specified under
1028 subdivision 1 b or 6 a of 12VAC5-421-90 or who was restricted under subdivision 6 b of
1029 12VAC5-421-90 if the person in charge obtains approval from the ~~regulatory~~
1030 ~~authority~~department and one of the following conditions is met:

- 1031 a. The excluded or restricted food employee provides to the person in charge written
1032 medical documentation from a health practitioner stating that the food employee is free
1033 of an infection from Shiga toxin-producing Escherichia coli based on test results that
1034 show two consecutive negative stool specimen cultures that are taken:
- 1035 (1) Not earlier than 48 hours after the discontinuance of antibiotics;^P and
1036 (2) At least 24 hours apart;^P
- 1037 b. The food employee was excluded or restricted after symptoms of vomiting or
1038 diarrhea resolved and more than seven calendar days have passed since the
1039 employee became asymptomatic;^P or
- 1040 c. The food employee was excluded or restricted and did not develop symptoms and
1041 more than seven days have passed since the employee was diagnosed.^P
- 1042 7. Reinstatement of a food employee who was excluded as specified under subsection 1 ~~ab~~ of
1043 12VAC5-421-90 or who was restricted as specified under subsection 7 of 12VAC5-421-
1044 90 if the person in charge obtains approval from the ~~regulatory authority~~ department^P and
1045 one of the following conditions is met:
- 1046 a. The excluded or restricted food employee provides to the person in charge written
1047 medical documentation from a health practitioner stating that the food employee is free
1048 of a Salmonella (nontyphoidal) infection based on test results showing two consecutive
1049 negative stool specimen cultures that are taken:
- 1050 (1) Not earlier than 48 hours after discontinuance of antibiotics;^P and
1051 (2) At least 24 hours apart;^P
- 1052 b. The food employee was restricted after symptoms of vomiting or diarrhea resolved,
1053 and more than 30 days have passed since the food employee became asymptomatic;^P
1054 or
- 1055 c. The food employee was excluded or restricted and did not develop symptoms and
1056 more than 30 days have passed since the food employee was diagnosed.^P
- 1057 8. Reinstatement of a food employee who was excluded or restricted as specified under
1058 subdivision 8 a or b of 12VAC5-421-90 if the food employee provides to the person in
1059 charge written medical documentation from a health practitioner stating that the food
1060 employee meets one of the following conditions:
- 1061 a. Has received antibiotic therapy for Streptococcus pyogenes infection for more than
1062 24 hours;^P
- 1063 b. Has at least one negative throat specimen culture for Streptococcus pyogenes
1064 infection;^P or
- 1065 c. Is otherwise determined by a health practitioner to be free of Streptococcus
1066 pyogenes infection.^P
- 1067 9. Reinstatement of a food employee who was restricted as specified under subdivision 9 of
1068 12VAC5-421-90 if the skin, infected wound, cut, or pustular boil is properly covered with
1069 one of the following:
- 1070 a. An impermeable cover such as a finger cot or stall and a single-use glove over the
1071 impermeable cover if the infected wound or pustular boil is on the hand, finger, or
1072 wrist;^P
- 1073 b. An impermeable cover on the arm if the infected wound or pustular boil is on the
1074 arm;^P or
- 1075 c. A dry, durable, tight-fitting bandage if the infected wound or pustular boil is on
1076 another part of the body.^P

- 1077 10. Reinstatement a food employee who was restricted as specified under subdivision 10 of
1078 12VAC5-421-90 and was exposed to one of the following pathogens as specified under
1079 12VAC5-421-80 A 4 or 5:
- 1080 a. Norovirus and one of the following conditions is met:
- 1081 (1) More than 48 hours have passed since the last day the food employee was
1082 potentially exposed;^P or
- 1083 (2) More than 48 hours have passed since the food employee's household contact
1084 became asymptomatic.^P
- 1085 b. Shigella spp. or Shiga toxin-producing Escherichia coli and one of the following
1086 conditions is met:
- 1087 (1) More than three calendar days have passed since the last day the food employee
1088 was potentially exposed;^P or
- 1089 (2) More than three calendar days have passed since the food employee's household
1090 contact became asymptomatic.^P
- 1091 c. Typhoid fever (caused by Salmonella typhi) and one of the following conditions is
1092 met:
- 1093 (1) More than 14 calendar days have passed since the last day the food employee
1094 was potentially exposed;^P or
- 1095 (2) More than 14 calendar days have passed since the food employee's household
1096 contact became asymptomatic.^P
- 1097 d. Hepatitis A virus and one of the following conditions is met:
- 1098 (1) The food employee is immune to Hepatitis A virus infection because of prior illness
1099 from Hepatitis A;^P
- 1100 (2) The food employee is immune to Hepatitis A virus infection because of vaccination
1101 against Hepatitis A;^P
- 1102 (3) The food employee is immune to Hepatitis A virus infection because of IgG
1103 administration;^P
- 1104 (4) More than 30 calendar days have passed since the last time the food employee
1105 was potentially exposed;^P
- 1106 (5) More than 30 calendar days have passed since the food employee's household
1107 contact became jaundiced;^P or
- 1108 (6) The food employee does not use an alternative procedure that allows bare hand
1109 contact with ready-to-eat food until at least 30 days after the potential exposure, as
1110 specified in subdivisions 10 d (4) and (5) of this section, and the food employee
1111 receives additional training about:
- 1112 (a) Hepatitis A symptoms and preventing the transmission of infection;^P
- 1113 (b) Proper handwashing procedures;^P and
- 1114 (c) Protecting ready-to-eat food from contamination introduced by bare hand contact.^P
- 1115 **12VAC5-421-180. Hand antiseptics.**
- 1116 A. A hand antiseptic used as a topical application, a hand antiseptic solution used as a hand
1117 dip, or a hand antiseptic soap shall:
- 1118 1. Comply with one of the following:
- 1119 a. Be an approved drug that is listed in the FDA publication "Approved Drug Products
1120 with Therapeutic Equivalence Evaluations," ~~34th Edition, 2014,~~ 39th Edition, 2019

1121 (U.S. Food and Drug Administration) as an approved drug based on safety and
1122 effectiveness;^{Pf} or

1123 b. Have active antimicrobial ingredients that are listed in the FDA monograph for OTC
1124 (over the counter) Health-Care Antiseptic Drug Products as an antiseptic handwash;^{Pf}

1125 2. Consist only of components which the intended use of each complies with one of the
1126 following:

1127 a. A threshold of regulation exemption under 21 CFR 170.39;^{Pf}

1128 b. 21 CFR Part 178, as regulated for use as a food additive with conditions of safe
1129 use;^{Pf}

1130 c. A determination of generally recognized as safe (GRAS). Partial listings of
1131 substances with food uses that are GRAS may be found in 21 CFR Part 182, 21 CFR
1132 184, or 21 CFR Part 186 for use in contact with food and in FDA's Inventory of GRAS
1133 Notices;^{Pf}

1134 d. A prior sanction listed under 21 CFR 181;^{Pf} or

1135 e. A ~~Food Contact Notification~~ food contact notification that is effective;^{Pf} and

1136 3. Be applied only to hands that are cleaned as specified under 12VAC5-421-140.^{Pf}

1137 B. If a hand antiseptic or a hand antiseptic solution used as a hand dip does not meet the
1138 criteria specified in subdivision A 2 of this section, use shall be:

1139 1. Followed by thorough hand rinsing in clean water before hand contact with food or by
1140 the use of gloves;^{Pf} or

1141 2. Limited to situations that involve no direct contact with food by the bare hands.^{Pf}

1142 C. A hand antiseptic solution used as a hand dip shall be maintained clean and at a strength
1143 equivalent to at least 100 ppm (mg/l) chlorine ~~or above~~.^{Pf}

1144 **12VAC5-421-190. Maintenance of fingernails.**

1145 A. Food employees shall keep their fingernails trimmed, filed, and maintained so the edges
1146 and surfaces are cleanable and not rough.^{Pf}

1147 B. Unless wearing intact gloves in good repair, a food employee shall not wear fingernail
1148 polish or artificial nails when working with exposed food.^{Pf}

1149 **12VAC5-421-235. Use of Bandages, Finger Cots, or Finger Stalls.**

1150 If used, an impermeable cover such as a bandage, finger cot, or finger stall located on the
1151 wrist, hand or finger of the food employee working with exposed food shall be covered with a
1152 single-use glove.

1153 **12VAC5-421-255. Clean-up of vomiting and diarrheal events.**

1154 A food establishment shall have written procedures for employees to follow when responding
1155 to vomiting or diarrheal events that involve the discharge of vomitus or fecal matter onto surfaces
1156 in the food establishment. The procedures shall address the specific actions employees must take
1157 to minimize the spread of contamination and the exposure of employees, consumers, food, and
1158 surfaces to vomitus or fecal matter.^{Pf}

1159 Part III

1160 Food

1161 Article 1

1162 Characteristics

1163 **12VAC5-421-260. ~~Safe and unadulterated.~~ Safe, Unadulterated, and Honestly Presented**

1164 Food shall be safe, and unadulterated, and, as specified in 12VAC5-421-890, honestly
1165 presented.^{PfP}

Article 2

Sources, Specifications, and Original Containers and Records

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12VAC5-421-270. Compliance with food law.

A. Food shall be obtained from sources that comply with law.^P

B. Food prepared in a private home shall not be used or offered for human consumption in a food establishment unless the home kitchen is inspected and regulated by the Virginia Department of Agriculture and Consumer Services.^P

C. Packaged food shall be labeled as specified in law, including 21 CFR Part 101, 9 CFR Part 317, and Subpart N of 9 CFR Part 381, and as specified under 12VAC5-421-400 and 12VAC5-421-410.^{Pf}

D. Fish, other than those specified in 12VAC5-421-730 B, that are intended for consumption in raw or undercooked form and allowed as specified in 12VAC5-421-700 D, may be offered for sale or service if they are obtained from a supplier that freezes fish as specified under 12VAC5-421-730 A; or if they are frozen on premises as specified under 12VAC5-421-730 A and records are retained as specified under 12VAC5-421-740.

E. Whole-muscle, intact beef steaks that are intended for consumption in an undercooked form without a consumer advisory as specified in 12VAC5-421-700 C shall be:

1. Obtained from a food processing plant that, upon request by the purchaser, packages the steaks and labels them to indicate that they meet the definition of whole-muscle, intact beef;^{Pf} or

2. Deemed acceptable by the ~~regulatory authority~~department based on other evidence, such as written buyer specifications or invoices, that indicates that the steaks meet the definition of whole-muscle, intact beef;^{Pf} and

3. If individually cut in a food establishment:

a. Cut from whole-muscle intact beef that is labeled by a food processing plant as specified in subdivision 1 of this subsection or identified as specified in subdivision 2 of this subsection;^{PfP}

b. Prepared so they remain intact;^{Pf} and

c. If packaged for undercooking in a food establishment, labeled as specified in subdivision 1 of this subsection or identified as specified in subdivision 2 of this subsection.^{Pf}

F. Meat and poultry that ~~are~~is not a ready-to-eat food and ~~are~~is in a packaged form when offered for sale or otherwise offered for consumption shall be labeled to include safe handling instructions as specified in law, including 9 CFR 317.2(l) and 9 CFR 381.125(b).

G. ~~Shell eggs~~Eggs that have not been specifically treated to destroy all viable Salmonellae shall be labeled to include safe handling instructions as specified in law, including 21 CFR 101.17(h).

12VAC5-421-295. Juice treated.

Prepackaged juice shall:

1. Be obtained from a processor with a HACCP system as specified in 21 CFR Part 120;^{Pf} and

2. Be obtained pasteurized or otherwise treated to attain a five-log reduction of the most resistant microorganism of public health significance as specified in 21 CFR 120.24.^P

12VAC5-421-300. Fish.

A. Fish that are received for sale or service shall be:

1. Commercially and legally caught or harvested;^P or

1212 2. Approved for sale or service ~~by a regulatory agency of competent jurisdiction.~~^P

1213 B. Molluscan shellfish that are recreationally caught shall not be received for sale or service.^P

1214 **12VAC5-421-310. Molluscan shellfish.**

1215 A. Molluscan shellfish shall be obtained from sources according to law and the requirements

1216 specified in the U.S. Department of Health and Human Services, Public Health Service, Food and

1217 Drug Administration, National Shellfish Sanitation Program (NSSP) Guide for the Control of

1218 Molluscan Shellfish, ~~2013~~2017 Revision, (U.S. Food and Drug Administration).^P

1219 B. Molluscan shellfish shall be from sources that are listed in the "Interstate Certified Shellfish

1220 Shippers List," ~~updated monthly~~ (U.S. Food and Drug Administration).^P

1221 **12VAC5-421-340. Temperature.**

1222 A. Except as specified in subsection B of this section, refrigerated, time/temperature control

1223 for safety food shall be at a temperature of 41°F (5°C) or below when received.^P

1224 B. If a temperature other than 41°F (5°C) for a time/temperature control for safety food is

1225 specified in law governing its distribution, such as laws governing milk and molluscan shellfish,

1226 the food may be received at the specified temperature.

1227 C. Raw shell-eggs shall be received in refrigerated equipment that maintains an ambient air

1228 temperature of 45°F (7°C) or less.^P

1229 D. ~~Time/temperature control for safety food that is cooked to a temperature and for a time~~

1230 ~~specified under 12VAC5-421-700, 12VAC5-421-710, and 12VAC5-421-720 and received hot~~

1231 ~~shall be at a temperature of 135° (57°C) or above.~~^P

1232 E. A food that is labeled frozen and shipped frozen by a food processing plant shall be

1233 received frozen.^{Pf}

1234 F. Upon receipt, time/temperature control for safety food shall be free of evidence of previous

1235 temperature abuse.^{Pf}

1236 **12VAC5-421-350. Additives.**

1237 Food shall not contain unapproved food additives or additives that exceed amounts ~~allowed~~

1238 specified in 21 CFR Parts 170-180 relating to food additives; generally recognized as safe

1239 (GRAS) or prior sanctioned substances that exceed amounts allowed in 21 CFR Parts 181-186;

1240 substances that exceed amounts specified in 9 CFR 424.21(b), Subpart C; or pesticide residues

1241 that exceed provisions specified in 40 CFR Part ~~485~~180 and exceptions.^P

1242 **12VAC5-421-400. Shucked shellfish, packaging, and identification.**

1243 A. Raw shucked shellfish shall be obtained in nonreturnable packages that bear a legible label

1244 that identifies the:^{Pf}

1245 1. Name, address, and certification number of the ~~shucker, packer, shucker-packer, or~~

1246 ~~repacker of the molluscan shellfish;~~^{Pf} and

1247 2. The "sell by" or "best if used by" date for packages with a capacity of less than ~~one-half~~

1248 ~~gallon (1.89 L),~~ 64 fluid ounces (1.89L) or the date shucked for packages with a capacity

1249 ~~of one-half gallon (1.89 L),~~ 64 fluid ounces (1.89L) or more.^{Pf}

1250 B. A package of raw shucked shellfish that does not bear a label or that bears a label which

1251 does not contain all the information as specified under subsection A of this section shall be subject

1252 to a hold order, as allowed by law, or seizure and destruction in accordance with 21 CFR

1253 1240.60(d), Subpart D.

1254 **12VAC5-421-410. Shellstock identification.**

1255 A. Shellstock shall be obtained in containers bearing legible source identification tags or labels

1256 that are affixed by a dealer that depurates, ships, or reships the shellstock, as specified in the

1257 National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish,

1258 20132017 Revision, (U.S. Food and Drug Administration), and that include the following
1259 information:^{Pf}

- 1260 1. The dealer's name and address, and the certification number assigned by the shellfish
1261 control authority.^{Pf}
- 1262 2. The original shipper's certification number assigned by the shellfish control authority.^{Pf}
- 1263 3. The harvest date, or if depurated, the date of depuration processing, or if wet stored,
1264 the original harvest date and the final harvest date.^{Pf}
- 1265 4. If wet stored or depurated, the wet storage or depuration cycle or lot number. The wet
1266 storage lot number shall begin with the letter "w."^{Pf}
- 1267 5. The harvest area, including the initials of the state or, as applicable, country of
1268 harvest.^{Pf}
- 1269 6. The type and quantity of shellstock.^{Pf}
- 1270 7. The following statement in bold, capitalized type: "~~THIS TAG IS REQUIRED TO BE~~
1271 ~~ATTACHED UNTIL CONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE FOR~~
1272 ~~90 DAYS.~~"^{Pf} "THIS TAG (OR LABEL) IS REQUIRED TO BE ATTACHED UNTIL
1273 CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE, IN
1274 CHRONOLOGICAL ORDER, FOR 90 DAYS." "RETAILERS: DATE WHEN LAST
1275 SHELLFISH FROM THIS CONTAINER SOLD OR SERVED (INSERT DATE)"^{Pf}; and
- 1276 8. All shellstock intended for raw consumption shall include a consumer advisory using
1277 the statement from 12VAC5-421-930 C, or an equivalent statement.

1278 B. A container of shellstock that does not bear a tag or label or that bears a tag or label that
1279 does not contain all the information as specified under subsection A of this section shall be subject
1280 to a hold order, as allowed by law, or seizure and destruction in accordance with 21 CFR
1281 1240.60(d), Subpart D.

1282 **12VAC5-421-440. Shellstock; maintaining identification.**

1283 A. Except as specified under subdivision C 2 of this section, shellstock tags or labels shall
1284 remain attached to the container in which the shellstock are received until the container is empty.^{Pf}

1285 B. The date when the last shellstock from the container is sold or served shall be recorded on
1286 the tag or label.^{Pf}

1287 C. The identity of the source of shellstock that are sold or served shall be maintained by
1288 retaining shellstock tags or labels for 90 calendar days from the date that is recorded on the tag
1289 or label as specified in subsection B of this section, by:^{Pf}

1290 1. Using an approved recordkeeping system that keeps the tags or labels in chronological
1291 order correlated to the date that is recorded on the tag or label, as specified under
1292 subsection B of this section;^{Pf} and

1293 2. If shellstock are removed from its tagged or labeled container:

1294 a. Preserving source identification by using a recordkeeping system as specified under
1295 subdivision C 1 of this section,^{Pf} and

1296 b. Ensuring that shellstock or shucked shellfish from one tagged or labeled container
1297 are not commingled with shellstock or shucked shellfish from another container with
1298 different certification numbers, different harvest dates, or different growing areas as
1299 identified on the tag or label before being ordered by the consumer.^{Pf}

1300 Article 3

1301 Protection from Contamination after Receiving

1302 **12VAC5-421-450. Preventing contamination from hands.**

1303 A. Food employees shall wash their hands as specified under 12VAC5-421-140.

1304 B. Except when washing fruits and vegetables as specified under 12VAC5-421-510 or as
1305 specified in subsections D and E of this section, food employees shall not contact exposed, ready-
1306 to-eat food with their bare hands and shall use suitable utensils such as deli tissue, spatulas,
1307 tongs, single-use gloves, or dispensing equipment.^P

1308 C. Food employees shall minimize bare hand and arm contact with exposed food that is not
1309 in a ready-to-eat form.^{Pf}

1310 D. Subsection B of this section does not apply to a food employee who contacts exposed,
1311 ready-to-eat food with bare hands at the time the ready-to-eat food is being added as an ingredient
1312 to food that:

1313 1. Contains a raw animal food and is to be cooked in the food establishment to heat all
1314 parts of the food to the minimum temperatures specified in subsection A or B of 12VAC5-
1315 421-700 or in 12VAC5-421-710; or

1316 2. Does not contain a raw animal food but is to be cooked in the food establishment to
1317 heat all parts of the food to a temperature of at least 145°F (63°C).

1318 E. Food employees not serving a highly susceptible population may contact exposed, ready-
1319 to-eat food with their bare hands if:

1320 1. The permit holder obtains prior approval from the ~~regulatory authority~~ department;

1321 2. Written procedures are maintained in the food establishment and made available to the
1322 ~~regulatory authority~~ department upon request that include:

1323 a. For each bare hand contact procedure, a listing of the specific ready-to-eat foods
1324 that are touched by bare hands;

1325 b. Diagrams and other information showing that handwashing facilities, installed,
1326 located, equipped, and maintained as specified under 12VAC5-421-2230, 12VAC5-
1327 421-2280, 12VAC5-421-2310, 12VAC5-421-3020, 12VAC5-421-3030, and 12VAC5-
1328 421-3045 are in an easily accessible location and in close proximity to the work station
1329 where the bare hand contact procedure is conducted;

1330 3. A written employee health policy that details how the food establishment complies with
1331 12VAC5-421-80, 12VAC5-421-90, and 12VAC5-421-100 including:

1332 a. Documentation that the food employees and conditional employees acknowledge
1333 that they are informed to report information about their health and activities as they
1334 relate to gastrointestinal symptoms and diseases that are transmittable through food
1335 as specified under 12VAC5-421-80 A;

1336 b. Documentation that food employees and conditional employees acknowledge their
1337 responsibilities as specified under 12VAC5-421-80 E and F; and

1338 c. Documentation that the person in charge acknowledges the responsibilities as
1339 specified under 12VAC5-421-80 B, C, and D, and 12VAC5-421-90 and 12VAC5-421-
1340 100;

1341 4. Documentation that the food employees acknowledge that they have received training
1342 in:

1343 a. The risks of contacting the specific ready-to-eat foods with their bare hands;

1344 b. Proper handwashing as specified under 12VAC5-421-140;

1345 c. When to wash their hands as specified under 12VAC5-421-160;

1346 d. Where to wash their hands as specified under 12VAC5-421-170;

1347 e. Proper fingernail maintenance as specified under 12VAC5-421-190;

1348 f. Prohibition of jewelry as specified under 12VAC5-421-200; and

- 1349 g. Good hygienic practices as specified under 12VAC5-421-220 and 12VAC5-421-
1350 230;
- 1351 5. Documentation that hands are washed before food preparation and as necessary to
1352 prevent cross-contamination by food employees as specified under 12VAC5-421-130
1353 through 12VAC5-421-170 during all hours of operation when the specific ready-to-eat
1354 foods are prepared;
- 1355 6. Documentation that food employees contacting ready-to-eat food with bare hands use
1356 two or more of the following control measures to provide additional safeguards to hazards
1357 associated with bare hand contact:
- 1358 a. Double handwashing;
- 1359 b. Nail brushes;
- 1360 c. A hand antiseptic after handwashing as specified under 12VAC5-421-180;
- 1361 d. Incentive programs such as paid sick leave that assist or encourage food employees
1362 not to work when they are ill; or
- 1363 e. Other control measures approved by the ~~regulatory authority~~department; and
- 1364 7. Documentation that corrective action is taken when subdivisions 1 through 6 of this
1365 subsection are not followed.
- 1366 **12VAC5-421-470. Packaged and unpackaged food - separation, packaging, and**
1367 **segregation.**
- 1368 A. Food shall be protected from cross contamination by:
- 1369 1. Except as specified in subdivision 1 ed of this subsection, separating raw animal foods
1370 during storage, preparation, holding, and display from:
- 1371 a. Raw ready-to-eat food including other raw animal food such as fish for sushi or
1372 molluscan shellfish, or other raw ready-to-eat food such as fruits and vegetables;^P and
1373 b. Cooked ready-to-eat food;^P
- 1374 c. Fruits and vegetables before they are washed;^P and
- 1375 ~~e.d.~~ Frozen, commercially processed, and packaged raw animal food may be stored
1376 or displayed with or above frozen, commercially processed and packaged, ready-to-
1377 eat food;
- 1378 2. Except when combined as ingredients, separating types of raw animal foods from each
1379 other such as beef, fish, lamb, pork, and poultry during storage, preparation, holding, and
1380 display by:
- 1381 a. Using separate equipment for each type;^P or
- 1382 b. Arranging each type of food in equipment so that cross contamination of one type
1383 with another is prevented;^P and
- 1384 c. Preparing each type of food at different times or in separate areas;^P
- 1385 3. Cleaning equipment and utensils as specified under 12VAC5-421-1780 A and sanitizing
1386 as specified under 12VAC5-421-1900;
- 1387 4. Except as specified in subsection B of this section and 12VAC5-421-810 B 2, storing
1388 the food in packages, covered containers, or wrappings;
- 1389 5. Cleaning hermetically sealed containers of food of visible soil before opening;
- 1390 6. Protecting food containers that are received packaged together in a case or overwrap
1391 from cuts when the case or overwrap is opened;
- 1392 7. Storing damaged, spoiled, or recalled food being held in the food establishment as
1393 specified under 12VAC5-421-3150; and

1394 8. Separating fruits and vegetables, before they are washed as specified under 12VAC5-
1395 421-510 from ready-to-eat food.

1396 B. Subdivision A 4 of this section does not apply to:

1397 1. Whole, uncut, raw fruits and vegetables and nuts in the shell that require peeling or
1398 hulling before consumption;

1399 2. Primal cuts, quarters, or sides of raw meat or slab bacon that are hung on clean,
1400 sanitized hooks or placed on clean, sanitized racks;

1401 3. Whole, uncut, processed meats such as country hams, and smoked or cured sausages
1402 that are placed on clean, sanitized racks;

1403 4. Food being cooled as specified under 12VAC5-421-810 B 2; or

1404 5. Shellstock.

1405 **12VAC5-421-540. Food contact with equipment and utensils.**

1406 Food shall only contact surfaces of:

1407 1. Equipment and utensils that are cleaned as specified under 12VAC5-421-1770 through
1408 ~~12VAC5-421-1870~~12VAC5-421-1860 and sanitized as specified under 12VAC5-421-
1409 1885, 12VAC5-421-1890 and 12VAC5-421-1900;^P

1410 2. Single-service and single-use articles;^P or

1411 3. Linens, such as cloth napkins, as specified under 12VAC5-421-560 that are laundered
1412 as specified under 12VAC5-421-1920 C.^P

1413 **12VAC5-421-660. Condiments; protection.**

1414 A. Condiments shall be protected from contamination by being kept in dispensers that are
1415 designed to provide protection, protected food displays provided with the proper utensils, original
1416 containers designed for dispensing, or individual packages or portions.

1417 B. Condiments at a vending machine location shall be in individual packages or provided in
1418 dispensers that are filled at a location that is approved by the ~~regulatory authority~~department,
1419 such as the food establishment that provides food to the vending machine location, a food
1420 processing plant that is regulated by the agency that has jurisdiction over the operation, or a
1421 properly equipped facility that is located on the site of the vending machine location.

1422 Article 4

1423 Destruction of Organisms of Public Health Concern

1424 **12VAC5-421-700. Raw animal foods.**

1425 A. Except as specified in subsections B, C, and D of this section, raw animal foods such as
1426 eggs, fish, meat, poultry, and foods containing these raw animal foods shall be cooked to heat all
1427 parts of the food to a temperature and for a time that complies with one of the following methods
1428 based on the food that is being cooked:

1429 1. 145°F (63°C) or above for 15 seconds for:^P

1430 a. Raw eggs that are broken and prepared in response to a consumer's order and for
1431 immediate service;^P and

1432 b. Except as specified under subdivisions A 2 and 3 and subsections B and C of this
1433 section, fish and intact meat, including game animals commercially raised for food and
1434 game animals under a voluntary inspection program as specified under 12VAC5-421-
1435 330 A 1;^P

1436 2. 155°F (68°C) for ~~15~~17 seconds or the temperature specified in the following chart that
1437 corresponds to the holding time for ratites ~~and~~, mechanically tenderized meats, and
1438 injected meats; the following if they are comminuted: fish, meat, game animals
1439 commercially raised for food and game animals under a voluntary inspection program as

1440 specified under 12VAC5-421-330 A 1; and raw eggs that are not prepared as specified
 1441 under subdivision 1 a of this subsection:^P

Minimum	
Temperature °F (°C)	Time
145 (63)	3 minutes
150 (66)	1 minute
158 (70)	<1 second (instantaneous)

1442 ; or

1443 3. 165°F (74°C) or above for ~~15 seconds~~ less than 1 second (instantaneous) for poultry,
 1444 baluts, wild game animals as specified under 12VAC5-421-330 A 2, stuffed fish, stuffed
 1445 meat, stuffed pasta, stuffed poultry, stuffed ratites, or stuffing containing fish, meat,
 1446 poultry, or ratites.^P

1447 B. Whole meat roasts including beef, corned beef, lamb, pork, and cured pork roasts such as
 1448 ham shall be cooked:

1449 2.1. As specified in the following chart, to heat all parts of the food to a temperature and
 1450 for the holding time that corresponds to that temperature:^P

<u>Temperature</u> <u>°F (°C)</u>	<u>Time¹ in</u> <u>Minutes</u>	<u>Temperature</u> <u>°F (°C)</u>	<u>Time¹ in</u> <u>Seconds</u>
<u>130 (54.4)</u>	<u>112</u>	<u>147 (63.9)</u>	<u>134</u>
<u>131 (55.0)</u>	<u>89</u>	<u>149 (65.0)</u>	<u>85</u>
<u>133 (56.1)</u>	<u>56</u>	<u>151 (66.1)</u>	<u>54</u>
<u>135 (57.2)</u>	<u>36</u>	<u>153 (67.2)</u>	<u>34</u>
<u>136 (57.8)</u>	<u>28</u>	<u>155 (68.3)</u>	<u>22</u>
<u>138 (58.9)</u>	<u>18</u>	<u>157 (69.4)</u>	<u>14</u>
<u>140 (60.0)</u>	<u>12</u>	<u>158 (70.0)</u>	<u>0</u>
<u>142 (61.1)</u>	<u>8</u>	-	-
<u>144 (62.2)</u>	<u>5</u>	-	-
<u>145 (62.8)</u>	<u>4</u>	-	-
¹ Holding time may include postoven heat rise.			

1451 ; and

1452 1. ~~In an oven that is preheated to the temperature specified for the roast's weight in the~~
 1453 ~~following chart and that is held at that temperature;~~^{Pf} and

1454 2. If cooked in an oven, use an oven that is preheated to the temperature specified for
 1455 the roast's weight in the following chart and that is held at that temperature:^{Pf}

Oven Type	Oven Temperature Based on Roast Weight	
	Less than 10 lbs (4.5 kg)	10 lbs (4.5 kg) or more

Still Dry	350°F (177°C) or more	250°F (121°C) or more
Convection	325°F (163°C) or more	250°F (121°C) or more
High Humidity ¹	250°F (121°C) or less	250°F (121°C) or less
¹ Relative humidity greater than 90% for at least one hour as measured in the cooking chamber or exit of the oven; or in a moisture-impermeable bag that provides 100% humidity.		

1456 2. As specified in the following chart, to heat all parts of the food to a temperature and for
1457 the holding time that corresponds to that temperature.^P

Temperature °F (°C)	Time ¹ in Minutes	Temperature °F (°C)	Time ¹ in Seconds
130 (54.4)	112	147 (63.9)	134
131 (55.0)	89	149 (65.0)	85
133 (56.1)	56	151 (66.1)	54
135 (57.2)	36	153 (67.2)	34
136 (57.8)	28	155 (68.3)	22
138 (58.9)	18	157 (69.4)	14
140 (60.0)	12	158 (70.0)	0
142 (61.1)	8	-	-
144 (62.2)	5	-	-
145 (62.8)	4	-	-
¹ Holding time may include postoven heat rise.			

1458 C. A raw or undercooked whole-muscle, intact beef steak may be served or offered for sale
1459 in a ready-to-eat form if:

- 1460 1. The food establishment serves a population that is not a highly susceptible population;
- 1461 2. The steak is labeled, as specified under 12VAC5-421-270 E, to indicate that it meets
- 1462 the definition of "whole-muscle, intact beef"; and
- 1463 3. The steak is cooked on both the top and bottom to a surface temperature of 145°F
- 1464 (63°C) or above and a cooked color change is achieved on all external surfaces.

1465 D. A raw animal food such as raw egg, raw fish, raw-marinated fish, raw molluscan shellfish,
1466 or steak tartare, or a partially cooked food such as lightly cooked fish, soft cooked eggs, or rare
1467 meat other than whole-muscle, intact beef steaks as specified in subsection C of this section, may
1468 be served or offered for sale upon request or consumer selection in a ready-to-eat form if:

- 1469 1. As specified under subdivisions 3 a and b of 12VAC5-421-950 the food establishment
- 1470 serves a population that is not a highly susceptible population;
- 1471 2. The food, if served or offered for service by consumer selection from a children's menu,
- 1472 does not contain comminuted meat;^{Pf} and
- 1473 3. The consumer is informed as specified under 12VAC5-421-930 that to ensure its safety,
- 1474 the food should be cooked as specified under subsection A or B of this section; or

- 1475 4. The ~~regulatory authority~~department grants a variance from subsection A or B of this
1476 section as specified in 12VAC5-421-3570 based on a HACCP plan that:
- 1477 a. Is submitted by the permit holder and approved as specified under 12VAC5-421-
1478 3570;
- 1479 b. Documents scientific data or other information that shows that a lesser time and
1480 temperature regimen results in a safe food; and
- 1481 c. Verifies that equipment and procedures for food preparation and training of food
1482 employees at the food establishment meet the conditions of the variance.

1483 **12VAC5-421-720. Plant food cooking for hot holding.**

1484 ~~Fruits and vegetables~~Plant foods that are cooked for hot holding shall be cooked to a
1485 temperature of 135°F (57°C).^{Pf}

1486 **12VAC5-421-725. Noncontinuous cooking.**

1487 Raw animal foods that are cooked using a noncontinuous cooking process shall be:

- 1488 1. Subject to an initial heating process that is no longer than 60 minutes in duration;^P
- 1489 2. Immediately after initial heating, cooled according to the time and temperature
1490 requirements specified for cooked time/temperature control for safety food under 12VAC5-
1491 421-800 A;^P
- 1492 3. After cooling, held frozen or cold, as specified for time/temperature control for safety
1493 food under 12VAC5-421-820 A 2;^P
- 1494 4. Prior to sale or service, cooked using a process that heats all parts of the food to a
1495 temperature and for a time as designated in 12VAC5-421-700 A, B, and C;^P
- 1496 5. Cooled according to the time and temperature parameters specified for cooked
1497 time/temperature control for safety food under 12VAC5-421-800 A if not either hot held as
1498 specified under 12VAC5-421-820 A 1, served immediately, or held using time as a public
1499 health control as specified under 12VAC5-421-850 after complete cooling;^P and
- 1500 6. Prepared and stored according to written procedures that:
- 1501 a. Have obtained prior approval from the ~~regulatory authority~~department;^{Pf}
- 1502 b. Are maintained in the food establishment and are made available to the ~~regulatory~~
1503 ~~authority~~department upon request;^{Pf}
- 1504 c. Describe how the requirements specified under subdivisions 1 through 5 of this
1505 section are to be monitored and documented by the permit holder and the corrective
1506 actions to be taken if the requirements are not met;^{Pf}
- 1507 d. Describe how the foods, after initial heating, but prior to complete cooking, are to
1508 be marked or otherwise identified as foods that must be cooked as specified under
1509 subdivision 4 of this section prior to being offered for sale or service;^{Pf} and
- 1510 e. Describe how the foods, after initial heating but prior to cooking as specified in
1511 subdivision 4 of this section, are to be separated from ready-to-eat foods as specified
1512 under 12VAC5-421-470 A.^{Pf}

1513 **12VAC5-421-730. Parasite destruction.**

1514 A. Except as specified in subsection B of this section, before service or sale in ready-to-eat
1515 form, raw, raw-marinated, partially cooked or marinated-partially cooked fish shall be:

- 1516 1. Frozen and stored at a temperature of -4°F (-20°C) or below for a minimum of 168 hours
1517 (seven days) in a freezer;^P
- 1518 2. Frozen at -31°F (-35°C) or below until solid and stored at -31°F (-35°C) or below for a
1519 minimum of 15 hours;^P or

- 1520 3. Frozen at -31°F (-35°C) or below until solid and stored at -4°F (-20°C) or below for a
1521 minimum of 24 hours.^P
- 1522 B. Subsection A of this section does not apply to:
- 1523 1. Molluscan shellfish, ~~including the shucked adductor muscle of scallops;~~
1524 2. A scallop product consisting only of the shucked adductor muscle;
- 1525 ~~2-3.~~ Tuna of the species *Thunnus alalunga*, *Thunnus albacares* (Yellowfin tuna), *Thunnus*
1526 *atlanticus*, *Thunnus maccoyii* (Bluefin tuna, Southern), *Thunnus obesus* (Bigeye tuna), or
1527 *Thunnus thynnus* (Bluefin tuna, Northern);
- 1528 ~~3-4.~~ Aquacultured fish, such as salmon, that:
- 1529 a. If raised in open water, are raised in net-pens; or
1530 b. Are raised in land-based operations such as ponds or tanks; and
1531 c. Are fed formulated feed, such as pellets, that contains no live parasites infective to
1532 the aquacultured fish, or
- 1533 ~~4-5.~~ Fish eggs that have been removed from the skein and rinsed.
- 1534 **12VAC5-421-740. Records, creation and retention.**
- 1535 A. Except as specified in 12VAC5-421-730 B and subsection B of this section, if raw,
1536 ~~marinated~~, raw-marinated, partially cooked, or marinated-partially cooked fish are served or sold
1537 in ready-to-eat form, the person in charge shall record the freezing temperature and time to which
1538 the fish are subjected and shall retain the records at the food establishment for 90 calendar days
1539 beyond the time of service or sale of the fish.^{Pf}
- 1540 B. If the fish are frozen by a supplier, a written agreement or statement from the supplier
1541 stipulating that the fish supplied are frozen to a temperature and for a time specified under
1542 12VAC5-421-730 may substitute for the records specified under subsection A of this section.
- 1543 C. If raw, raw-marinated, partially cooked, or marinated-partially cooked fish are served or
1544 sold in ready-to-eat form, and the fish are raised and fed as specified in 12VAC5-421-730 B ~~34~~,
1545 a written agreement or statement from the supplier or aquaculturist stipulating that the fish were
1546 raised and fed as specified in 12VAC5-421-730 B ~~34~~ shall be obtained by the person in charge
1547 and retained in the records of the food establishment for 90 calendar days beyond the time of
1548 service or sale of the fish.^{Pf}
- 1549 **12VAC5-421-760. Reheating for hot holding.**
- 1550 A. Except as specified under subsections B, C, and E of this section, time/temperature control
1551 for safety food that is cooked, cooled, and reheated for hot holding shall be reheated so that all
1552 parts of the food reach at least 165°F (74°C) for 15 seconds.^P
- 1553 B. Except as specified under subsection C of this section, time/temperature control for safety
1554 food reheated in a microwave oven for hot holding shall be reheated so that all parts of the food
1555 reach a temperature of at least 165°F (74°C) and the food is rotated or stirred, covered, and
1556 allowed to stand covered two minutes after reheating.^P
- 1557 C. Ready-to-eat time/temperature control for safety food that has been commercially
1558 processed and packaged in a food processing plant that is inspected by the ~~regulatory~~
1559 ~~authority~~department that has jurisdiction over the plant shall be heated to a temperature of at least
1560 135°F (57°C) when being reheated for hot holding.^P
- 1561 D. Reheating for hot holding as specified under subsections A, B, and C of this section shall
1562 be done rapidly and the time the food is between 41°F (5°C) and the temperatures specified under
1563 subsections A, B, and C of this section may not exceed two hours.^P

1564 E. Remaining unsliced portions of meat roasts that are cooked as specified under 12VAC5-
1565 421-700 B may be reheated for hot holding using the oven parameters and minimum time and
1566 temperature conditions specified under 12VAC5-421-700 B.

1567 **12VAC5-421-830. Ready-to-eat, time/temperature control for safety food; date marking.**

1568 A. Except when packaging food using a reduced oxygen packaging method as specified under
1569 12VAC5-421-870, and except as specified in subsections ~~D~~ and ~~EE~~ and F of this section,
1570 refrigerated ready-to-eat time/temperature control for safety food prepared and held in a food
1571 establishment for more than 24 hours shall be clearly marked to indicate the date or day by which
1572 the food shall be consumed on the premises, sold, or discarded when held at a temperature of
1573 41°F (5°C) or less for a maximum of seven days. The day of preparation shall be counted as day
1574 1.^{Pf}

1575 B. Except as specified in subsections ~~D~~, ~~E~~, and ~~FE~~ through G of this section, refrigerated
1576 ready-to-eat, time/temperature control for safety food prepared and packaged by a food
1577 processing plant shall be clearly marked at the time the original container is opened in a food
1578 establishment and if the food is held for more than 24 hours, to indicate the date or day by which
1579 the food shall be consumed on the premises, sold, or discarded, based on the temperature and
1580 time combinations specified in subsection A of this section and:^{Pf}

1581 1. The day the original container is opened in the food establishment shall be counted as
1582 day 1;^{Pf} and

1583 2. The day or date marked by the food establishment shall not exceed a manufacturer's
1584 "use by" date if the manufacturer determined the "use by" date based on food safety.^{Pf}

1585 C. A refrigerated, ready-to-eat, time/temperature control for safety food ingredient or a portion
1586 of a refrigerated, ready-to-eat, time/temperature control for safety food that is subsequently
1587 combined with additional ingredients or portions of food shall retain the date marking of the
1588 earliest-prepared or first-prepared ingredient.^{Pf}

1589 D. A date marking system that meets the criteria specified in subsections A and B of this
1590 section may include:

1591 1. Using a method approved by the ~~regulatory authority~~ department for refrigerated, ready-
1592 to-eat time/temperature control for safety food that is frequently rewrapped, such as
1593 lunchmeat or a roast, or for which date marking is impractical, such as soft-serve mix or
1594 milk in a dispensing machine;

1595 2. Marking the date or day of preparation, with a procedure to discard the food on or before
1596 the last date or day by which the food must be consumed on the premises, sold, or
1597 discarded as specified in subsection A of this section;

1598 3. Marking the date or day the original container is opened in a food establishment, with a
1599 procedure to discard the food on or before the last date or day by which the food must be
1600 consumed on the premises, sold, or discarded as specified under subsection B of this
1601 section; or

1602 4. Using calendar dates, days of the week, color-coded marks, or other effective marking
1603 methods, provided that the marking system is disclosed to the ~~regulatory~~
1604 ~~authority~~ department upon request.

1605 E. Subsections A and B of this section do not apply to individual meal portions served or
1606 repackaged for sale from a bulk container upon a consumer's request.

1607 F. Subsections A and B of this section do not apply to shellstock.

1608 G. Subsection B of this section does not apply to the following foods prepared and packaged
1609 by a food processing plant inspected by a regulatory authority:

- 1610 1. Deli salads, such as ham salad, seafood salad, chicken salad, egg salad, pasta salad,
 1611 potato salad, and macaroni salad, manufactured in accordance with 21 CFR Part 110;
 1612 2. Hard cheeses containing not more than 39% moisture as defined in 21 CFR Part 133,
 1613 such as cheddar, gruyere, parmesan and reggiano, and romano;
 1614 3. Semi-soft cheese containing more than 39% moisture, but not more than 50% moisture,
 1615 as defined in 21 CFR Part 133, such as blue, edam, gorgonzola, gouda, and monterey
 1616 jack;
 1617 4. Cultured dairy products as defined in 21 CFR Part 131, such as yogurt, sour cream,
 1618 and buttermilk;
 1619 5. Preserved fish products, such as pickled herring and dried or salted cod, and other
 1620 acidified fish products as defined in 21 CFR Part 114;
 1621 6. Shelf stable, dry fermented sausages, such as pepperoni and Genoa salami; and
 1622 7. Shelf stable salt-cured products such as prosciutto and Parma (ham).

1623 **12VAC5-421-850. Time as a public health control.**

1624 A. Except as specified under subsection D of this section, if time without temperature control
 1625 is used as the public health control for a working supply of time/temperature control for safety
 1626 food before cooking or for ready-to-eat time/temperature control for safety food that is displayed
 1627 or held for sale or service, written procedures shall be prepared in advance, maintained in the
 1628 food establishment, and made available to the ~~regulatory authority~~department upon request that
 1629 specify:^{Pf}

- 1630 1. Methods of compliance with subdivisions B 1, 2, and 3 or C 1 through 5 of this section;^{Pf}
 1631 and
 1632 2. Methods of compliance with 12VAC5-421-800 for food that is prepared, cooked, and
 1633 refrigerated before time is used as a public health control.^{Pf}

1634 B. If time without temperature control is used as the public health control up to a maximum of
 1635 four hours:

- 1636 1. The food shall have an initial temperature of 41°F (5°C) or less when removed from
 1637 cold holding temperature control or 135°F (57°C) or greater when removed from hot
 1638 holding temperature control;^P
 1639 2. The food shall be marked or otherwise identified to indicate the time that is four hours
 1640 past the point in time when the food is removed from temperature control;^{P,Pf}
 1641 3. The food shall be cooked and served, served at any temperature if ready-to-eat, or
 1642 discarded, within four hours from the point in time when the food is removed from
 1643 temperature control;^P and
 1644 4. The food in unmarked containers or packages, or marked to exceed a four-hour limit
 1645 shall be discarded.^P

1646 C. If time without temperature control is used as the public health control up to a maximum of
 1647 six hours:

- 1648 1. The food shall have an initial temperature of 41°F (5°C) or less when removed from
 1649 temperature control and the food temperature may not exceed 70°F (21°C) within a
 1650 maximum time period of six hours;^P
 1651 2. The food shall be monitored to ensure the warmest portion of the food does not exceed
 1652 70°F (21°C) during the six-hour period, unless an ambient air temperature is maintained
 1653 that ensures the food does not exceed 70°F (21°C) during the six-hour holding period;^{P,Pf}
 1654 3. The food shall be marked or otherwise identified to indicate:^{Pf}

- 1655 a. The time when the food is removed from 41°F (5°C) or less cold-holding temperature
1656 control,^{Pf} and
- 1657 b. The time that is six hours past the point in time when the food is removed from 41°F
1658 (5°C) or less cold-holding temperature control;^{Pf}
- 1659 4. The food shall be:
- 1660 a. Discarded if the temperature of the foods exceeds 70°F (21°C);^P or
- 1661 b. Cooked and served, served at any temperature if ready-to-eat, or discarded within
1662 a maximum of six hours from the point in time when the food is removed from 41°F
1663 (5°C) or less cold-holding temperature control;^P and
- 1664 5. The food in unmarked containers or packages, or marked with a time that exceeds the
1665 six-hour limit shall be discarded.^P
- 1666 D. A food establishment that serves a highly susceptible population may not use time as
1667 specified under subsection A, B, or C of this section as the public health control for raw eggs.
- 1668 **12VAC5-421-860. Variance requirement.**
- 1669 A food establishment shall obtain a variance from the ~~regulatory authority~~department as
1670 specified in 12VAC5-421-3570 and 12VAC5-421-3580 before.^{Pf}
- 1671 1. Smoking food as a method of food preservation rather than as a method of flavor
1672 enhancement;^{Pf}
- 1673 2. Curing food;^{Pf}
- 1674 3. Using food additives or adding components such as vinegar:^{Pf}
- 1675 a. As a method of food preservation rather than as a method of flavor enhancement;^{Pf}
1676 or
- 1677 b. To render a food so that it is not a time/temperature control for safety food;^{Pf}
- 1678 4. Packaging time/temperature control for safety food using a reduced oxygen packaging
1679 method except where the growth of and toxin formation by *Clostridium botulinum* and the
1680 growth of *Listeria monocytogenes* are controlled as specified under 12VAC5-421-870;^{Pf}
- 1681 5. Operating a molluscan shellfish life-support system display tank used to store or display
1682 shellfish that are offered for human consumption;^{Pf}
- 1683 6. Custom processing animals that are for personal use as food and not for sale or service
1684 in a food establishment;^{Pf}
- 1685 7. Sprouting seeds or beans;^{Pf} or
- 1686 8. Preparing food by another method that is determined by the ~~regulatory authority~~
1687 department to require a variance.^{Pf}
- 1688 **12VAC5-421-870. Reduced oxygen packaging without a variance, criteria.**
- 1689 A. Except for a food establishment that obtains a variance as specified under 12VAC5-421-
1690 860, a food establishment that packages time/temperature control for safety food using a reduced
1691 oxygen packaging method shall control the growth and toxin formation of *Clostridium botulinum*
1692 and the growth of *Listeria monocytogenes*.^P
- 1693 B. Except as specified under subsection F of this section, a food establishment that packages
1694 time/temperature control for safety food using a reduced oxygen method shall ~~have~~implement a
1695 HACCP plan that contains the ~~following~~ information specified under subdivisions 3 and 4 of
1696 12VAC5-421-3630 and that:^{Pf}
- 1697 1. Identifies food to be packaged;^{Pf}

- 1698 2. Except as specified in subsections C ~~and through E of this section~~ and ~~as specified in~~
1699 ~~subsection D of this section~~, requires that the packaged food shall be maintained at 41°F
1700 (5°C) or less and meet at least one of the following criteria:^{Pf}
- 1701 a. Has an A_w of 0.91 or less;^{Pf}
 - 1702 b. Has a pH of 4.6 or less;^{Pf}
 - 1703 c. Is a meat or poultry product cured at a food processing plant regulated by the USDA
1704 using substances specified in 9 CFR 424.21 and is received in an intact package;^{Pf} or
 - 1705 d. Is a food with a high level of competing organisms such as raw meat, raw poultry,
1706 or raw vegetables;^{Pf}
- 1707 3. Describes how the package shall be prominently and conspicuously labeled on the
1708 principal display panel in bold type on a contrasting background, with instructions to:^{Pf}
- 1709 a. Maintain food at 41°F (5°C) or below;^{Pf} and
 - 1710 b. Discard the food if within 30 calendar days of its packaging it is not served for on-
1711 premises consumption, or consumed if served or sold for off-premises consumption;^{Pf}
- 1712 4. Limits the refrigerated shelf life to no more than 30 calendar days from packaging to
1713 consumption, except the time the product is maintained frozen, or the original
1714 manufacturer's "sell by" or "use by" date, whichever occurs first;^P
- 1715 5. Includes operational procedures that:
- 1716 a. Prohibit contacting ready-to-eat food with bare hands as specified in 12VAC5-421-
1717 450 B;^{Pf}
 - 1718 b. Identify a designated work area and the method by which:^{Pf}
 - 1719 (1) Physical barriers or methods of separation of raw foods and ready-to-eat foods
1720 minimize cross contamination;^{Pf} and
 - 1721 (2) Access to the processing equipment is limited to responsible trained personnel
1722 familiar with the potential hazards of the operation;^{Pf} and
 - 1723 c. Delineate cleaning and sanitization procedures for food contact surfaces;^{Pf}
- 1724 6. Describes the training program that ensures that the individual responsible for the
1725 reduced oxygen packaging operation understands the:^{Pf}
- 1726 a. Concepts required for safe operation;^{Pf}
 - 1727 b. Equipment and facilities;^{Pf} and
 - 1728 c. Procedures specified under subdivision B 5 of this section and subdivisions 3 and 4
1729 of 12VAC5-421-3630;^{Pf} and
- 1730 7. Is provided to the ~~regulatory authority~~department prior to implementation as specified
1731 under 12VAC5-421-3620 B.
- 1732 C. Except for fish that is frozen before, during, and after packaging and bears a label indicating
1733 that it is to be kept frozen until time of use, a food establishment may not package fish using a
1734 reduced oxygen packaging method.^P
- 1735 D. Except as specified in subsections C and F of this section, a food establishment that
1736 packages time/temperature control for safety food using a cook-chill or sous-vide process shall:
- 1737 1. Provide to the ~~regulatory authority~~department prior to implementation a HACCP plan
1738 that contains the information as specified under subdivisions 3 and 4 of 12VAC5-421-
1739 3630;^{Pf}
 - 1740 2. Ensure the food is:

- 1741 a. Prepared and consumed on the premises, or prepared and consumed off the
1742 premises but within the same business entity with no distribution or sale of the bagged
1743 product to another business entity or the consumer;^{Pf}
- 1744 b. Cooked to heat all parts of the food to a temperature and for a time as specified
1745 under subsections A, B, and C of 12VAC5-421-700;^P
- 1746 c. Protected from contamination before and after cooking as specified in 12VAC5-421-
1747 450 through 12VAC5-421-765;^P
- 1748 d. Placed in a package with an oxygen barrier and sealed before cooking, or placed in
1749 a package and sealed immediately after cooking, and before reaching a temperature
1750 below 135°F (57°C);^P
- 1751 e. Cooled to 41°F (5°C) in the sealed package as specified under 12VAC5-421-800;
1752 and:^P
- 1753 (1) Cooled to 34°F (1°C) within 48 hours of reaching 41°F (5°C) and held at that
1754 temperature until consumed or discarded within 30 days after the date of packaging;^P
- 1755 (2) Held at 41°F (5°C) or less for no more than seven days, at which time the food
1756 must be consumed or discarded;^P or
- 1757 (3) Held frozen with no shelf-life restriction while frozen until consumed or used;^P
- 1758 f. Held in a refrigeration unit that is equipped with an electronic system that
1759 continuously monitors time and temperature and is visually examined for proper
1760 operation twice daily;^{Pf}
- 1761 g. If transported off site to a satellite location of the same business entity, equipped
1762 with verifiable electronic monitoring devices to ensure that times and temperatures are
1763 monitored during transportation;^{Pf} and
- 1764 h. Labeled with the product name and the date packaged;^{Pf} and
- 1765 3. Maintain the records required to confirm that cooling and cold holding refrigeration
1766 time/temperature parameters are required as part of the HACCP plan, ~~are~~ maintained and
1767 ~~are~~:
- 1768 a. Made available to the ~~regulatory authority~~ department upon request;^{Pf} and
- 1769 b. Held for six months;^{Pf} and
- 1770 4. Implement written operational procedures as specified under subdivision B 5 of this
1771 section and a training program as specified under subdivision B 6 of this section.^{Pf}
- 1772 E. Except as specified under subsection F of this section, a food establishment that packages
1773 cheese using a reduced oxygen packaging method shall:
- 1774 1. Limit the cheeses packaged to those that are commercially manufactured in a food
1775 processing plant with no ingredients added in the food establishment and that meet the
1776 Standards of Identity as specified in 21 CFR 133.150, 21 CFR 133.169, or 21 CFR
1777 133.187;^P
- 1778 2. Have a HACCP plan that contains the information specified in subdivisions 3 and 4 of
1779 12VAC5-421-3630 and as specified under subdivisions B 1, B 3 a, B 5, and B 6 of this
1780 section;^{Pf}
- 1781 3. Label the package on the principal display panel with a "use by" date that does not
1782 exceed 30 days from its packaging or the original manufacturer's "sell by" or "use by" date,
1783 whichever occurs first;^{Pf} and
- 1784 4. Discard the reduced oxygen packaged cheese if it is not sold for off-premises
1785 consumption or consumed within 30 calendar days of its packaging.^{Pf}

1786 F. A HACCP plan is not required when a food establishment uses a reduced oxygen
1787 packaging method to package time/temperature control for safety food that is always:

- 1788 1. Labeled with the production time and date;
1789 2. Held at 41°F (5°C) or less during refrigerated storage; and
1790 3. Removed from its packaging in the food establishment within 48 hours after packaging.

1791 **12VAC5-421-900. Food labels.**

1792 A. Food packaged in a food establishment, shall be labeled as specified in accordance with
1793 all applicable laws and regulations, including 21 CFR Part 101 and 9 CFR Part 317.

1794 B. Label information shall include:

- 1795 1. The common name of the food, or absent a common name, an adequately descriptive
1796 identity statement;
1797 2. If made from two or more ingredients, a list of ingredients and sub-ingredients in
1798 descending order of predominance by weight, including a declaration of artificial colors,
1799 artificial flavors, and chemical preservatives, if contained in the food;
1800 3. An accurate declaration of the net quantity of contents;
1801 4. The name and place of business of the manufacturer, packer, or distributor; and
1802 5. The name of the food source for each major food allergen contained in the food unless
1803 the food source is already part of the common or usual name of the respective ingredient;^{Pf}
1804 6. Except as exempted in the Federal Food, Drug, and Cosmetic Act § 403(Q)(3) through
1805 (5), nutrition labeling as specified in 21 CFR Part 101 and 9 CFR Part 317, Subpart B; and
1806 7. For any salmonid fish containing canthaxanthin or astaxanthin as a color additive, the
1807 labeling of the bulk fish container, including a list of ingredients, displayed on the retail
1808 container or by other written means, such as a counter card, that discloses the use of
1809 canthaxanthin or astaxanthin.

1810 C. Bulk food that is available for consumer self-dispensing shall be prominently labeled with
1811 the following information in plain view of the consumer:

- 1812 1. The manufacturer's or processor's label that was provided with the food; or
1813 2. A card, sign, or other method of notification that includes the information specified under
1814 subdivisions B 1, 2 and ~~5~~6 of this section.

1815 D. Bulk, unpackaged foods such as bakery products and unpackaged foods that are portioned
1816 to consumer specification need not be labeled if:

- 1817 1. A health, nutrient content, or other claim is not made;
1818 2. There are no state or local laws requiring labeling; and
1819 3. The food is manufactured or prepared on the premises of the food establishment or at
1820 another food establishment or a food processing plant that is owned by the same person
1821 and is regulated by the food regulatory agency that has jurisdiction.

1822 **12VAC5-421-930. Consumer advisory: consumption of animal foods that are raw,**
1823 **undercooked, or not otherwise processed to eliminate pathogens.**

1824 A. Except as specified in 12VAC5-421-700 C and D 4 and under 12VAC5-421-9503, if an
1825 animal food such as beef, eggs, fish, lamb, pork, poultry, or shellfish is served or sold raw,
1826 undercooked, or without otherwise being processed to eliminate pathogens, either in ready-to-eat
1827 form or as an ingredient in another ready-to-eat food, the permit holder shall inform consumers of
1828 the significantly increased risk of consuming such foods by way of a disclosure and reminder, as
1829 specified in subsections B and C of this section, using brochures, deli case or menu advisories,
1830 label statements, table tents, placards, or other effective written means.^{Pf}

- 1831 B. Disclosure shall include:
- 1832 1. A description of the animal-derived foods, such as "oysters on the half shell (raw
- 1833 oysters)," "raw-egg Caesar salad," and "hamburgers (can be cooked to order)";^{Pf} or
- 1834 2. Identification of the animal-derived foods by asterisking them to a footnote that states
- 1835 that the items are served raw or undercooked, or contain (or may contain) raw or
- 1836 undercooked ingredients.^{Pf}
- 1837 C. Reminder shall include asterisking the animal-derived foods requiring disclosure to a
- 1838 footnote that states:
- 1839 1. "Regarding the safety of these items, written information is available upon request";^{Pf}
- 1840 2. "Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may
- 1841 increase your risk of foodborne illness";^{Pf} or
- 1842 3. "Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may
- 1843 increase your risk of foodborne illness, especially if you have certain medical conditions."^{Pf}

1844 Article 7

1845 Contaminated Food

1846 **12VAC5-421-940. Discarding or Reconditioning unsafe, adulterated, or contaminated food.**

1847 A. A food that is unsafe, adulterated, or not honestly presented as specified in 12VAC5-421-

1848 260 from an approved source as specified under 12VAC5-421-270 through 12VAC5-421-330

1849 shall be discarded or reconditioned according to an approved procedure. ~~rendered unusable and~~

1850 ~~discarded.~~^P

1851 B. Food that is not from an approved source as specified under 12VAC5-421-270 through

1852 12VAC5-421-330 shall be discarded.^P

1853 ~~B-C.~~ Ready-to-eat food that may have been contaminated by an employee who has been

1854 restricted or excluded as specified under 12VAC5-421-90 shall be rendered unusable and

1855 discarded.^P

1856 ~~C-D.~~ Food that is contaminated by food employees, consumers, or other persons through

1857 contact with their hands, bodily discharges, such as nasal or oral discharges, or other means shall

1858 be ~~rendered unusable and~~ discarded.^P

1859 Article 8

1860 Special Requirements for Highly Susceptible Populations

1861 **12VAC5-421-950. Pasteurized foods, prohibited reservice, and prohibited food.**

1862 In a food establishment that serves a highly susceptible population:

- 1863 1. The following criteria apply to juice:
- 1864 a. For the purposes of this paragraph only, children who are age nine or less and
- 1865 receive food in a school, day care setting, or similar facility that provides custodial care
- 1866 are included as highly susceptible populations;
- 1867 b. Prepackaged juice or a prepackaged beverage containing juice that bears a warning
- 1868 label as specified in 21 CFR 101.17(g) (~~Juices that have not been specifically~~
- 1869 ~~processed to prevent, reduce or eliminate the presence of pathogens~~) or a packaged
- 1870 juice or beverage containing juice that bears a warning label as specified under
- 1871 subdivision 2 of 12VAC5-421-765 may not be served or offered for sale;^P and
- 1872 c. Unpackaged juice that is prepared on the premises for service or sale in a ready-to-
- 1873 eat form shall be processed under a HACCP plan that contains the information
- 1874 specified in subdivisions ~~23~~ through 5 of 12VAC5-421-3630 and as specified in 21
- 1875 CFR 120.24.^P

- 1876 2. Pasteurized eggs or egg products shall be substituted for raw eggs in the preparation
1877 of:^P
- 1878 a. Foods such as Caesar salad, hollandaise or ~~bearnaise~~ bèarnaise sauce,
1879 mayonnaise, meringue, eggnog, ice cream, and egg-fortified beverages;^P and
- 1880 b. Except as specified in subdivision 6 of this section, recipes in which more than one
1881 egg is broken and the eggs are combined.^P
- 1882 3. The following foods shall not be served or offered for sale in a ready-to-eat form:^P
- 1883 a. Raw animal foods such as raw fish, raw-marinated fish, raw molluscan shellfish,
1884 and steak tartare;^P
- 1885 b. A partially cooked animal food such as lightly cooked fish, rare meat, soft-cooked
1886 eggs that are made from raw eggs, and meringue;^P and
- 1887 c. Raw seed sprouts.^P
- 1888 4. Food employees shall not contact ready-to-eat food as specified in 12VAC5-421-450 B
1889 and E.^P
- 1890 5. Time only, as the public health control as specified under 12VAC5-421-850 D, may not
1891 be used for raw eggs.^P
- 1892 6. Subdivision 2 b of this section does not apply if:
- 1893 a. The raw eggs are combined immediately before cooking for one consumer's serving
1894 at a single meal, cooked as specified under 12VAC5-421-700 A 1, and served
1895 immediately, such as an omelet, soufflé, or scrambled eggs;
- 1896 b. The raw eggs are combined as an ingredient immediately before baking and the
1897 eggs are thoroughly cooked to a ready-to-eat form, such as a cake, muffin, or bread;
1898 or
- 1899 c. The preparation of the food is conducted under a HACCP plan that:
- 1900 (1) Identifies the food to be prepared;
- 1901 (2) Prohibits contacting ready-to-eat food with bare hands;
- 1902 (3) Includes specifications and practices that ensure:
- 1903 (a) Salmonella Enteritidis growth is controlled before and after cooking; and
- 1904 (b) Salmonella Enteritidis is destroyed by cooking the eggs according to the
1905 temperature and time specified in 12VAC5-421-700 A 2;
- 1906 ~~e.~~(4) Contains the information specified under subdivision 4 of 12VAC5-421-3630
1907 including procedures that:
- 1908 ~~(1)~~(a) Control cross contamination of ready-to-eat food with raw eggs; and
- 1909 ~~(2)~~(b) Delineate cleaning and sanitization procedures for food-contact surfaces; and
- 1910 e.~~(5)~~ Describes the training program that ensures that the food employee responsible
1911 for the preparation of the food understands the procedures to be used.
- 1912 7. Except as specified in subdivision 8 of this section, food may be re-served as specified
1913 under 12VAC5-421-680 B 1 and 2.
- 1914 8. ~~Foods~~Food may not be re-served under the following conditions:
- 1915 a. Any food served to patients or clients who are under contact precautions in medical
1916 isolation or quarantine, or protective environment isolation may not be re-served to
1917 others outside.
- 1918 b. Packages of food from any patients, clients, or other consumers should not be re-
1919 served to persons in protective environment isolation.

1920 **12VAC5-421-1180. Temperature measuring devices; food.**

1921 A. Food temperature measuring devices that are scaled only in ~~Fahrenheit~~Celsius or dually
1922 scaled in ~~Fahrenheit and Celsius~~Celsius and Fahrenheit shall be scaled in ~~2°F increments and~~
1923 accurate to ~~$\pm 2^{\circ}\text{F}$~~ $\pm 1^{\circ}\text{C}$ in the intended range of use.^{Pf}

1924 B. Food temperature measuring devices that are scaled only in ~~Celsius~~Fahrenheit shall be
1925 scaled in ~~1°C increments~~ accurate to ~~$\pm 1^{\circ}\text{C}$~~ $\pm 2^{\circ}\text{F}$ in the intended range of use.^{Pf}

1926 **12VAC5-421-1190. Temperature measuring devices; ambient air and water.**

1927 A. Ambient air and water temperature measuring devices that are scaled in ~~Fahrenheit~~Celsius
1928 or dually scaled in ~~Fahrenheit and Celsius~~Celsius and Fahrenheit shall be designed to be easily
1929 readable and scaled in ~~3°F increments~~ and accurate to ~~$\pm 3^{\circ}\text{F}$~~ $\pm 1.5^{\circ}\text{C}$ in the intended range of use.^{Pf}

1930 B. Ambient air and water temperature measuring devices that are scaled only in
1931 ~~Celsius~~Fahrenheit shall be scaled in ~~1.5°C increments and~~ accurate to ~~$\pm 1.5^{\circ}\text{C}$~~ $\pm 3^{\circ}\text{F}$ in the intended
1932 range of use.^{Pf}

1933 **12VAC5-421-1300. Molluscan shellfish tanks.**

1934 A. Except as specified under subsection B of this section, molluscan shellfish life support
1935 system display tanks shall not be used to store or display shellfish that are offered for human
1936 consumption and shall be conspicuously marked so that it is obvious to consumers that the
1937 shellfish are for display only.^P

1938 B. Molluscan shellfish life-support system display tanks that are used to store ~~and~~or display
1939 shellfish that are offered for human consumption shall be operated and maintained in accordance
1940 with a variance granted by the ~~regulatory authority~~department as specified in 12VAC5-421-3570
1941 and a HACCP plan that:^{Pf}

1942 1. Is submitted by the permit holder and approved as specified under ~~12VAC5-421-~~
1943 ~~3580~~12VAC5-421-3620;^{Pf} and

1944 2. Ensures that:

1945 a. Water used with fish other than molluscan shellfish does not flow into the molluscan
1946 tank;^{Pf}

1947 b. The safety and quality of the shellfish as they were received are not compromised
1948 by the use of the tank;^{Pf} and

1949 c. The identity of the source of the shellstock is retained as specified under 12VAC5-
1950 421-440.^{Pf}

1951 **12VAC5-421-1380. Warewashing machines, flow pressure device.**

1952 A. Warewashing machines that provide a fresh hot water sanitizing rinse shall be equipped
1953 with a pressure gauge or similar device such as a transducer that measures and displays the
1954 water pressure in the supply line immediately before entering the warewashing machine; and

1955 B. If the flow pressure measuring device is upstream of the fresh hot water sanitizing rinse
1956 control valve, the device shall be mounted in a one-fourth inch or 6.4 millimeter Iron Pipe Size
1957 (IPS) valve.

1958 C. Subsections A and B of this section do not apply to a machine that uses only a pumped or
1959 recirculated sanitizing rinse.

1960 ~~D. Subsections A and B of this section shall not apply to home model dishwashers used in~~
1961 ~~bed and breakfast operations serving 18 or fewer guests.~~

1962 **12VAC5-421-1520. Temperature measuring devices, manual and mechanical warewashing.**

1963 A. In manual warewashing operations, a temperature measuring device shall be provided and
1964 readily accessible for frequently measuring the washing and sanitizing temperatures.^{Pf}

1965 B. In hot water mechanical warewashing operations, an irreversible registering temperature
 1966 indicator shall be provided and readily accessible for measuring the utensil surface temperature.
 1967 ^{Pf}

1968 **12VAC5-421-1535. Cleaning agents and sanitizers, availability.**

1969 A. Cleaning agents that are used to clean equipment and utensils as specified under Article 6
 1970 (12VAC5-421-1770 et seq.) of this part shall be provided and available for use during all hours of
 1971 operation.

1972 B. Except for chemical sanitizers that are generated on site at the time of use, chemical
 1973 sanitizers that are used to sanitize equipment and utensils as specified under Article 67 shall be
 1974 provided and available for use during all hours of operation.

1975 **12VAC5-421-1550. Fixed equipment, spacing or sealing.**

- 1976 A. Equipment that is fixed because it is not easily movable shall be installed so that it is:
- 1977 1. Spaced to allow access for cleaning along the sides, behind, and above the equipment;
 - 1978 2. Spaced from adjoining equipment, walls, and ceilings a distance of not more than 1/32
 - 1979 inch or 1 millimeter; or
 - 1980 3. Sealed to adjoining equipment or walls, if the equipment is exposed to spillage or
 - 1981 seepage.

1982 B. Counter-mounted equipment that is not easily movable shall be installed to allow cleaning
 1983 of the equipment and areas underneath and around the equipment by being:

- 1984 1. Sealed to the table; or
- 1985 2. Elevated on legs as specified under 12VAC5-421-1560 D.

1986 **12VAC5-421-1620. Warewashing sinks, use limitation.**

- 1987 A. A warewashing sink shall not be used for handwashing.
- 1988 B. If a warewashing sink is used to wash wiping cloths, wash produce, or thaw food, the sink
 1989 shall be cleaned as specified under 12VAC5-421-1600 before and after each time it is used to
 1990 wash wiping cloths or wash produce or thaw food. Sinks used to wash or thaw food shall be
 1991 sanitized as specified under Article 7 (~~12VAC5-421-1880 et seq.~~)(12VAC5-421-1885 et seq.) of
 1992 this part before and after using the sink to wash produce or thaw food.

1993 **12VAC5-421-1700. Manual and mechanical warewashing equipment, chemical**
 1994 **sanitization - temperature, pH, concentration, and hardness.**

1995 A chemical sanitizer used in a sanitizing solution for a manual or mechanical operation at
 1996 contact times specified under subdivision 3 of 12VAC5-421-1900 shall ~~be listed in 40 CFR~~
 1997 ~~180.940, shall meet the criteria as specified under 12VAC5-421-3380, shall~~ be used in
 1998 accordance with the EPA-registered label use instructions,^P and shall be used as follows:

- 1999 1. A chlorine solution shall have a minimum temperature based on the concentration and
 2000 pH of the solution as listed in the following chart:^P

Minimum Concentration	Minimum Temperature	
	pH 10 or less °F (°C)	pH 8 or less °F (°C)
25-49	120 (49)	120 (49)
50-99	100 (38)	75 (24)
100	55 (13)	55 (13)

- 2001 2. An iodine solution shall have a:
- 2002 a. Minimum temperature of 68°F (20°C);^P
- 2003 b. pH of 5.0 or less or a pH no higher than the level for which the manufacturer
- 2004 specifies the solution is effective;^P and
- 2005 c. Concentration between 12.5 mg/L (ppm) and 25 mg/L (ppm);^P
- 2006 3. A quaternary ammonium compound solution shall:
- 2007 a. Have a minimum temperature of 75°F (24°C);^P
- 2008 b. Have a concentration as specified under ~~40 CFR 180.9401~~12VAC5-421-3380 and
- 2009 as indicated by the manufacturer's use directions included in the labeling;^P and
- 2010 c. Be used only in water with 500 mg/L hardness or less or in water having a hardness
- 2011 no greater than specified by the manufacturer's label;^P
- 2012 4. If another solution of a chemical specified under subdivisions 1, 2 and 3 of this section
- 2013 is used, the permit holder shall demonstrate to the ~~regulatory authority~~ department that
- 2014 the solution achieves sanitization and the use of the solution shall be approved;^P
- 2015 5. If a chemical sanitizer other than chlorine, iodine, or a quaternary ammonium compound
- 2016 is used, it shall be applied in accordance with the EPA-registered label use instructions;^P
- 2017 and
- 2018 6. If a chemical sanitizer is generated by a device located on site at the food establishment
- 2019 it shall be used as specified in subdivisions 1 through 4 of this section and shall be
- 2020 produced by a device that:
- 2021 a. Complies with regulation as specified in §§ 2(q)(1) and 12 of the Federal Insecticide,
- 2022 Fungicide and Rodenticide Act (FIFRA);^P
- 2023 b. Complies with 40 CFR 152.500 and 40 CFR 156.10;^P
- 2024 c. Displays the EPA device manufacturing facility registration number on the device;^{Pf}
- 2025 and
- 2026 d. Is operated and maintained in accordance with manufacturer's instructions.^{Pf}
- 2027 **12VAC5-421-1920. Laundering frequency for linens, cloth gloves, napkins, and wiping**
- 2028 **cloths.**
- 2029 A. Linens that do not come in direct contact with food shall be laundered between operations
- 2030 if they become wet, sticky, or visibly soiled.
- 2031 B. Cloth gloves used as specified in 12VAC5-421-580 D shall be laundered before being used
- 2032 with a different type of raw animal food such as beef, fish, lamb, pork, and ~~fish~~poultry.
- 2033 C. Linens ~~and napkins~~ that are used as specified under 12VAC5-421-560 and cloth napkins
- 2034 shall be laundered between each use.
- 2035 D. Wet wiping cloths shall be laundered daily.
- 2036 E. Dry wiping cloths shall be laundered as necessary to prevent contamination of food and
- 2037 clean serving utensils.
- 2038 **12VAC5-421-2090. Nonpotable water.**
- 2039 A. A nonpotable water supply shall be used only if its use is approved by the ~~regulatory~~
- 2040 ~~authority.~~^P department.^P
- 2041 B. Nonpotable water shall be used only for nonculinary purposes such as air conditioning,
- 2042 nonfood equipment cooling, and fire protection, ~~and irrigation.~~^P
- 2043 **12VAC5-421-2100. Sampling.**
- 2044 Water from a private well shall be sampled and tested at least annually for nitrate and total
- 2045 coliform.^{Pf}

2046 1. If nitrate, which is reported as "N" on the test results, exceeds 10 mg/L (ppm), the owner
2047 shall notify the ~~regulatory authority.~~^{Pf} department within 24 hours from when the owner is
2048 notified of the nitrate positive test result. ^{Pf}

2049 2. If a sample is total coliform positive, the positive culture medium shall be further
2050 analyzed to determine if E. coli is present. The owner shall notify the ~~regulatory~~
2051 ~~authority~~department within two calendar days from when the owner is notified of the
2052 coliform positive test result. ^{Pf}

2053 3. If E. coli is present, the owner shall notify the ~~regulatory authority~~department within 24
2054 hours from when the owner is notified of the E. coli positive test result. ^{Pf}

2055 **12VAC5-421-2110. Sample report.**

2056 All sample reports for the private well shall be retained on file in the food establishment for a
2057 minimum of five years and be made available to the ~~regulatory authority~~department upon request.

2058 **12VAC5-421-2140. [Reserved] Water System.**

2059 Water shall be received from the source through the use of:

2060 1. An approved public water main;^{Pf} or

2061 2. One or more of the following that shall be constructed, maintained, and operated
2062 according to law: ^{Pf}

2063 a. Nonpublic water main, water pumps, pipes, hoses, connections, and other
2064 appurtenances; ^{Pf}

2065 b. Water transport vehicles; ^{Pf} or

2066 c. Water containers. ^{Pf}

2067

2068 **12VAC5-421-2270. Backflow prevention device, carbonator.**

2069 A. If not provided with an air gap as specified under 12VAC5-421-2200, a ~~double~~ dual check
2070 valve with an intermediate vent preceded by a screen of not less than 100 mesh to 1 inch (100
2071 mesh to 25.4mm) shall be installed upstream from a carbonating device and downstream from
2072 any copper in the water supply line. ^P

2073 B. A dual check valve attached to the carbonator need not be of the vented type if an air gap
2074 or vented backflow prevention device has been otherwise ~~approved~~provided as specified under
2075 subsection A of this section.

2076 **12VAC5-421-2330. Scheduling inspection and service for a water system device.**

2077 A device such as a water treatment device or backflow preventer shall be scheduled for
2078 inspection and service, in accordance with manufacturer's instructions and as necessary to
2079 prevent device failure based on local water conditions, and records demonstrating inspection and
2080 service shall be maintained by the person in charge for a minimum of five years and made
2081 available to the department upon request. ^{Pf}

2082 **12VAC5-421-2350. System maintained in good repair.**

2083 ~~A plumbing system shall be (i) repaired according to law^P and (ii) maintained in good repair.~~

2084 A plumbing system shall be:

2085 1. Repaired according to law; ^P and

2086 2. Maintained in good repair.

2087 **12VAC5-421-2505. Establishment Drainage System.**

2088 Food establishment drainage systems, including grease traps, that convey sewage shall be
2089 designed and installed as specified under 12 VAC5-421-2180 A.

2090 **12VAC5-421-2570. Approved sewage disposal system.**

2091 Sewage shall be disposed through an approved facility that is:

2092 1. A public sewage treatment plant;^P or

2093 2. An individual sewage disposal system that is sized, constructed, maintained, and
2094 operated according to the State Board of Health's regulations promulgated pursuant to
2095 Chapter 6 (§ 32.1-163 et seq.) of Title 32 of the Code of Virginia, including 12VAC5-610,
2096 (Sewage Handling and Disposal Regulations), 12VAC5-613, ~~and 12VAC5-640.~~^P
2097 (Regulations for Alternative Onsite Sewage Systems), or otherwise according to law.^P

2098 **12VAC5-421-2720. Covering receptacles.**

2099 Receptacles and waste handling units for refuse, recyclables, and returnables shall be kept
2100 covered:

2101 1. Inside the food establishment if the receptacles and units: ~~(i) contain food residue and~~
2102 ~~are not in continuous use or (ii) after they are filled; and~~

2103 a. Contain food residue and are not in continuous use; or

2104 b. After they are filled; and

2105 2. With tight-fitting lids or doors if kept outside the food establishment.

2106 **12VAC5-421-2750. Cleaning receptacles.**

2107 A. Receptacles and waste handling units for refuse, recyclables, and returnables shall be
2108 thoroughly cleaned in a way that does not contaminate food, equipment, utensils, linens, or single-
2109 service and single-use articles, and waste water shall be disposed of as specified under ~~42VAC5-~~
2110 ~~421-2550~~12VAC5-421-2540.

2111 B. Soiled receptacles and waste handling units for refuse, recyclables, and returnables shall
2112 be cleaned at a frequency necessary to prevent them from developing a buildup of soil or
2113 becoming attractants for insects and rodents.

2114 **12VAC5-421-3040. Handwashing aids and devices, use restrictions.**

2115 A sink used for food preparation or utensil washing, or a service sink or curbed cleaning facility
2116 used for the disposal of mop water or similar wastes, shall not be provided with the handwashing
2117 aids and devices required for a handwashing sink as specified under 12VAC5-421-3020 ~~and~~,
2118 12VAC5-421-3030, and 12VAC5-421-2650 C.

2119 **12VAC5-421-3310. Prohibiting animals.**

2120 A. Except as specified in subsections B and C of this section, live animals shall not be allowed
2121 on the premises of a food establishment.^{Pf}

2122 B. Live animals may be allowed in the following situations if the contamination of food; clean
2123 equipment, utensils, and linens; and unwrapped single-service and single-use articles cannot
2124 result:

2125 1. Edible fish or decorative fish in aquariums, shellfish or crustacea on ice or under
2126 refrigeration, and shellfish and crustacea in display tank systems;

2127 2. Patrol dogs accompanying police or security officers in offices and dining, sales, and
2128 storage areas, and sentry dogs running loose in outside fenced areas;

2129 3. In areas that are not used for food preparation and that are usually open for customers,
2130 such as dining and sales areas, service animals that are controlled by the disabled
2131 employee or person if a health or safety hazard will not result from the presence or
2132 activities of the service animal;

2133 4. Pets in the common dining areas of institutional care facilities such as nursing homes,
2134 assisted living facilities, group homes, residential care facilities, and bed and breakfast
2135 operations at times other than during meals if:

- 2136 a. Effective partitioning and self-closing doors separate the common dining areas from
2137 food storage or food preparation areas;
- 2138 b. Condiments, equipment, and utensils are stored in enclosed cabinets or removed
2139 from the common dining areas when pets are present; and
- 2140 c. Dining areas including tables, countertops, and similar surfaces are effectively
2141 cleaned before the next meal service;
- 2142 5. In areas that are not used for food preparation, storage, sales, display, or dining, in
2143 which there are caged animals or animals that are similarly restricted, such as in a variety
2144 store that sells pets or a tourist park that displays animals; and
- 2145 6. Dogs in outdoor dining areas if:
- 2146 a. The outdoor dining area is not fully enclosed with floor to ceiling walls and is not
2147 considered a part of the interior physical facility;:
- 2148 b. The outdoor dining area is equipped with an entrance that is separate from the main
2149 entrance to the food establishment and the separate entrance serves as the sole
2150 means of entry for patrons accompanied by dogs;:
- 2151 c. A sign stating that dogs are allowed in the outdoor dining area is posted at each
2152 entrance to the outdoor dining area in such a manner as to be clearly observable by
2153 the public;:
- 2154 d. A sign within the outdoor dining area stating the requirements as specified in
2155 subdivisions 6 e, 6 f, and 6 g of this subsection is provided in such a manner as to be
2156 clearly observable by the public;:
- 2157 e. Food and water provided to dogs is served using equipment that is not used for
2158 service of food to persons or is served in single-use articles;:
- 2159 f. Dogs are not allowed on chairs, seats, benches, or tables;:
- 2160 g. Dogs are kept on a leash or within a pet carrier and under the control of an adult at
2161 all times; and
- 2162 h. Establishment provides effective means for cleaning up dog vomitus and fecal
2163 matter.
- 2164 C. Live or dead fish bait may be stored if contamination of food; clean equipment, utensils,
2165 and linens; and unwrapped single-service and single-use articles cannot result.
- 2166 ~~D. In bed and breakfast operations serving 18 or fewer guests, live animals shall be allowed~~
2167 ~~in the facility but shall not be fed using the same equipment or utensils that are used to feed~~
2168 ~~humans.~~
- 2169 **12VAC5-421-3360. Conditions of use.**
- 2170 Poisonous or toxic materials shall be:
- 2171 1. Used according to:
- 2172 a. Law and this chapter;
- 2173 b. Manufacturer's use directions included in labeling, and, for a pesticide,
2174 manufacturer's label instructions that state that use is allowed in a food establishment;^P
- 2175 c. The conditions of certification, if certification is required, for use of the pest control
2176 materials;^P and
- 2177 d. Additional conditions that may be established by the ~~regulatory authority.~~^P
2178 department;and
- 2179 2. Applied so that:
- 2180 a. A hazard to employees or other persons is not constituted;^P and

2181 b. Contamination including toxic residues due to drip, drain, fog, splash, or spray on
2182 food, equipment, utensils, linens, and single-service and single-use articles is
2183 prevented, and for a restricted-use pesticide, this is achieved by:^P

2184 ~~(1) Removing the items, covering the items with impermeable covers, or taking other~~
2185 ~~appropriate preventive actions;~~^P and

2186 ~~(2) Cleaning and sanitizing equipment and utensils after the application.~~^P

2187 (1) Removing the items;^P

2188 (2) Covering the items with impermeable covers; ^P or

2189 (3) Taking other appropriate preventive actions; ^P and

2190 (4) Cleaning and sanitizing equipment and utensils after the application.^P

2191 3. A restricted use pesticide shall be applied only by an applicator certified as defined in 7
2192 USC § 136(e) (Federal Insecticide, Fungicide and Rodenticide Act), or a person under the
2193 direct supervision of a certified applicator.^{Pf}

2194 **12VAC5-421-3390. Chemicals for washing fruits and vegetables, criteria. Chemicals for**
2195 **Washing, Treatment, Storage and Processing Fruits and Vegetables, Criteria.**

2196 A. Chemicals, including those generated on site, used to wash or peel raw, whole fruits and
2197 vegetables or used in the treatment, storage, and processing of fruits and vegetables shall:

2198 1. Be an approved food additive listed for this intended use in 21 CFR Part 173;^P or

2199 2. Be generally recognized as safe (GRAS) for this intended use;^P or

2200 3. Be the subject of an effective food contact notification for this intended use (only
2201 effective for the manufacturer or supplier identified in the notification);^P and

2202 4. Meet the requirements in ~~the~~ 40 CFR Part 156.^P

2203 ~~B. Ozone as an antimicrobial agent used in the treatment, storage, and processing of fruits~~
2204 ~~and vegetables in a food establishment shall meet the requirements specified in 21 CFR~~
2205 ~~173.368.~~^P

2206 **12VAC5-421-3410. Drying agents, criteria.**

2207 Drying agents used in conjunction with sanitization shall:

2208 1. Contain only components that are listed as one of the following:

2209 a. ~~Generally recognized as safe~~GRAS for use in food as specified in 21 CFR Part 182
2210 or 21 CFR Part 184,^P

2211 b. ~~Generally recognized as safe~~GRAS for the intended use as specified in 21 CFR
2212 Part 186,^P

2213 c. ~~Generally recognized as safe~~GRAS for the intended use as determined by experts
2214 qualified in scientific training and experience to evaluate the safety of substances
2215 added, directly or indirectly, to food as described in 21 CFR 170.30,^P

2216 d. Subject of an effective Food Contact Notification as described in the Federal Food
2217 Drug and Cosmetic Act (FFDCA) § 409(h),^P

2218 e. Approved for use as a drying agent under a prior sanction specified in 21 CFR Part
2219 181 as specified in the Federal Food Drug and Cosmetic Act (FFDCA) § 201(s)(4),^P

2220 f. Specifically regulated as an indirect food additive for use as a drying agent as
2221 specified in 21 CFR Parts ~~175~~174 through 178,^P or

2222 g. Approved for use as a drying agent under the threshold of regulation process
2223 established by 21 CFR 170.39;^P and

2224 2. When sanitization is with chemicals, the approval required under subdivision 1 e or g of
2225 this section or the regulation as an indirect food additive required under subdivision 1 f of
2226 this section, shall be specifically for use with chemical sanitizing solutions.^P

2227 Part VIII

2228 Compliance and Enforcement

2229 Article 1

2230 Applicability of Chapter

2231 **12VAC5-421-3510. Public health protection.**

2232 A. The ~~regulatory authority~~department shall apply this ~~regulation~~chapter to promote its
2233 underlying purpose, as specified in 12VAC5-421-30, of safeguarding public health and ensuring
2234 that food is safe, ~~and unadulterated~~ and honestly presented when offered to the consumer.

2235 B. In enforcing the provisions of this regulation, the ~~regulatory authority~~department shall
2236 assess existing facilities or equipment that were in use before ~~March 1, 2002~~the effective date of
2237 this chapter, based on the following considerations:

2238 1. Whether the facilities or equipment are in good repair and capable of being maintained
2239 in a sanitary condition;

2240 2. Whether food-contact surfaces comply with 12VAC5-421-960 through 12VAC5-421-
2241 1060; and

2242 3. Whether the capacities of cooling, heating, and holding equipment are sufficient to
2243 comply with 12VAC5-421-1450.

2244 **12VAC5-421-3520. Preventing health hazards, provision for conditions not addressed.**

2245 A. If necessary to protect against public health hazards or nuisances, the ~~regulatory~~
2246 ~~authority~~department may impose specific requirements in addition to the requirements contained
2247 in this regulation that are authorized by law.

2248 B. The ~~regulatory authority~~department shall document the conditions that necessitate the
2249 imposition of additional requirements and the underlying public health rationale. The
2250 documentation shall be provided to the permit applicant or permit holder and a copy shall be
2251 maintained in the ~~regulatory authority's~~department's file for the food establishment.

2252 **~~12VAC5-421-3550. Food Service Advisory Committee. (Repealed.)~~**

2253 ~~The commissioner shall appoint a Food Service Advisory Committee (FSAC). He shall appoint~~
2254 ~~to the FSAC as many members as he wishes, but a minimum of one individual each from the~~
2255 ~~following: Department of Agriculture and Consumer Services, Department of Housing and~~
2256 ~~Community Development, Department of Social Services, Virginia Hospitality and Travel~~
2257 ~~Association, Virginia Retail Merchants Association, public at large, Virginia Public Health~~
2258 ~~Association, Virginia Environmental Health Association, Virginia Caterers Association, Virginia~~
2259 ~~Food Dealers Association, a consumer and/or civic organization representative, and an~~
2260 ~~environmental health specialist.~~

2261 ~~Ex-officio members shall be the Director of the Division of Food and General Environmental~~
2262 ~~Services and the Director of Health Facilities Regulation.~~

2263 ~~Appointed members of the FSAC shall serve at the discretion of the commissioner and shall~~
2264 ~~make recommendation to the commissioner regarding food service policies, procedures and other~~
2265 ~~food program operations. The FSAC shall meet at least annually.~~

2266 **~~12VAC5-421-3560. Exemptions to regulations. (Repealed.)~~**

2267 A. The following are exempt from this chapter as defined in ~~§§ 35.1-25 and 35.1-26 of the~~
2268 ~~Code of Virginia.~~

2269 1. ~~Boarding houses that do not accommodate transients;~~

- 2270 ~~2. Cafeterias operated by industrial plants for employees only;~~
- 2271 ~~3. Churches, fraternal, school and social organizations and volunteer fire departments and~~
- 2272 ~~rescue squads which hold dinners and bazaars of not more than one time per week and~~
- 2273 ~~not in excess of two days duration at which food prepared in homes of members or in the~~
- 2274 ~~kitchen of the church or organization and is offered for sale to the public;~~
- 2275 ~~4. Grocery stores, including the delicatessen that is a part of a grocery store, selling~~
- 2276 ~~exclusively for off-premises consumption and places manufacturing or selling packaged~~
- 2277 ~~or canned goods;~~
- 2278 ~~5. Churches that serve meals for their members as a regular part of their religious~~
- 2279 ~~observance;~~
- 2280 ~~6. Convenience stores or gas stations that are subject to the State Board of Agriculture~~
- 2281 ~~and Consumer Services' Retail Food Establishment Regulations (2VAC5-585) or any~~
- 2282 ~~regulations subsequently adopted and that (i) have 15 or fewer seats at which food is~~
- 2283 ~~served to the public on the premises of the convenience store or gas station and (ii) are~~
- 2284 ~~not associated with a national or regional restaurant chain. Notwithstanding this~~
- 2285 ~~exemption, such convenience stores or gas stations shall remain responsible for collecting~~
- 2286 ~~any applicable local meals tax; and~~
- 2287 ~~7. Any bed and breakfast operation that prepares food for and offers food to guests,~~
- 2288 ~~regardless of the time the food is prepared and offered, if (i) the premises of the bed and~~
- 2289 ~~breakfast operation is a home that is owner occupied or owner-agent occupied, (ii) the~~
- 2290 ~~bed and breakfast operation prepares food for and offers food to transient guests of the~~
- 2291 ~~bed and breakfast only, (iii) the number of guests served by the bed and breakfast~~
- 2292 ~~operation does not exceed 18 on any single day, and (iv) guests for whom food is prepared~~
- 2293 ~~and to whom food is offered are informed by statements contained in published~~
- 2294 ~~advertisements, mailed brochures, and placards posted at the registration area that the~~
- 2295 ~~food is prepared in a kitchen that is not licensed as a restaurant and is not subject to~~
- 2296 ~~regulations governing restaurants.~~
- 2297 ~~B. The governing body of any county, city or town may provide by ordinance that this chapter~~
- 2298 ~~shall not apply to food booths at fairs and youth athletic activities if such booths are promoted or~~
- 2299 ~~sponsored by any political subdivision of the Commonwealth or by any charitable nonprofit~~
- 2300 ~~organization or group thereof. The ordinance shall provide that the director of the county, city, or~~
- 2301 ~~town in which the fair and youth athletic activities are held, or a qualified person designated by~~
- 2302 ~~the director, shall exercise such supervision of the sale of food as the ordinance may prescribe.~~
- 2303 **12VAC5-421-3570. Variances.**
- 2304 ~~A. The commissioner or his designee may grant a variance to this chapter by following the~~
- 2305 ~~appropriate procedures set forth in this section and 12VAC5-421-3580.~~
- 2306 ~~B. The commissioner or his designee may grant a variance if he finds that the hardship~~
- 2307 ~~imposed, which may be economic, outweighs the benefits that may be received by the public and~~
- 2308 ~~that granting such a variance does not subject the public to unreasonable health risks or~~
- 2309 ~~environmental pollution.~~
- 2310 ~~C. Any owner or permit holder who seeks a variance shall apply in writing ~~within the time~~~~
- 2311 ~~period specified in ~~12VAC5-421-4000.~~ The request ~~should~~shall be sent to the local health~~
- 2312 ~~department. The application shall include:~~
- 2313 ~~1. A citation to the regulation from which a variance is requested;~~
- 2314 ~~2. The nature and duration of the variance requested;~~
- 2315 ~~3. Any relevant analytical results including result of relevant tests conducted pursuant to~~
- 2316 ~~the requirements of these regulations;~~

- 2317 4. Statements or evidence which establishes that the public health, welfare and
 2318 environment would not be adversely affected if the variance were granted;
- 2319 5. Suggested conditions that might be imposed on the granting of a variance that would
 2320 limit the detrimental impact on the public health and welfare;
- 2321 6. A HACCP plan if required as specified under 12VAC5-421-3620 A that includes the
 2322 information specified under 12VAC5-421-3630 as it is relevant to the variance requested.
- 2323 7. Other information believed pertinent by the applicant; and
- 2324 8. Such other information as the district or local health department or commissioner may
 2325 require.

2326 **12VAC5-421-3580. Evaluation of a variance application.**

2327 A. The commissioner shall act on any variance request submitted pursuant to 12VAC5-421-
 2328 3570 ~~B C~~ within 60 days of receipt of the request.

2329 B. In evaluating a variance application, the commissioner shall consider such factors as the
 2330 following:

- 2331 1. The effect that such a variance would have on the operation of the food establishment.
- 2332 2. The cost and other economic considerations imposed by this requirement;
- 2333 3. The effect that such a variance would have on protection of the public health, safety,
 2334 welfare and the environment;
- 2335 4. Such other factors as the commissioner, deputy commissioner, or director of the office
 2336 of environmental health services may deem appropriate.

2337 **12VAC5-421-3595. Conformance with Approved Procedures.**

2338 If the commissioner or his designee grants a variance as specified in 12VAC5-421-3570, or a
 2339 HACCP Plan is otherwise required as specified under 12VAC5-421-3620, the permit holder shall:

- 2340 1. Comply with the HACCP plans and procedures that are submitted as specified under
 2341 12VAC5-421-3630 and approved as a basis for the variance;^P and
- 2342 2. Maintain and provide to the department, upon request, records specified under
 2343 12VAC5-421-3630 4 and 5 c that demonstrate that the following are routinely employed:
- 2344 a. Procedures for monitoring the critical control points, ^{PF}
- 2345 b. Monitoring of the critical control points, ^{PF}
- 2346 c. Verification of the effectiveness of the operation or process, ^{PF} and
- 2347 d. Necessary corrective actions if there is failure at the critical control point. ^{PF}

2348 Article 2
 2349 Plan Submission and Approval

2350 **12VAC5-421-3600. Facility and operating plans.**

2351 A permit applicant or permit holder shall submit to the ~~regulatory authority~~department properly
 2352 prepared plans and specifications for review and approval before:

- 2353 1. The construction of a food establishment;^{Pf}
- 2354 2. The conversion of an existing structure for use as a food establishment;^{Pf} or
- 2355 3. The remodeling of a food establishment or a change of type of food establishment or
 2356 food operation as specified under subdivision 3 of 12VAC-421-3700 if the ~~regulatory~~
 2357 ~~authority~~department determines that plans and specifications are necessary to ensure
 2358 compliance with this chapter.^{Pf}

2359 **12VAC5-421-3610. Contents of the plans and specifications.**

2360 The plans and specifications for a food establishment, including a food establishment
2361 specified under 12VAC5-421-3620, shall include, as required by the ~~regulatory~~
2362 ~~authority~~department based on the type of operation, type of food preparation, and foods prepared,
2363 the following information to demonstrate conformance with the provisions of this chapter:

- 2364 1. Intended menu;
- 2365 2. Anticipated volume of food to be stored, prepared, and sold or served;
- 2366 3. Proposed layout, mechanical schematics, construction materials, and finish schedules;
- 2367 4. Proposed equipment types, manufacturers, model numbers, locations, dimensions,
2368 performance capacities, and installation specifications;
- 2369 5. Evidence that standard procedures ensuring compliance with the requirements of this
2370 chapter are developed or are being developed; and
- 2371 6. Other information that may be required by the ~~regulatory authority~~department for the
2372 proper review of the proposed construction, conversion or modification, and procedures
2373 for operating a food establishment.

2374 **12VAC5-421-3620. When a HACCP plan is required.**

2375 A. Before engaging in an activity that requires a HACCP plan, a permit applicant or permit
2376 holder shall submit to the ~~regulatory authority~~department for approval a properly prepared HACCP
2377 plan as specified under 12VAC5-421-3630 and the relevant provisions of this chapter if:

- 2378 1. Submission of a HACCP plan is required according to law;
- 2379 2. A variance is required as specified under 12VAC421-700 D 4, 12VAC5-421-860,
2380 12VAC5-421-1300 B, ~~or 12VAC5-421-700 D 4~~; or
- 2381 3. The ~~regulatory authority~~department determines that a food preparation or processing
2382 method requires a variance based on a plan submittal specified under 12VAC5-421-3610,
2383 an inspectional finding, or a variance request.

2384 B. Before engaging in reduced oxygen packaging without a variance as specified under
2385 12VAC5-421-870, a permit applicant or permit holder shall submit a properly prepared HACCP
2386 plan to the ~~regulatory authority~~department.

2387 **12VAC5-421-3630. Contents of a HACCP plan.**

2388 For a food establishment that is required under 12VAC5-421-3620 to have a HACCP plan,
2389 the permit applicant or permit holder shall submit to the ~~regulatory authority~~department a properly
2390 prepared HACCP plan that includes:

- 2391 1. General information such as the name of the permit applicant or permit holder, the food
2392 establishment address, and contact information;^{Pf}
- 2393 2. A categorization of the types of time/temperature control for safety food that is to be
2394 controlled under the HACCP plan;^{Pf}
- 2395 3. A flow diagram or chart for each specific food or category type that identifies:^{Pf}
- 2396 a. Each step in the process,^{Pf}
- 2397 b. The hazards and controls for each step in the flow diagram or chart,^{Pf}
- 2398 c. The steps that are critical control points,^{Pf}
- 2399 d. The ingredients, materials, and equipment used in the preparation of that food,^{Pf}
2400 and
- 2401 e. Formulations or recipes that delineate methods and procedural control measures
2402 that address the food safety concerns involved;^{Pf}

- 2403 4. A critical control ~~point~~points summary for each specific food or category type that clearly
 2404 identifies:
- 2405 a. Each critical control point;^{Pf}
 - 2406 b. The critical limits for each critical control point;^{Pf}
 - 2407 c. The method and frequency for monitoring and controlling each critical control point
 2408 by the food employee designated by the person in charge;^{Pf}
 - 2409 d. The method and frequency for the person in charge to routinely verify that the food
 2410 employee is following standard operating procedures and monitoring critical control
 2411 points;^{Pf}
 - 2412 e. Action to be taken by the person in charge if the critical limits for each critical control
 2413 point are not met;^{Pf} and
 - 2414 f. Records to be maintained by the person in charge to demonstrate that the HACCP
 2415 plan is properly operated and managed;^{Pf}
- 2416 5. Supporting documents such as:
 2417 a. Food employee and supervisory training plan addressing food safety issues;^{Pf}
 2418 b. Copies of blank records forms that are necessary to implement ~~at~~the HACCP plan;^{Pf}
 2419 c. Additional scientific data or other information, as required by the ~~regulatory~~
 2420 ~~authority~~department supporting the determination that food safety is not compromised
 2421 by the proposal;^{Pf} and
- 2422 6. Any other information required by the ~~regulatory authority~~department.

2423 **12VAC5-421-3640. Confidentiality -- trade secrets.**

2424 The ~~regulatory authority~~department shall treat as confidential in accordance with law,
 2425 information that meets the criteria specified in law for a trade secret and is contained on inspection
 2426 report forms and in the plans and specifications submitted as specified under 12VAC5-421-3610
 2427 and 12VAC5-421-3630.

2428 **12VAC5-421-3650. Preoperational inspections.**

2429 The ~~regulatory authority~~department shall conduct one or more preoperational inspections to
 2430 verify that the food establishment is constructed and equipped in accordance with the approved
 2431 plans and approved modifications of those plans, has established standard operating procedures
 2432 as specified under subdivision 5 of 12VAC5-421-3610 and is in compliance with law and this
 2433 chapter.

2434 Article 3
 2435 Permit to Operate

2436 **12VAC5-421-3660. Permits.**

2437 A. No person shall own, establish, conduct, maintain, manage, or operate any food
 2438 establishment in this Commonwealth unless the food establishment is permitted as provided in
 2439 this section. All permits shall be in the name of the owner ~~or lessee~~. Permits shall not be issued
 2440 to newly constructed or extensively remodeled food establishments until a certificate of occupancy
 2441 has been issued by the Building Official. Only a person who complies with the requirements of
 2442 this part shall be entitled to receive or retain such a permit.

2443 B. Permits issued shall not be transferable from one person to another or from one location
 2444 to another. A new owner shall be required to make a written application for a permit. The
 2445 application forms are obtainable at all local health departments.

2446 C. Any person operating a food establishment with a valid permit who desires to expand or
 2447 modify the establishment, shall notify the ~~director~~local health department in the jurisdiction where
 2448 the food establishment is located, and the ~~director~~local health department shall determine whether

2449 such expansion, modification, or reclassification is in compliance with the applicable sections of
2450 this chapter.

2451 D. The permit shall be posted in every food establishment in a place where it is readily
2452 observable by the public transacting business with the establishment.

2453 E. Permits shall expire annually otherwise not to exceed twelve months from the date of
2454 issuance.

2455 **12VAC5-421-3670. Application procedure, submission before proposed opening.**

2456 A. An applicant seeking to operate a nontemporary food establishment shall submit an
2457 application for a permit at least 30 calendar days before the date planned for opening a food
2458 establishment or at least 30 calendar days before the expiration date of the current permit for an
2459 existing facility.

2460 B. An applicant seeking to operate a temporary food establishment shall submit an
2461 application for a permit at least 10 calendar days before the date planned for opening the
2462 temporary food establishment.

2463 C. Any applicant who fails to complete the application process within 12 months of receipt of
2464 the application by the local health department's office may be required to submit a new application
2465 and plan.

2466 **12VAC5-421-3680. Form of submission.**

2467 A person desiring to operate a food establishment shall submit to the ~~regulatory~~
2468 ~~authority~~department a written application for a permit on a form provided by the ~~regulatory~~
2469 ~~authority~~department.

2470 **12VAC5-421-3690. Qualifications and responsibilities of applicants.**

2471 To qualify for a permit, an applicant shall:

- 2472 1. Be an owner of the food establishment or an officer of the legal ownership;
- 2473 2. Comply with the requirements of this ~~regulation~~chapter; and
- 2474 3. As specified under 12VAC5-421-3820, agree to allow access to the food establishment
2475 and to provide required information.

2476 **12VAC5-421-3700. Contents of the application.**

2477 The application shall include:

- 2478 1. The name, mailing address, telephone number, and signature of the person applying
2479 for the permit and the name, mailing address, and location of the food establishment;
- 2480 2. Information specifying whether the food establishment is owned by an association,
2481 corporation, individual, partnership, or other legal entity;
- 2482 3. A statement specifying whether the food establishment:
 - 2483 a. Is mobile or stationary, and temporary or permanent; and
 - 2484 b. Is an operation that includes one or more of the following:
 - 2485 (1) Prepares, offers for sale, or serves time/temperature control for safety food:
 - 2486 (a) Only to order upon a consumer's request;
 - 2487 (b) In advance in quantities based on projected consumer demand and discards food
2488 that is not sold or served at an approved frequency; or
 - 2489 (c) Using time as the public health control as specified under 12VAC5-421-850;
 - 2490 (2) Prepares time/temperature control for safety food in advance using a food
2491 preparation method that involves two or more steps which may include combining
2492 time/temperature control for safety food ingredients; cooking; cooling; reheating; hot
2493 or cold holding; freezing; or thawing;

2494 (3) Prepares food as specified under subdivision 3 b (2) of this section for delivery to
2495 and consumption at a location off the premises of the food establishment where it is
2496 prepared;

2497 (4) Prepares food as specified under subdivision 3 b (2) of this section for service to a
2498 highly susceptible population;

2499 (5) Prepares only food that is not time/temperature control for safety food; or

2500 (6) Does not prepare, but offers for sale only prepackaged food that is not
2501 time/temperature control for safety food;

2502 4. The name, title, address, and telephone number of the person directly responsible for
2503 the food establishment;

2504 5. The name, title, address, and telephone number of the person who functions as the
2505 immediate supervisor of the person specified under subdivision 4 of this section such as
2506 the zone, district, or regional supervisor;

2507 6. The names, titles, and addresses of:

2508 a. The persons comprising the legal ownership as specified under subdivision 2 of this
2509 section including the owners and officers; and

2510 b. The local resident agent if one is required based on the type of legal ownership;

2511 7. A statement signed by the applicant that:

2512 a. Attests to the accuracy of the information provided in the application; and

2513 b. Affirms that the applicant will:

2514 (1) Comply with this chapter; and

2515 (2) Allow the ~~regulatory authority~~department access to the establishment as specified
2516 under 12VAC5-421-3820 and to the records specified under 12VAC5-421-440 and
2517 12VAC5-421-2330 and subdivision 4 of 12VAC5-421-3630; and

2518 8. Other information required by the ~~regulatory authority~~department.

2519 **12VAC5-421-3710. New, converted, or remodeled establishments.**

2520 For food establishments that are required to submit plans as specified under 12VAC5-421-
2521 3600 the ~~regulatory authority~~department shall issue a permit to the applicant after:

2522 1. A properly completed application is submitted;

2523 2. Any required fee is submitted;

2524 3. The required plans, specifications, and information are reviewed and approved; and

2525 4. A preoperational inspection as specified in 12VAC5-421-3650 shows that the
2526 establishment is built or remodeled in accordance with the approved plans and
2527 specifications and that the establishment is in compliance with this chapter.

2528 **12VAC5-421-3720. Existing establishments, permit renewal, and change of ownership, or**
2529 **termination.**

2530 A. The ~~regulatory authority~~department may renew a permit for an existing food establishment
2531 or may issue a permit to a new owner of an existing food establishment after a properly completed
2532 application is submitted, reviewed, and approved, any fees are paid, and an inspection shows
2533 that the establishment is in compliance with this chapter.

2534 B. An existing food establishment shall notify the department in writing of a change of legal
2535 ownership or when business operations have terminated. Such notice shall be submitted, in
2536 writing, to the department at least 30 days prior to the legal ownership transfer or termination of
2537 business operation.

2538 **12VAC5-421-3730. Denial of application for permit, notice.**

2539 If an application for a permit to operate is denied, the ~~regulatory authority~~department shall
2540 provide the applicant with a notice that includes:

- 2541 1. The specific reasons and chapter citations for the permit denial;
- 2542 2. The actions, if any, that the applicant must take to qualify for a permit; and
- 2543 3. Advisement of the applicant's right of appeal and the process and time frames for appeal
2544 that are provided in law.

2545 **12VAC5-421-3740. Responsibilities of the ~~regulatory authority~~department.**

2546 A. At the time a permit is first issued, the ~~regulatory authority~~department shall provide to the
2547 permit holder a copy (or opportunity to obtain a copy) of this chapter so that the permit holder is
2548 notified of the compliance requirements and the conditions of retention, as specified under
2549 12VAC5-421-3750, that are applicable to the permit.

2550 B. Failure to provide the information specified in subsection A of this section does not prevent
2551 the ~~regulatory authority~~department from taking authorized action or seeking remedies if the permit
2552 holder fails to comply with this chapter or an order, warning, or directive of the ~~regulatory~~
2553 authority~~department~~.

2554 **12VAC5-421-3750. Responsibilities of the permit holder.**

2555 ~~Upon acceptance of the permit issued~~In order to retain a permit issued by the ~~regulatory~~
2556 authority~~department~~, the permit holder ~~in order to retain the permit~~ shall:

- 2557 1. Post the permit in a location in the food establishment that is conspicuous to consumers;
- 2558 2. Comply with the provisions of this chapter including the conditions of a granted variance
2559 as specified under 12VAC5-421-3590 and 12VAC5-421-3595, and approved plans as
2560 specified under 12VAC5-421-3610;
- 2561 3. If a food establishment is required under 12VAC5-421-3620 to operate under a HACCP
2562 plan, comply with the plan as specified under ~~12VAC5-421-3590~~12VAC5-421-3595;
- 2563 4. Immediately contact the ~~regulatory authority~~department to report an illness of a food
2564 employee or conditional employee as specified under 12VAC5-421-80 B;
- 2565 5. Immediately discontinue operations and notify the ~~regulatory authority~~department if an
2566 imminent health hazard may exist as specified under 12VAC5-421-3910;
- 2567 6. Allow representatives of the ~~regulatory authority~~department access to the food
2568 establishment as specified under 12VAC5-421-3820;
- 2569 7. Replace existing facilities and equipment specified in 12VAC5-421-3510 with facilities
2570 and equipment that comply with this chapter if:
- 2571 a. The ~~regulatory authority~~department directs the replacement because the facilities
2572 and equipment constitute a public health hazard or nuisance or no longer comply with
2573 the criteria upon which the facilities and equipment were accepted;
- 2574 b. The ~~regulatory authority~~department directs the replacement of the facilities and
2575 equipment because of a change of ownership; or
- 2576 c. The facilities and equipment are replaced in the normal course of operation;
- 2577 8. Comply with directives of the ~~regulatory authority~~department including time frames for
2578 corrective actions specified in inspection reports, notices, orders, warnings, and other
2579 directives issued by the ~~regulatory authority~~department in regard to the permit holder's
2580 food establishment or in response to community emergencies;
- 2581 9. Accept notices issued and served by the ~~regulatory authority~~department according to
2582 law; and

2583 10. Be subject to the administrative, civil, injunctive, and criminal remedies authorized in
2584 law for failure to comply with this chapter or a directive of the ~~regulatory~~
2585 ~~authority~~department, including time frames for corrective actions specified in inspection
2586 reports, notices, orders, warnings, and other directives.

2587 11. Notify customers that a copy of the most recent establishment inspection report is
2588 available upon request by:

2589 a. Posting a sign or placard in a location in the food establishment that is conspicuous
2590 to customers; or

2591 b. By another method acceptable to the department.

2592 **12VAC5-421-3770. Summary suspension of a permit.**

2593 The director may summarily suspend a permit to operate a ~~restaurant~~food establishment if
2594 the director finds the continued operation constitutes a substantial and imminent threat to the
2595 public health, ~~except the director may summarily suspend the permit of a temporary restaurant~~
2596 ~~as addressed under 12VAC5-421-3870.~~ Upon receipt of such notice that a permit is suspended,
2597 the permit holder shall cease food operations immediately and begin corrective action.

2598 Whenever a permit is suspended, the holder of the permit or the person in charge shall be
2599 notified in writing by ~~certified~~ mail or by hand delivery. Upon ~~service~~receipt of notice that the permit
2600 is immediately suspended, the former permit holder shall be given an opportunity for an informal
2601 fact-finding conference in accordance with § 2.2-4019 of the Code of Virginia. The request for an
2602 informal fact-finding conference shall be in writing. The written request shall be filed with the local
2603 department by the former holder of the permit. If written request for an informal fact-finding
2604 conference is not filed within 10 working days, the suspension is sustained. Each holder of a
2605 suspended permit shall be afforded an opportunity for an informal fact-finding conference, within
2606 three working days of receipt of a request for the informal fact-finding conference. The director
2607 may end the suspension at any time if the reasons for the suspension no longer exist.

2608 **12VAC5-421-3780. Revocation of a permit.**

2609 The director may, after ~~providing an opportunity for~~conducting an informal fact-finding
2610 conference in accordance with § 2.2-4019 of the Code of Virginia, revoke a permit for ~~flagrant or~~
2611 ~~continuing violation of~~ violation of any of the requirements of this part.

2612 Article 4
2613 Inspection and Correction of Violations

2614 **12VAC5-421-3800. Periodic inspection.**

2615 Food establishments shall be inspected by the ~~designee of the director~~department.
2616 Inspections of the food establishments shall be performed as often as necessary for the
2617 enforcement of this ~~part~~chapter in accordance with the following:

2618 1. Except as specified in subdivisions 2 and 3 of this section, the ~~regulatory~~
2619 ~~authority~~department shall inspect a food establishment at least once every six months.

2620 2. The ~~regulatory authority~~department may increase the interval between inspections
2621 beyond six months if:

2622 a. The food establishment is fully operating under an approved and validated HACCP
2623 plan as specified under 12VAC5-421-3595 and 12VAC5-421-3630;

2624 b. The food establishment is assigned a less frequent inspection frequency based on
2625 an established risk-based inspection schedule uniformly applied throughout the
2626 Commonwealth and updated annually upon reissuance of the annual permit; or

2627 c. The establishment's operation involves only coffee service and other unpackaged
2628 or prepackaged food that is not time/temperature control for safety food, such as
2629 carbonated beverages and snack food such as chips, nuts, popcorn, and pretzels.

2630 3. The ~~regulatory authority~~department shall inspect a temporary food establishment during
2631 its permit period, unless the ~~Virginia Department of Health~~department develops a written
2632 risk-based plan for adjusting the frequency of inspections of temporary food
2633 establishments that is uniformly applied throughout the Commonwealth.

2634 **12VAC5-421-3810. Performance-based and risk-based inspections.**

2635 Within the parameters specified in 12VAC5-421-3800, the ~~regulatory authority~~department
2636 shall ~~prioritize, the and conduct~~conducting of more frequent inspections based upon its
2637 assessment of a food establishment's history of compliance with this chapter and the
2638 establishment's potential as a vector of foodborne illness by evaluating:

- 2639 1. Past performance for nonconformance with this chapter or HACCP plan requirements
2640 that are priority items or priority foundation items;
- 2641 2. Past performance for numerous or repeat violations of this chapter or HACCP plan
2642 requirements that are core items;
- 2643 3. Past performance for complaints investigated and found to be valid;
- 2644 4. The hazards associated with the particular foods that are prepared, stored, or served;
- 2645 5. The type of operation including the methods and extent of food storage, preparation,
2646 and service;
- 2647 6. The number of people served; and
- 2648 7. Whether the population served is a highly susceptible population.

2649 **12VAC5-421-3815. Competency of environmental health specialists.**

2650 A. An authorized representative of the commissioner who inspects a food establishment or
2651 conducts plan review for compliance with this chapter shall have the knowledge, skills, and ability
2652 to adequately perform the required duties. For the purposes of this section, competency shall be
2653 demonstrated when an environmental health specialist meets the training and standardization
2654 requirements ~~as determined by the department specified in the Virginia Department of Health~~
2655 ~~Procedures for Certification and Standardization of Retail Food Protection Staff, 2014, (VDH,~~
2656 ~~Division of Food and Environmental Services).~~

2657 B. The ~~regulatory authority~~department shall ensure that authorized representatives who
2658 inspect a food establishment or conduct plan review for compliance with this chapter have access
2659 to training and continuing education as needed to properly identify violations and apply this
2660 chapter.

2661 **12VAC5-421-3820. Access allowed at reasonable times after due notice.**

2662 After the ~~regulatory authority~~department presents official credentials and provides notice of
2663 the purpose of, and an intent to conduct, an inspection, the person in charge shall allow the
2664 ~~regulatory authority~~department to determine if the food establishment is in compliance with this
2665 chapter by allowing access to the establishment, allowing inspection, and providing information
2666 and records specified in this chapter and to which the ~~regulatory authority~~department is entitled
2667 according to law, during the food establishment's hours of operation and other reasonable times.

2668 **12VAC5-421-3830. Refusal, notification of right to access, and final request for access.**

2669 If a person denies access to the ~~regulatory authority~~department, the ~~regulatory~~
2670 ~~authority~~department shall:

- 2671 1. Inform the person that:
 - 2672 a. The permit holder is required to allow access to the ~~regulatory authority~~department
2673 as specified under 12VAC5-421-3820,
 - 2674 b. Access is a condition of the acceptance and retention of a food establishment permit
2675 to operate as specified under 12VAC5-421-3750 F6, and

2676 c. If access is denied, the commissioner ~~or his designee~~ may apply to an appropriate
2677 circuit court for an inspection warrant authorizing such inspection, testing, or taking
2678 samples for testing as provided in Chapter 24 (§ 19.2-393 et seq.) of Title 19.2 of the
2679 Code of Virginia; and

2680 2. Make a final request for access.

2681 **12VAC5-421-3840. Refusal, reporting.**

2682 If after the ~~regulatory authority~~department presents credentials and provides notice as
2683 specified under 12VAC5-421-3820, explains the authority upon which access is requested, and
2684 makes a final request for access as specified in 12VAC5-421-3830, the person in charge
2685 continues to refuse access, the ~~regulatory authority~~department shall provide details of the denial
2686 of access on an inspection report form.

2687 **12VAC5-421-3850. Inspection warrants.**

2688 If denied access to a food establishment for an authorized purpose and after complying with
2689 12VAC5-421-3830, the commissioner ~~or his designee~~ may apply to an appropriate circuit court
2690 for an inspection warrant authorizing such inspection, testing, or taking samples for testing as
2691 provided in Chapter 24 (§ 19.2-393 et seq.) of Title 19.2 of the Code of Virginia.

2692 **12VAC5-421-3860. Documenting information and observations.**

2693 The ~~regulatory authority~~department shall document on an inspection report form:

2694 1. Administrative information about the food establishment's legal identity, street and
2695 mailing addresses, type of establishment and operation as specified under 12VAC5-421-
2696 3700, inspection date, and other information such as type of water supply and sewage
2697 disposal, status of the permit, and personnel certificates that may be required; and

2698 2. Specific factual observations of violative conditions or other deviations from this chapter
2699 that require correction by the permit holder including:

2700 a. Failure of the person in charge to demonstrate the knowledge of foodborne illness
2701 prevention, application of HACCP principles, and the requirements of this chapter
2702 specified under 12VAC5-421-60;

2703 b. Failure of food employees, conditional employees, and the person in charge to
2704 report a disease or medical condition as specified under 12VAC5-421-80 B and D;

2705 c. Nonconformance with priority ~~items or~~ priority foundation, or core items of this
2706 chapter;

2707 d. Failure of the appropriate food employees to demonstrate their knowledge of, and
2708 ability to perform in accordance with, the procedural, monitoring, verification, and
2709 corrective action practices required by the ~~regulatory authority~~department as specified
2710 under 12VAC5-421-60;

2711 e. Failure of the person in charge to provide records required by the ~~regulatory~~
2712 ~~authority~~department for determining conformance with a HACCP plan as specified
2713 under subdivision 4 f of 12VAC5-421-3630; and

2714 f. Nonconformance with critical limits of a HACCP plan.

2715 **12VAC5-421-3870. Specifying time frame for corrections.**

2716 The ~~regulatory authority~~department shall specify on the inspection report form the time frame
2717 for correction of the violations as specified under 12VAC5-421-3910, 12VAC5-421-3930, and
2718 12VAC5-421-3950. ~~In the case of temporary food establishments, all violations shall be corrected~~
2719 ~~within a maximum of 24 hours or the permit shall be suspended. The establishment shall~~
2720 ~~immediately cease food service operations until authorized to resume by the director.~~

2721 **12VAC5-421-3880. Issuing report and obtaining acknowledgment of receipt.**

2722 At the conclusion of the inspection and according to law, the ~~regulatory authority~~department
2723 shall provide a copy of the completed inspection report and the notice to correct violations to the
2724 permit holder or to the person in charge, and request a signed acknowledgment of receipt.

2725 **12VAC5-421-3890. Refusal to sign acknowledgment.**

2726 The ~~regulatory authority~~department shall:

2727 1. Inform a person who declines to sign an acknowledgment of receipt of inspectional
2728 findings as specified in 12VAC5-421-3880 that:

2729 a. An acknowledgment of receipt is not an agreement with findings,

2730 b. Refusal to sign an acknowledgment of receipt will not affect the permit holder's
2731 obligation to correct the violations noted in the inspection report within the time frames
2732 specified, and

2733 c. A refusal to sign an acknowledgment of receipt is noted in the inspection report and
2734 conveyed to the ~~regulatory authority's~~department's historical record for the food
2735 establishment; and

2736 2. Make a final request that the person in charge sign an acknowledgment receipt of
2737 inspectional findings.

2738 **12VAC5-421-3900. Public records.**

2739 Except as specified in 12VAC5-421-3640, the ~~regulatory authority~~department shall treat the
2740 inspection report as a public record and shall make it available for disclosure to a person who
2741 requests it as provided in law.

2742 **12VAC5-421-3910. Imminent health hazard, ceasing operations and reporting.**

2743 A. Except as specified in subsection B and C of this section, a permit holder shall immediately
2744 discontinue operations and notify the ~~regulatory authority~~department if an imminent health hazard
2745 may exist because of an emergency such as a fire, flood, extended interruption of electrical or
2746 water service, sewage backup, misuse of poisonous or toxic materials, onset of an apparent
2747 foodborne illness outbreak, gross insanitary occurrence or condition, or other circumstance that
2748 may endanger public health.^P

2749 B. A permit holder need not discontinue operations in an area of an establishment that is
2750 unaffected by the imminent health hazard.

2751 C. Considering the nature of the potential hazard involved and the complexity of the corrective
2752 action needed, the department may agree to continuing operations in the event of an extended
2753 interruption of electrical or water service if:

2754 1. A written emergency operating plan has been approved by the department;

2755 2. Immediate corrective action is taken to eliminate, prevent, or control any food safety
2756 risk and imminent health hazard associated with the electrical or water service interruption;
2757 and

2758 3. The department is informed upon implementation of the written emergency operating
2759 plan.

2760 **12VAC5-421-3920. Resumption of operations.**

2761 If operations are discontinued as specified under 12VAC5-421-3910 or otherwise according
2762 to law, the permit holder shall obtain approval from the ~~regulatory authority~~department before
2763 resuming operations.

2764 **12VAC5-421-3930. Timely correction.**

2765 A. Except as specified in subsection B of this section, a permit holder shall at the time of
2766 inspection correct a priority item or priority foundation item in this chapter and implement
2767 corrective actions for a HACCP plan provision that is not in compliance with its critical limit. ^{Pf}

2768 B. Considering the nature of the potential hazard involved and the complexity of the corrective
2769 action needed, the ~~regulatory authority~~department may agree to or specify a longer timeframe,
2770 not to exceed:

2771 1. 72 hours after the inspection for the permit holder to correct priority items; or

2772 2. 10 calendar days after the inspection for the permit holder to correct priority foundation
2773 items or HACCP plan deviations.

2774 C. In the case of temporary food establishments, priority items shall be corrected within a
2775 maximum of 24 hours after inspection.

2776 **12VAC5-421-3940. Verification and documentation of correction.**

2777 A. After observing at the time of inspection a correction of a priority item, ~~or~~ priority foundation
2778 item, or a HACCP plan deviation, the ~~regulatory authority~~department shall enter the observation
2779 and information about the corrective action on the inspection report.

2780 B. As specified under 12VAC5-421-3930 B, after receiving notification that the permit holder
2781 has corrected a priority item, ~~or~~ priority foundation item, or a HACCP plan deviation, or at the end
2782 of the specified period of time, the ~~regulatory authority~~department shall verify correction,
2783 document the information on an inspection report, and enter the report in the ~~regulatory~~
2784 authority's~~department~~ records.

2785 **12VAC5-421-3950. Core item, timeframe for correction.**

2786 A. Except as specified in subsection B of this section, the permit holder shall correct core
2787 items by a date and time agreed to or specified by the ~~regulatory authority~~department but no later
2788 than 90 calendar days after the inspection.

2789 B. The ~~regulatory authority~~department may approve a compliance schedule that extends
2790 beyond the time limits specified under subsection A of this section if a written schedule of
2791 compliance is submitted by the permit holder and no health hazard exists or will result from
2792 allowing an extended schedule for compliance.

2793 **12VAC5-421-3960. Examination for condemnation of food. (Repealed.)**

2794 ~~Food may be examined or sampled by the department as often as necessary for enforcement~~
2795 ~~of this chapter. Also, the department may, upon written notice to the owner or permit holder or~~
2796 ~~person in charge impound any food which it believes is in violation of Part III (12VAC5-421-260~~
2797 ~~et seq.) or any other section of this chapter. The department shall tag, label, or otherwise identify~~
2798 ~~any food subject to impoundment. No food under conditions specified in the impoundment shall~~
2799 ~~be used, served or moved from the establishment. The department shall permit storage of the~~
2800 ~~food under conditions specified in the impoundment unless storage is not possible without risk to~~
2801 ~~the public health in which case immediate destruction shall be accomplished by the owner or~~
2802 ~~permit holder or person in charge. The impoundment shall state that a request for an informal~~
2803 ~~fact-finding conference may be filed within 10 days and that if no conference is requested, the~~
2804 ~~food shall be destroyed by the owner or permit holder or person in charge. The department shall~~
2805 ~~hold an informal fact-finding conference if so requested, and on the basis of evidence produced~~
2806 ~~at the hearing, the impoundment may be vacated, or the owner or permit holder or person in~~
2807 ~~charge of the food may be directed in writing by the director to denature or destroy such food or~~
2808 ~~to bring it into compliance with the provisions of this chapter.~~

2809 **12VAC5-421-3961. Hold Order, Justifying Conditions and Removal of Food.**

2810 Upon written notice to the owner, permit holder, or person in charge, the department may
2811 place a hold order on food that:

- 2812 1. Originated from an unapproved source;
2813 2. May be unsafe, adulterated, or not honestly presented; or
2814 3. Is not otherwise in compliance with this chapter.

2815 **12VAC5-421-3962. Hold Order, Contents.**

2816 The hold order notice shall:

- 2817 1. State food subject to the order may not be used, sold, moved from the food
2818 establishment, or destroyed without a written release of the order from the department;
2819 2. State the specific reasons for placing the food under the hold order with reference to
2820 the applicable provisions of this chapter and the hazard or adverse effect created by the
2821 observed condition;
2822 3. Sufficiently identify the food subject to the hold order by the common name, the label
2823 information, a container description, quantity, department's tag or identification
2824 information, and location; and
2825 4. Notify the permit holder of the right to request an informal fact-finding conference
2826 pursuant to the Virginia Administrative Process Act (§ 2.2-4000 et seq. of the Code of
2827 Virginia) within ten calendar days of receipt of the hold order notice. Otherwise, the food
2828 under the hold order shall be destroyed by the owner, permit holder, or the person in
2829 charge.

2830 **12VAC5-421-3963. Hold Order, Official Tagging of Food.**

2831 A. The department shall securely place an official tag or label on the food or containers or
2832 otherwise conspicuously identify food subject to the holder order.

2833 B. The tag or label use to identify a food that is subject of a hold order shall include a summary
2834 of the provisions specified in 12VAC5-421-3962 and shall be signed and dated by the department.

2835 C. Only the department may remove hold order tags, labels, or other identification from food
2836 subject to a hold order.

2837 **12VAC5-421-3964. Hold Order, Food May Not Be Used or Moved.**

2838 A. Except as specified in subsection B of this section, food placed under a hold order may not
2839 be used, sold, served, or moved from the food establishment.

2840 B. The department may allow the permit holder to store the food in an area of the food
2841 establishment if the food is protected from subsequent deterioration.

2842 **12VAC5-421-3965. Appeals, Releasing Hold Order.**

2843 A. Any appeal of a hold order must be made in writing and received by the department within
2844 ten calendar days of receipt of the hold order.

2845 B. The department shall issue a notice of release from a hold order and shall remove hold
2846 tags, labels, or other identification from the food if the hold order is lifted.

2847 **12VAC5-421-3966. Destroying or Denaturing Food.**

2848 The department may order the permit holder to bring food under a hold order into compliance
2849 with this chapter or to destroy or denature food if:

- 2850 1. Following an informal fact-finding conference held pursuant to the Virginia
2851 Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia) the director affirms
2852 the hold order; or

2853 2. The permit holder fails to file an appeal within ten calendar days of receipt of the hold
2854 order notice.

2855 **12VAC5-421-3970. Enforcement of regulation.**

2856 ~~A. This chapter shall be enforced by the State Board of Healthboard and the State Health~~
2857 ~~Commissionercommissioner, as executive officer of the board.~~

2858 ~~B.A. The directors are appointed by the board and commissioner as duly designated officers~~
2859 ~~and a department is responsible for the implementation and enforcement of this chapter.~~

2860 ~~C. All food establishments shall operate in compliance with the requirements set forth in this~~
2861 ~~chapter and shall not operate without a valid permit.~~

2862 ~~D. The commissioner shall be vested with all the authority of the board when it is not in~~
2863 ~~session, subject to such rules and regulations as may be prescribed by the board.~~

2864 ~~E.B~~ Pursuant to the authority granted in §§ 32.1-26 and 35.1-6 of the Code of Virginia, the
2865 commissioner may issue orders to require any owner or permit holder or other person to comply
2866 with the provisions of this chapter. The order may require the following:

- 2867 1. The immediate cessation and correction of the violation;
- 2868 2. Appropriate remedial action to ensure that the violation does not continue or recur;
- 2869 3. The submission of a plan to prevent future violations;
- 2870 4. The submission of an application for a variance; and
- 2871 5. Any other corrective action deemed necessary for proper compliance with the
- 2872 regulations.

2873 ~~F.C.~~ The commissioner may act as the agent of the board to enforce all effective orders and
2874 this chapter. Should any owner or permit holder fail to comply with any effective order or this
2875 chapter, the commissioner may:

- 2876 1. Institute a proceeding to revoke the owner's or permit holder's permit in accordance
- 2877 with 12VAC5-421-3780;
- 2878 2. Request the attorney for the Commonwealth to bring a criminal action;
- 2879 3. Request the Attorney General to bring an action for civil penalty, injunction, or other
- 2880 appropriate remedy; or
- 2881 4. Do any combination of the above.

2882 ~~G. Not exclusive means of enforcement.~~ D. Nothing contained in this section shall be
2883 interpreted to require the commissioner to issue an order prior to seeking enforcement of any
2884 regulations or statute through an injunction, mandamus or criminal prosecution.

2885 ~~H.E.~~ Proceedings before the commissioner or his designee shall include any of the following
2886 forms depending on the nature of the controversy and the interests of the parties involved.

- 2887 1. Informal fact-finding conferences. An informal fact-finding conference is a meeting with
- 2888 a district or local health department with the ~~district or local health~~ director presiding and
- 2889 held in conformance with § 2.2-4019 of the Code of Virginia.
- 2890 2. Adjudicatory hearing. The adjudicatory hearing is a formal, public adjudicatory
- 2891 proceeding before a hearing officer as defined by § 2.2-4001 of the Code of Virginia, and
- 2892 held in conformance with § 2.2-4020 of the Code of Virginia.

2893 **12VAC5-421-4010. Penalties, injunctions, civil penalties and charges for violations.**
2894 **(Repealed.)**

2895 ~~1. Any person willfully violating, or refusing, failing, or neglecting to comply with any~~
2896 ~~regulations or order of the board or commissioner, or any provision of this title, shall be guilty of~~
2897 ~~a Class 3 misdemeanor unless a different penalty is specified. Each day of violation shall~~
2898 ~~constitute a separate offense.~~

2899 ~~2. Any person violating, or failing, neglecting, or refusing to obey any order of the board or~~
2900 ~~commissioner, or any provision of this part may be compelled, in a proceeding instituted in an~~
2901 ~~appropriate court by the board or commissioner, to obey and comply with such regulations, order,~~
2902 ~~or any applicable provision of Title 35.1 of the Code of Virginia. The proceeding may be by~~
2903 ~~injunction, mandamus, or other appropriate remedy.~~

2904 ~~3. Without limiting the remedies which may be obtained pursuant to the above subsection,~~
2905 ~~any person violating or failing, neglecting, or refusing to obey any injunction, mandamus, or other~~
2906 ~~remedy obtained pursuant to the above subsection shall be subject, in the discretion of the court,~~
2907 ~~to a civil penalty not to exceed ten thousand dollars for each violation. Each day of violation shall~~
2908 ~~constitute a separate offense.~~

2909 ~~4. With the consent of any person who has violated or failed, neglected or refused to obey~~
2910 ~~any regulation or order of the board or commissioner or any applicable provision of Title 35.1, the~~
2911 ~~board may provide, in an order issued by the board against such person, for the payment of civil~~
2912 ~~charges for past violations in specific sums not to exceed the limit set forth in the above~~
2913 ~~subsection. Such civil charges shall be in place of any appropriate civil penalty which could be~~
2914 ~~imposed under the above subsection.~~

2915 **12VAC5-421-4020. Compliance with the Uniform Statewide Building Code.**

2916 All buildings or structures utilized as ~~restaurants~~food establishments constructed prior to the
2917 effective date of the Virginia Uniform Statewide Building Code shall be maintained in conformance
2918 with the Virginia Fire Safety Law or other code in effect at the time of construction.

2919 **12VAC5-421-4035. Exempt facilities that choose to be regulated. (Repealed.)**

2920 Exempt facilities, as defined in subdivision 6 of 12VAC5-421-10 of the definition of a "food
2921 establishment" and subdivision A 7 of 12VAC5-421-3560, that choose to be regulated by this
2922 chapter, shall be exempt from the following requirements:

2923 1. In lieu of 12VAC5-421-1200, home model dishwashers may be used in lieu of manual
2924 cleaning and drying of utensils;

2925 2. 12VAC5-421-1340, the requirement for internal baffles in warewashing machines does
2926 not apply to home model dishwashers;

2927 3. 12VAC5-421-1350, the requirement for temperature measuring devices does not apply
2928 to home model dishwashers;

2929 4. 12VAC5-421-1360, manual warewashing equipment, heaters and baskets are not
2930 required but manual warewashing shall include, as a minimum, thorough washing with
2931 adequate soap or detergent, thorough rinsing, and drying before storage or use. Drying
2932 may be by clean towels used for no other purpose;

2933 5. 12VAC5-421-1370, the requirement for a sanitizer level indicator does not apply to
2934 home model dishwashers;

2935 6. 12VAC5-421-1380, the requirement for flow pressures device does not apply to home
2936 model dishwashers;

2937 7. 12VAC5-421-1460, the requirement for sink compartments does not apply to exempt
2938 facilities. It shall include thorough washing with adequate soap or detergent, thorough
2939 rinsing, and drying before storage or use. Drying may be by clean towels used for no other
2940 purpose;

2941 8. 12VAC5-421-1520, temperature measuring devices for manual warewashing are not
2942 required;

2943 9. 12VAC5-421-1530, sanitizing solutions testing devices are not required;

- 2944 ~~10. 12VAC5-421-1620, warewashing sinks in exempt facilities may be used for~~
 2945 ~~handwashing, however, approved dispensers, soap, and single-use paper towels are~~
 2946 ~~provided;~~
- 2947 ~~11. 12VAC5-421-1640, clean solutions in warewashing equipment is not required for~~
 2948 ~~exempt facilities. It shall include, as a minimum, thorough washing with adequate soap or~~
 2949 ~~detergent, thorough rinsing, and drying before storage or use. Drying may be by clean~~
 2950 ~~towels used for no other purpose;~~
- 2951 ~~12. 12VAC5-421-1660, minimum wash solution temperature for mechanical warewashing~~
 2952 ~~equipment shall not be required for home model dishwashers;~~
- 2953 ~~13. 12VAC5-421-1670, minimum hot water sanitization temperatures for manual~~
 2954 ~~warewashing equipment shall not be required;~~
- 2955 ~~14. 12VAC5-421-1680, minimum hot water sanitization temperatures for mechanical~~
 2956 ~~warewashing equipment shall not be required for home model dishwashers;~~
- 2957 ~~15. 12VAC5-421-1690, sanitization pressure for mechanical warewashing equipment~~
 2958 ~~shall not be required;~~
- 2959 ~~16. 12VAC5-421-1700, minimum and maximum pressure, pH, sanitizer concentration,~~
 2960 ~~and hardness levels shall not be required for home model dishwashers;~~
- 2961 ~~17. 12VAC5-421-1710, chemical sanitization for manual warewashing using detergent~~
 2962 ~~sanitizers shall not be required;~~
- 2963 ~~18. 12VAC5-421-1720, determination of chemical sanitizer concentration shall not be~~
 2964 ~~required;~~
- 2965 ~~19. 12VAC5-421-1885, food contact surfaces and utensils shall not be required to be~~
 2966 ~~sanitized;~~
- 2967 ~~20. 12VAC5-421-1890, before use after cleaning, utensils and food contact surfaces shall~~
 2968 ~~not be required to be sanitized;~~
- 2969 ~~21. 12VAC5-421-1900, hot water and chemical sanitizing shall not be required;~~
- 2970 ~~22. 12VAC5-421-2790, floors, walls, and ceilings shall be in good repair and kept clean;~~
- 2971 ~~23. 12VAC5-421-2810, floors, walls, and ceilings in exempt facilities shall not be required~~
 2972 ~~to meet the cleanability requirements but shall be in good repair and kept clean;~~
- 2973 ~~24. 12VAC5-421-2820, the prohibition of exposed utility service lines and pipes shall not~~
 2974 ~~apply;~~
- 2975 ~~25. 12VAC5-421-2840, floor carpeting in exempt facilities may be installed in food~~
 2976 ~~preparation areas, walk-in refrigerators, warewashing areas, toilet rooms, refuse storage~~
 2977 ~~rooms or other areas, however they shall be kept in good repair and kept clean;~~
- 2978 ~~26. 12VAC5-421-2850, floor covering, mats and duckboards may be used in exempt~~
 2979 ~~facilities, however, they shall be kept clean and in good repair.~~
- 2980 ~~27. 12VAC5-421-2870, attachments to walls and ceilings in exempt facilities shall be kept~~
 2981 ~~in good repair and kept clean;~~
- 2982 ~~28. 12VAC5-421-3130, approved dispensers, soap and single-use paper towels shall be~~
 2983 ~~made available to accommodate hand washing;~~
- 2984 ~~29. 12VAC5-421-3310, live animals may be allowed in the facility but shall not be fed using~~
 2985 ~~the same equipment or utensils that are used to feed humans.~~

2986 12VAC5-421-4040. Investigation and control, obtaining information: personal history of
 2987 **illness, medical examination, and specimen analysis.**

2988 The regulatory authority department shall act when it has reasonable cause to believe that a
 2989 food employee or conditional employee has possibly transmitted disease; may be infected with a

2990 disease in a communicable form that is transmissible through food; may be a carrier of infectious
2991 agents that cause a disease that is transmissible through food; or is affected with a boil, an
2992 infected wound, or acute respiratory infection, by:

- 2993 1. Securing a confidential medical history of the employee suspected of transmitting
2994 disease or making other investigations as deemed appropriate; and
2995 2. Requiring appropriate medical examinations, including collection of specimens for
2996 laboratory analysis, of a suspected ~~employee and other employees.~~ food employee or
2997 conditional employee.

2998 **12VAC5-421-4050. Restriction or exclusion of food employee, or summary suspension of**
2999 **permit.**

3000 Based on the findings of an investigation related to a food employee or conditional employee
3001 who is suspected of being infected or diseased, the ~~regulatory authority~~department may issue an
3002 order to the suspected food employee, conditional employee, or permit holder instituting one or
3003 more of the following control measures:

- 3004 1. Restricting the food employee or conditional employee;
3005 2. Excluding the food employee or conditional employee; or
3006 3. Closing the food establishment by summarily suspending a permit to operate in
3007 accordance with law.

3008 **12VAC5-421-4060. Restriction or exclusion order: warning or hearing not required,**
3009 **information required in order.**

3010 Based on the findings of the investigation as specified in 12VAC5-421-4040 and to control
3011 disease transmission, the ~~regulatory authority~~department may issue an order of restriction or
3012 exclusion to a suspected food employee or the permit holder without prior warning, notice of a
3013 hearing, or a hearing if the order:

- 3014 1. States the reasons for the restriction or exclusion that is ordered;
3015 2. States the evidence that the food employee or permit holder shall provide in order to
3016 demonstrate that the reasons for the restriction or exclusion are eliminated;
3017 3. States that the suspected food employee or the permit holder may request an appeal
3018 hearing by submitting a timely request as provided in law; and
3019 4. Provides the name and address of the ~~regulatory authority~~department representative to
3020 whom a request for an appeal hearing may be made.

3021

Board of Health Annual Report: Virginia's Plan for Well-Being, 2019

Introduction

The Plan for Well-Being outlines a path for improving the health and well-being of Virginians through four aims, 13 goals, and 29 measures. The 2019 Annual Report indicates the updated figure for each measure in The Plan, with the most current data available. In some instances, this year's report also includes additional analysis of metrics, to better understand any disparities or trends in subpopulations. This year, the Annual Report also includes a "Health Equity Brief" that highlights examples of efforts to improve health equity throughout the Commonwealth. Lastly, the enclosed technical document provides more detail on values, data sources, and descriptions of each measure.

Of the 29 measures, when compared to baseline measures reported in 2016, 16 show improvement, although at different degrees. Of these, four measures (Percent of Adults Who Report Positive Well-Being, Disability-Free Life Expectancy, Percent of High School Graduates Enrolled in an Institution of Higher Learning, and Teen Pregnancy Rates) have exceeded the goal that was originally set forth in The Plan. The remaining 13 measures persist as areas of needed focus, in that they have evidenced little to no change, or in some cases, have decreased further away from the intended goal.

It is important to recognize the measures in The Plan provide high level, statewide data. Therefore, in some instances these statewide data will obscure racial, geographic or other disparities. For example, although the black infant mortality rate in and of itself is improving, the disparity between black infant mortality and white infant mortality persists. Similarly, the consumer opportunity measure differs when comparing rural vs. urban communities. There is also disparity in that measure by race. These are examples indicating that much work remains, even in areas where metrics are improving.

Improving Measures:

- Percent of Adults Who Report Positive Well Being
- Percent of High School Graduates Enrolled in an Institution of Higher Education within 16 months after graduation
- Percent of Cost Burdened Households
- Consumer Opportunity: Townsend Material Deprivation Index
- Percent of Health Districts that Have Established a Collaborative Community Health Planning Process
- Pregnancies Per 1,000 Females Ages 15-19 years old
- Black Infant Deaths Per 1,000 Black Live Births
- Percent of Households That Are Food Insecure For Some Part of the Year
- Percent of Adults Who Currently Use Tobacco
- Percent of Adolescent Girls Who Receive Two Doses of HPV Vaccine
- Percent of Adolescent Boys Who Receive Two Doses of HPV Vaccine
- Average Years of Disability Free Life Expectancy
- Percent of Healthcare Providers Who Have Implemented a Certified Electronic Health Record

- Number of Entities Connected through Connect Virginia, HIE, and The Electronic HIE and the National e-Health exchange
- Percent of hospitals that meet the State Goal for Prevention of Hospital-Onset *Clostridium difficile* Infections

Areas of Needed Improvement (Little to no change or moving away from the goal):

- Economic Opportunity Index: Gini Income Inequality Index
- Percent of Children who do not meet the PALS-K Benchmark
- Percent of Third-Graders who pass the Standards of Learning Reading Assessment
- Percent of Adults Who Did Not Participate in Any Physical Activity During the Past 30 days
- Percent of Adults who are Overweight or Obese
- Percent of Adults Who Receive an Annual Influenza Vaccine
- Percent of Adults Who Receive a Colorectal Cancer Screening
- Percent of Adults who Report at least one Adverse Childhood Experience (ACE)
- Percent of Adults who have a regular health care provider
- Rate of Avoidable Hospital Stays for Ambulatory Care Sensitive Conditions
- Rate of Avoidable Deaths from Heart Disease, Stroke or Hypertensive Disease
- Rate of Mental Health and Substance Use Disorder Hospitalizations
- Percent of Adults Who Report Having 1+ Days of Poor Health
- Number of local health districts that have an electronic health record (EHR)

Well-Being

Well-being in Virginia is improving; over 73% of adults report positive well-being in 2018 compared to 68% in 2016. Well-being is an indicator of life satisfaction, defined as living an ideal life in excellent conditions and having the important things desired in life. This measure gives us a general context to the areas of improvement and focus within the four aims of the Plan for Well-Being.

AIM 1 — Healthy, Connected Communities

Goal 1.1: Virginia’s Families Maintain Economic Stability

Economic stability for families is a critical aspect of health and well-being as individuals and in communities. Social conditions that promote equitable economic stability include education, affordable housing, employment, transportation, and adequate income. In many ways, Virginia families and communities are improving yet inequalities exist and should remain areas of focus.

- The percentage of high school graduates enrolled in an institution of higher education within 16 months after graduation has increased to 77.7%, above the 2020 goal of 75%.
- The percentage of cost-burdened households (more than 30% of monthly income spent on housing costs) has decreased to 28.5%, below the 2020 goal of 29%.
- The Townsend Material Deprivation Index score decreased from 4.06 in 2014 to 3.94 in 2017, indicating that unemployment, overcrowding, non-car ownership, and non-home ownership has marginally improved.
- The Gini Income Inequality Index trend indicates a stagnant mean from 39.20 in 2014 to 39.91 in 2017.

“Cost-burdened households” are those that spend more than 30% of their monthly income on housing costs. Table 1 indicates that of those households making less than \$20,000 per year, 82% are considered

cost-burdened, compared to only 8% of households that earn \$75,000 or more. The majority (67%) of these higher earning households spend less than 20% on housing costs as a percent of their household income. The overall statewide percentage of cost-burdened households may be generally decreasing, but these data by income level indicate there is significant disparity and inequity when it comes to affordable housing in Virginia.

Table 1: Monthly Housing Cost as a Percent of Household Income, Virginia, 2017
 Source: U.S. Census, American Community Survey

Monthly Housing Cost as a Percent of Household Income (2017)			
Income Level	Less than 20 percent	20 to 29 percent	30 percent or more
Less than \$20,000	7.3	11.2	81.5
\$20,000 to \$34,999	20.3	16.3	63.4
\$35,000 to \$49,999	29.4	25.4	45.2
\$50,000 to \$74,999	38.9	32.0	29.1
\$75,000 or more	66.6	25.4	8.0

Affordable and equitable housing is a primary driver of economic stability for Virginia families, and there is significantly more to be done. As part of this effort, VDH partners with the Virginia Department of Housing and Community Development (VDHCD) by participating in its Permanent Supportive Housing Steering Committee, the Housing People with Serious Mental Illness Strategy Group, and its Interagency Leadership Team. In 2019, the Virginia Department of Health (VDH) successfully competed for a Pew Charitable Trusts grant to improve maternal and infant outcomes with a focus on health equity. Through this grant, and together with DMAS and DCHD, VDH will develop a project will be developed to address the intersection of maternal health and housing.

Goal 1.2: Virginia’s Communities Collaborate to Improve the Population’s Health

All local health districts have completed or participated in some form of a community health assessment or improvement/strategic planning process since 2016. This has enabled better understanding of the capacity and resources needed to address priority health issues and populations. Issues identified across many community health assessments include obesity, smoking, behavioral health, chronic diseases, as well as integrated healthcare, continuum of care and strategies to address cultural, economic, geographic and racial health disparities.

Partnering for a Healthy Virginia

To complement the community health assessment and improvement planning processes at the local level, statewide planning and improvement activities provide guidance and alignment where it makes sense. Founded by VDH and the Virginia Hospital and Healthcare Association (VHHA) in April 2018, Partnering for a Healthy Virginia (PHV) is Virginia’s state-level population health improvement collaborative. PHV has grown to include over 25 partner organizations, including stakeholders from local health districts, hospitals, community health coalitions, businesses, and foundations. The goal of PHV is to ensure that every Virginian has a fair and equitable opportunity to achieve optimal health, making Virginia the healthiest state in the nation. In 2019, PHV continued its work towards population health improvement and established three strategic focal areas:

- Encourage collaborative, evidence based investments to improve population health
- Foster multi-sector collaboration to help connect patients with the social supports needed to optimize their health
- Use and share enhanced data to help clearly define root causes and their effect on health

Population Health Assessment and Improvement Learning Collaborative

Under PHV, a Population Health Assessment and Improvement Learning Collaborative has taken shape. The Collaborative initiated on October 2, 2019 and will focus on eight aims over the course of the next year through webinars and in-person meetings to bridge local health departments and hospitals together on assessing and improving the health and well-being with their communities.

1. A vision for strategic collaboration
2. An internal team strategy
3. Efficient pathways for data development
4. Efficient methods for obtaining community input
5. Efficient formats for reporting
6. Effective strategies for action planning
7. Evidence-informed intervention models
8. Effective strategies for evaluation

State Health Assessment and Improvement Plan (SHAIP)

The State Health Assessment and Improvement Plan process kicked off with a meeting of the Advisory Council on November 20, 2019. Using a framework grounded in health equity, the Advisory Council will undertake assessing the Commonwealth's primary health problems and identify strategies to address the root causes. This work is also supported by PHV. The goal is to introduce the next version of the Plan for Well-Being in January 2021.

AIM 2 — Strong Start for Children

Goal 2.1: Virginians Plan Their Pregnancies

Teen pregnancy continues to decline, reaching an all-time low at 19.7 per 1,000 females ages 15 to 19 years old (2017). VDH attributes this to many influences, including education and contraception.

VDH supports or administers several programs aimed at reducing unintended pregnancy, some examples include:

- VDH's Adolescent Health Program offers evidence-based, positive youth development programs designed to promote healthy outcomes among teens. Some examples include Project AIM (Adult Identity Mentoring), Teen Outreach Program (TOP), and Resource Mothers, a program for pregnant and parenting teens.
- The Virginia Long Acting Reversible Contraception (LARC) Initiative is a two-year pilot program designed to increase access to hormonal LARCs to uninsured, low-income women, with the goal of reducing unintended pregnancies and improving birth outcomes. Funded through federal TANF funds allocated by the Virginia General Assembly, the LARC Initiative reimburses eighteen health providers for offering LARC insertions and removals to eligible patients. During the first year, the LARC Initiative has served over 1,000 women. VDH coordinates the LARC Workgroup, a network of agencies working towards reducing unintended pregnancies among women of childbearing age and increasing access to quality, comprehensive family planning services.

- Through Title V funding, VDH’s text program provides an opportunity for youth to obtain accurate, objective information about sex, sexuality, relationships, pregnancy, sexually transmitted infections, and other sensitive topics. VDH partners with the American Sexual Health Association (ASHA) to provide this service to Virginia teens. In the upcoming year, VDH’s Adolescent Health program will include youth advisory councils and comprehensive sex education initiatives.
- VDH’s Title X Family Planning program provides comprehensive family planning services at approximately 140 clinical sites across the Commonwealth, including 34 local health districts and three federally qualified health centers. As the nation’s only federally funded family planning program, Title X provides structure, funding, and technical support to funded sites so patients receive quality family planning services according to CDC guidelines. VDH is Virginia’s sole Title X grantee. VDH’s Title X program serves approximately 38,000 patients each year.

Goal 2.2: Virginia’s Children Are Prepared to Succeed in Kindergarten

Children not meeting the PALS-K benchmarks in the fall of Kindergarten has increased. In 2014-2015, 12.7% of students needed literacy interventions, which rose to 17.0% in 2018-2019. This measure is also an indicator of Kindergarten readiness, placing an emphasis on preschool enrollment and participation during the early childhood years. Healthy children are more ready to learn. To support the connection between health and education, VDH serves on many cross agency committees, including the Leadership Council for Home Visiting, and the School Readiness Committee of the Governor's Children's Cabinet; these groups address the myriad of drivers that impact children's health, including school readiness and food security.

The Plan also monitors the percentage of third-graders who pass the Standards of Learning (SOL) reading assessment. This measure has shown minimal improvement, from 69% (2014-2015) to 71% (2018-2019). The downward trend in the kindergarten measure and the stagnant nature of the third-grade metric are consistent with the national decline in reading proficiency. The National Center for Education Statistics released the [2019 Nation’s Report Card](#), which noted that two out of three fourth- and eighth-graders do not meet the standards for reading proficiency. Pass rates on SOL reading assessment are lowest among Black third graders at 56.5% and highest among Asian third graders at 92.9%. There are cultural, social and economic factors that contribute to this disparity, and VDH will continue to collaborate with the Virginia Department of Education and other partners.

Table 2: Third-Grade Standards of Learning (SOL) Pass Rate, Virginia, 2018-19 School Year

Source: Virginia Department of Education

School Year	Subject	Race	Test Level	Test Source	Pass Rate
2018-2019	Reading	Asian	Grade 3	SOL	92.9
2018-2019	Reading	Hispanic	Grade 3	SOL	76.0
2018-2019	Reading	White, not of Hispanic origin	Grade 3	SOL	74.4
2018-2019	Reading	Native Hawaiian or Pacific Islander	Grade 3	SOL	65.2
2018-2019	Reading	American Indian or Alaska Native	Grade 3	SOL	59.7
2018-2019	Reading	Black, not of Hispanic origin	Grade 3	SOL	56.5

Goal 2.3: The Racial Disparity in Virginia’s Infant Mortality Rate is Eliminated

The infant mortality rate among Black infants has improved from 12.2 in 2013 to 9.6 deaths per 1,000 Black live births in 2017. This decrease is an encouraging trend; however, there is still disparity in comparison to the infant mortality rate among White infants. In 2017, there were 4.4 deaths per 1,000 White live births, thus perpetuating the disparity.

In the Tidewater and Petersburg communities, the Healthy Start home visiting program is a resource available to families at risk for poor birth outcomes. Healthy Start specifically focuses on reducing infant mortality and perinatal health disparities by providing high quality prevention strategies to individuals, families and communities. Additionally, quality improvement efforts are underway in health systems across the Commonwealth through the work of the Virginia Neonatal Perinatal Collaborative (VNPC) to ensure every baby has the best start to life. Current efforts focus on providing evidence based care to infants with neonatal abstinence syndrome and advancing antibiotic stewardship. The slow but steady improvement evidenced in infant mortality validates these efforts but there is much work to be done to keep moms and babies healthy through pregnancy and postpartum, and to achieve equity in these health outcomes.

Maternal health indicators are equally of concern, in that women in the US die within a year of childbirth more than women in any other advanced economic nation. In the US, the maternal mortality rate is 20.7 deaths per 100,000 live births. In Virginia, the rate is 15.6. Further, there is racial disparity in this statistic; white women in Virginia have a rate of 11 deaths per 100,000, and black women have a rate of 36.6.

Maternal Health continues to be a priority for Governor Northam. On June 5, 2019, Governor Northam [announced a goal](#) to eliminate the racial disparity in the maternal mortality rate in Virginia by 2025. This has led to regional listening sessions on maternal health, development of training for healthcare providers on implicit bias, and improved data collection through VDH. VDH is partnering with the Virginia Hospital and Healthcare Association to improve equity in maternal health outcomes by undertaking quality improvement in targeted hospitals through the development of hospital-community partnerships.

AIM 3 — Preventive Actions

Goal 3.1: Virginians Follow a Healthy Diet and Live Actively

Prevention and health promotion are key disciplines in public health. Reducing the burden of chronic diseases and conditions requires living an active, healthy lifestyle. Health behaviors can be positively influenced by policy, system and environmental change strategies when funding and capacity align.

Trends include:

- The percentage of adults who did not participate in any physical activity during the past 30 days has decreased from 23.5% in 2014 to 22% in 2018.
- Overweight and obesity among adults continues to slightly increase; from 64.7% in 2014 to 66.3% in 2018.
- Food insecurity is improving as 10.2% of households in 2017 report scarcity for some part of the year, compared to 11.9% in 2013.

When looking at the data on adults who did not participate in any physical activity during the past 30 days, those with less than a high school diploma were more at risk (40.4%) than those with a college degree (11.2%). This is an important health behavior that is a factor pertaining to chronic disease development and management (Table 3). Analyzing overweight/obesity data by race (Table 4) indicates that there is racial disparity in adults who are overweight or obese, with 75% of Black/Non-Hispanic Adults who are overweight/obese as compared to 65% of White Non-Hispanic Adults.

Table 3: Adults Who did Not Participate in any Physical Activity, by Education Level, 2017.

Source: Behavioral Risk Factor Surveillance System, VDH

	Sample Size	Weighted Counts	Weighted Percent (%)	LowerCL	UpperCL
Virginia	2,514	1,463,864	22.0	20.9	23.0
< H.S.	357	299,450	40.4	35.9	44.9
H.S. or G.E.D.	878	494,801	29.4	27.1	31.8
Some College	646	411,340	21.0	19.0	23.0
College Graduate	622	253,522	11.2	10.0	12.4

Table 4: Adults Who are Overweight or Obese, by Race Virginia, 2017.

Source: Behavioral Risk Factor Surveillance System, VDH

	Sample Size	Weighted Counts	Weighted Percent (%)	LowerCL	UpperCL
Virginia	6,481	4,024,306	66.3	64.9	67.7
Black/Non-Hispanic	1,147	852,871	75.1	71.9	78.3
White/Non-Hispanic	4,570	2,571,561	65.2	63.6	66.8
Hispanic	299	253,059	63.0	56.8	69.2
Other/Non-Hispanic	346	282,958	58.4	51.2	65.5

To promote consumption of a healthy diet, VDH has implemented strategies across the lifespan through strategic partnerships with Child Care Aware of Virginia, Virginia Early Childhood Foundation, and Virginia Breastfeeding Coalition:

- VDH has established the Virginia Breastfeeding Friendly Recognition Program, and recognized 23 early care and education (ECE) settings and 24 workplaces for their effort in providing breastfeeding friendly environments for families so that they may continue breastfeeding after returning to work.
- To increase the consumption of water, fruits, vegetables, and other healthy foods VDH partnered with Child Care Aware of Virginia by offering focused training and technical assistance to expand healthy eating best practices to Child and Adult Care Feeding Programs (CACFP),

including subsidy/religious-exempt, ECE programs. Through these efforts, nearly 60 childcare environments improved wellness standards impacting more than 1,600 children in 2019.

Additional notable efforts in 2019 include:

- The expansion of the Chief Movement Officer (CMO) Cadre, a cohort of trained health and physical activity teachers who provide onsite training/technical assistance to teachers on how to incorporate physical activity through movement breaks and reduced screen time, provided training across 15 local education agencies (LEAs) throughout the state. Efforts focused on LEAs with high rates of childhood obesity that then received technical assistance and training on how to improve school wellness policies that result in increased physical activity and improved health outcomes.
- Virginia Walkability Action Institute (VWAI): The 2019 VWAI funded five local/regional multi-sector teams to pursue policy, systems, and environmental changes and interventions to improve population health and reduce chronic disease risk and burden through increased access to physical activity, with a primary focus on walking and walkability. The following local health districts participated: Central Shenandoah, Chesapeake, Eastern Shore, Hampton, and Richmond City.

Goal 3.2: Virginia Prevents Nicotine Dependency

Tobacco use rates have declined from 21.9% in 2014 to 17.3% in 2018. This is a notable improvement; however, uptake of vaping and electronic nicotine delivery systems (ENDS) continue to rise. Almost 20% of all Virginians have used ENDS, including 35.4% of young adults (ages 18–25 years). A large majority of adults who used ENDS (84.4%), including 94.6% of young adults, use flavored ENDS products.

Regional differences in smoking exist: southwest (18.1%), central (17.6%), northwest (15.5%), eastern (14.7%), and northern (7.7%). Opinions on tobacco use and smoking strongly favor banning smoking at hospital and healthcare facilities (92.3%), private home daycares (92.2%), indoor work areas (89.2%), private areas of restaurants (80.6%), outdoor recreation areas (70.9%), and on school grounds (84.3%). In March 2019, Governor Northam signed the [Tobacco-Free Schools Legislation](#) (HB2384/SB1295) that expanded the current law to ban tobacco and vaping products on school property.

Tobacco use is higher among those with less than a high school diploma, and lowest among those who are college graduates (Table 5). This indicates that increased educational attainment may facilitate less association with poor health behaviors like tobacco use.

Table 5: Adults who use tobacco, by level of education, Virginia, 2017
 Source: Behavioral Risk Factor Surveillance System, VDH

	Sample Size	Weighted Counts	Weighted Percent (%)	LowerCL	UpperCL
Virginia	1,673	1,119,728	17.3	16.3	18.4
< H.S.	211	191,613	26.8	22.8	30.7
H.S. or G.E.D.	598	387,693	23.9	21.6	26.1
Some College	523	384,163	20.2	18.1	22.3
College Graduate	341	156,259	7.1	6.0	8.2

2019 Outbreak of E-Cigarette Product Use Associated Lung Injury (EVALI)

In late 2019, VDH joined the CDC and partners in a multi-state investigation of an outbreak of lung injury associated with e-cigarette product use. As of November 13, 2019, there have been 2,172 cases of e-cigarette, or vaping, product use associated lung injury (EVALI) reported to the CDC from 49 states, the District of Columbia, and 2 U.S. territories; 42 deaths have been confirmed in 24 states (including Virginia) and the District of Columbia. The majority of cases are male (70%) with a median age of 24 years. As of fall 2017, 11.8% of Virginia high school students were using ENDS, almost twice as many as the number of kids smoking traditional cigarettes.

As of November 15, there have been 81 cases, including one reported death, associated with the electronic vaping-associated lung injury outbreak in Virginia. All patients have reported a history of e-cigarette product use, or vaping. Vitamin E acetate has been identified as a chemical of concern among these patients, and most patients report a history of using THC-containing e-cigarette, or vaping, products. Evidence is not yet sufficient to rule out contributions of other chemicals of concern to EVALI. Many different substances and product sources are still under investigation, and it may be that there is more than one cause of this outbreak.

Goal 3.3: Virginians Are Protected Against Vaccine-Preventable Diseases

Adults who receive their annual influenza vaccine increased slightly to 50.6% (2018-19). Increasing vaccination coverage across the Commonwealth is an ongoing focus of VDH. Each year, local health districts conduct flu vaccine clinics to ensure that members of the community can receive their flu vaccine. VDH partners with medical providers to raise awareness of the importance of flu vaccine.

The percentage of youth (ages 13-17 years old) receiving vaccination against Human Papilloma Virus (HPV), the virus that contributes to cancer, has increased since 2016—59.1% of girls and 50.8% of boys were vaccinated in 2018, up from 41.1% and 37.4% (2016), respectively. To continue the upward trend of HPV vaccination coverage for boys and girls, VDH partners with the Cancer Action Coalition of Virginia (CACV) to coordinate the Virginia HPV Immunization Task Force (VHIT). Task force action has included two education summits for providers, community screening and discussion of “Lady Ganga,” (a film chronicling one woman’s journey with cervical cancer) and enhanced partnerships with schools and parent-teacher associations to facilitate access to HPV immunizations in the school setting. A media

campaign about the importance of HPV vaccination was developed and deployed to target areas of the Commonwealth with low HPV immunizations rates.

Goal 3.4: Cancers Are Prevented or Diagnosed at the Earliest Stage Possible

Colorectal cancer screening among adults aged 50-75 years old has remained at 69-70% the past four years. Through the Virginia Colorectal Cancer Screening Project and the Virginia Comprehensive Cancer Control Program, VDH has partnered with health systems to implement evidence based interventions aimed at increasing colorectal cancer screening rates among patient populations. Partners have included eight Federally Qualified Health Centers (Blue Ridge Medical Center, Clinch River Health Services, Central Virginia Health Services, Eastern Shore Rural Health Systems, Greater Prince William Community Health Center, Johnson Health Center, New Horizons Healthcare and Southwest Virginia Community Health Services) and a non-profit health system (Bon Secours Hampton Roads). All partner health systems have experienced increased screening rates among their patient population since initiation of the project in 2015.

In addition, the Cancer Action Coalition of Virginia's Colorectal Cancer Taskforce, in collaboration with VDH, hosted six Colorectal Cancer Roundtables throughout Virginia in 2016 – 2017 to align with the National Colorectal Cancer Roundtable's (NCCRT) 80% by 2018 campaign. The taskforce is being reconvened in 2020 in alignment of NCCRT's new 80% in Every Community initiative that emphasizes the use of evidence-based colorectal cancer screening activities that respond to individualized needs, barriers, and motivations within individual communities.

Goal 3.5: Virginians Have Life-Long Wellness

The opportunity to live well into old age is dependent on many factors. Developing a disability is natural and the average point at which an individual may expect to live a life free from disability has slightly increased from 66.1 years in 2013 to 67.9 years in 2017. Disability is defined as hearing difficulty, vision difficulty, cognitive difficulty, ambulatory difficulty, self-care difficulty, or independent living difficulty.

Adverse childhood experiences (ACEs) are associated with many chronic diseases, mental and behavioral disorders, violence and victimization, and other significant social risks. Roughly 60% of adults in Virginia reported at least one ACE in 2018, which is unchanged since 2016. This means that three out of five adults lived, prior to 18 years old, with someone who was depressed or mentally ill, was a problem drinker or alcoholic, used illegal drugs or abused prescription medicine, was incarcerated or served time, had parents who separated or divorced, or witnessed abuse or neglect in the home (including sexually and emotionally). When compared by income level, there are higher reports of ACEs among those making less than \$25,000 per year, when compared to those making more than \$50,000 per year (Table 6). This is indicative of the chronic stress and trauma that many families face, especially among those who do not have economic stability.

During 2019, VDH contributed to the efforts to address ACEs in many ways:

- In May 2019, VDH participated in ASTHO's leadership summit on ACEs to promote engagement and cross-sector partnerships in state health leadership.
- In August 2019, VDH participated in the "Beyond ACEs, Building Community Resilience Summit", in Petersburg, an event aimed to give providers and laypersons the opportunity to understand the basic language of ACEs and to learn more about Trauma Informed Care.

- VDH serves on the Governor’s Trauma-Informed Leadership Team (TILT); the TILT focuses on developing a statewide dashboard of short and long-term children and family resiliency metrics, recommending agency legislation and budget requests, and fulfilling the work of the “Linking Systems of Care” project.

Table 6: Adults who have experienced 1+ ACE, by income level, Virginia, 2017

Source: Behavioral Risk Factor Surveillance System, VDH

	Sample Size	Weighted Counts	Weighted Percent (%)	LowerCL	UpperCL
Virginia	5,267	3,432,680	60.7	59.3	62.2
\$15,000 or less	383	250,632	67.8	62.4	73.2
\$15,000 to less than \$25,000	694	433,612	66.3	62.7	70.0
\$25,000 to less than \$35,000	434	270,729	61.3	56.1	66.5
\$35,000 to less than \$50,000	545	357,857	62.1	57.6	66.6
\$50,000 or more	2,565	1,682,797	60.7	58.6	62.8

AIM 4 — System of Health Care

Goal 4.1: Virginia Has a Strong Primary Care System

Strengthening health systems is an effective way to manage the population’s health. Connecting people to adequate and available healthcare is important for managing chronic diseases, mental health and substance use disorders. Many of these data points below pre-date Virginia’s more recent expansion of Medicaid; as this significant policy change has more time to take root, one would expect many of these metrics to improve with an increased access to health care for more Virginians.

- The percent of adults who have a regular primary care provider remains at 71%.
- Avoidable hospital stays for ambulatory care sensitive conditions (per 100,000 adults) increased from 1,294 in 2013 to 1,330 in 2017.
- Hospitalizations due to mental health and substance use disorders (per 100,000 adults) showed a slight decrease to 795.3 in 2017 from 803.4 in 2016.
- Avoidable deaths from heart disease, stroke or hypertensive disease (per 100,000 adults) increased to 47.07 in 2018 from 45.99 in 2015.
- The percent of adults whose poor health kept them from doing their usual activities for one or more days in the past months continued to increase, from 19.5% in 2014 to 23.3% in 2018.

Goal 4.2: Virginia’s Health IT System Connects People, Services and Information to Support Optimal Health Outcomes

Health technology and informatics advance integration and interoperability of data and care, which can be leveraged to ensure Virginia prevents hospital readmissions and premature death.

- Implementing a certified electronic health record system among healthcare providers increased to 86% in 2017 from 70.6% in 2014.

- Entities connected through the state health information exchange (HIE) decreased in 2018 to 5,107, which is down from 6,289 in 2017.
- While still a goal of VDH, no local health district has yet implemented an electronic health record system to be able to connect with local healthcare providers or transfer information via the HIE.

In 2018, VDH submitted a budget amendment request in support of its goal of implementing an electronic health record system. More recently, the Commonwealth began a focus on a plan to implement an EHR among selected agencies within the SHHR. This effort would allow for a common platform that ensures interoperability with and between VDH and other SHHR agencies, as well as other healthcare partners. VDH's inclusion in this much larger SHHR study will provide a broader and more efficient system with increased data sharing across all needs.

Emergency Department Care Coordination (EDCC)

The 2017 Virginia General Assembly established the EDCC in VDH to provide a single, statewide technology solution that connects all hospital EDs in the Commonwealth. This program uses the HIE for data exchange between healthcare providers, health plans, and care teams for patients receiving emergency services. The EDCC also integrates directly with Virginia's Prescription Monitoring Program; using prescription data, the tool provides real-time alerts to clinicians about their patients when they show up in the ED. VDH serves on the EDCC Clinical Consensus Group and its Advisory Council. The functionality of EDCC continues to expand, now including Opioid Overdose alerts and sending data to VDH's syndromic surveillance system. The EDCC Program continues to increase the number of downstream providers using the Program's information. The expansion includes CSBs, FQHCs, Accountable Care Organizations, medical staffs and others who benefit from real time information on their patient's use of health care services to better coordinate care, reduce readmissions and duplicative tests.

Virginia Stroke Systems Task Force (VSSTF)

The 2018 General Assembly passed legislation, to require the VDH to implement systems for data collection and information sharing, apply evidence-based guidelines for community-based follow-up care, and implement quality improvement initiatives to improve the quality of stroke care. Under this legislation, through the VSSTF, VDH has convened the Virginia Stroke Care Quality Improvement Advisory Group to provide recommendations for quality improvement across the Commonwealth related to establishing stroke metrics and improving data collection for the prevention and management of strokes.

Clinical Community Linkages

Through a partnership with the Virginia Hospital and Healthcare Association (VHHA), VDH has used an EHR and social determinants of health data-driven approach to identify high burden areas of with disparities in diabetes, chronic kidney disease, and cardiovascular disease hospitalizations. VDH is working with multi-sectoral partners to create sustainable interventions and supports that reduce the development of chronic disease and disease-related complications of Virginians by linking them to social supportive services and clinical care.

Goal 4.3: Health Care-Associated Infections Are Prevented and Controlled in Virginia

Preventing healthcare-associated infections (HAI) is a priority across the entire healthcare system in Virginia. There has been a marked increase in the percentage of hospitals that are meeting the state

goal for the prevention of hospital-onset *Clostridioides difficile* infections, from 64.9% in 2015 to 87.2% in 2018.

In 2015, Virginia reporting regulations were revised to expand the amount of data acute care hospitals share with VDH; this led to a greater focus on the prevention of *C. difficile* infections. *C. difficile* prevention was adopted as a priority by VDH, the Virginia HAI Advisory Group, and VHHA. VDH shares data quarterly with VHHA to track statewide progress, and annually with the HAI Advisory Group to set reduction goals. VDH sends Targeted Assessment for Prevention reports to hospitals quarterly to help identify facilities and units where additional infection prevention and control resources may be needed to reduce HAIs, including *C. difficile*. VDH partnered with Virginia Health Information to create a two-page *C. difficile* educational flyer using all available statewide data; it was shared with providers and consumers via social media and the websites of both organizations. Statewide efforts have also focused on antibiotic stewardship; decreased antibiotic use leads to reductions in *C. difficile*.

As of 2018, 98% of Virginia hospitals had met all seven core elements of hospital antibiotic stewardship programs. Collectively, Virginia acute care hospitals have surpassed the Health and Human Services 2020 National HAI Action Plan goal of achieving a 30% reduction in hospital-onset *C. difficile* infections. However, there is still work to be done. The 100% goal has not been met, and *C. difficile* still causes significant morbidity and mortality for Virginians. In 2018, 1,446 hospital-onset *C. difficile* infections were reported statewide.

Appendix A

Office of Health Equity Report



COMMUNITY INTEGRATION

The Virginia State Office of Rural Health (SORH) provides funds to local agencies who need experience applying for grants or have projects that are not large enough to attract other funders.

- SORH was the recipient of a Rural Communities Opioids Response Planning grant which worked with the **Appalachian Substance Abuse Coalition** to apply for a 501c3 in order to receive future funding. SORH worked with the **St. Mary's Health Wagon** who was awarded \$1 Million to continue the work in southwest VA.



- SORH provided funds to the United Way of Southwest Virginia to hold a 1-day **Rural Childhood Summit** in May 2019. Over 600 people attended the Summit with Keynote addresses by First Lady Pamela Northam and author Jeanette Walls. The purpose of the summit was to bring together all agencies who work with children to begin to address those who are adversely affected by adverse childhood experiences (ACES) and the opioid crisis.

- SORH has provided seed funding to the **Healthy Harvest South Boston Community Garden** to educate high school and middle school students about nutrition, business and how to grow food.



HEALTH EQUITY CONFERENCE & THINK TANK, OCTOBER 2018

The OHE's inaugural conference and think tank featured a dynamic roster of multi-sector speakers, presenters and panelists focused on tackling issues in health disparities and inequities in VA. Attendees also participated in VA's first ever statewide health equity think tank—to collectively brainstorm practical, community-rooted solutions to health inequities. In addition, the health equity work of graduate and professional degree students was highlighted in an evening poster presentation and reception.

TARGETING RESOURCES

DIVISION OF SOCIAL EPIDEMIOLOGY

Health inequities often persist because they go unseen. The Division of Social Epidemiology (DSE) uncovers the harsh reality of health disparities in VA, ensuring they are not ignored. Once identified, we work to help decision-makers target the right resources to the right people, to address the right problems.



Bringing *Visability* to the most vulnerable populations

TO ADDRESS HEALTH INEQUITIES

COST-BENEFIT ANALYSIS

Finding the most effective solution while using the least amount of resources allows us to help more people. The DSE's Health Economist specializes in cost-benefit analysis, outcomes-based financing and economic impact analysis. Our economics capability will allow more robust analysis of the cost and benefits of solutions, resulting in better use of our health dollars.

HEALTH OPPORTUNITY INDEX (HOI)

Identifying disparities comes first but solutions are necessary to end them. When residents of the Norfolk City Health District identified low birth weight as a barrier to well-being, they turned to the OHE's HOI to point them in the right direction. The HOI is a 13-factor index, built at the neighborhood level, to help communities understand how social and economic disparities affect health in their communities.

Innovation begins in RURAL COMMUNITIES

STATE OFFICE OF RURAL HEALTH

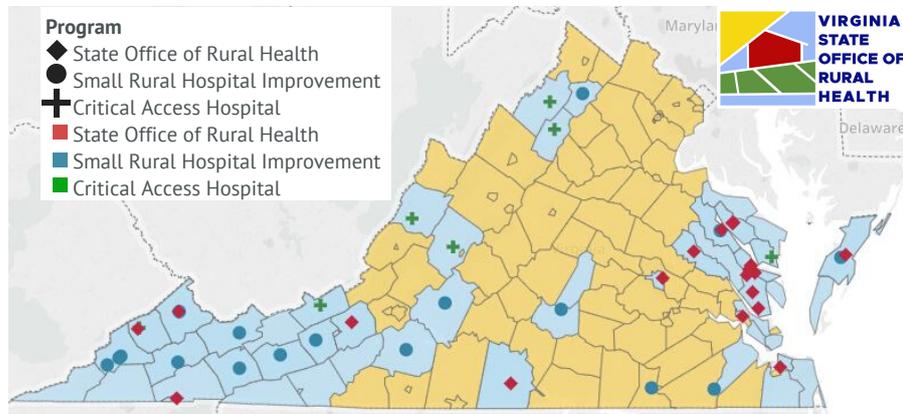
Virginia's SORH distributed over \$200,000 in funds to 11 local agencies to implement programs in these focus areas:

- Workforce Development
- Telehealth Services
- Substance Misuse & Recovery
- Behavioral and Mental Health
- Community Paramedicine/Mobile
- Integrated Healthcare

HEALTH PROFESSIONAL SHORTAGE AREAS (HPSAS)

Too often, policy-makers depend on state or county averages. These metrics hide vulnerable populations and mask disparities. The DSE uses **Health Professional Shortage Area** (HPSA) designations to make vulnerable populations visible. The DSE uses granular data to create neighborhood sized HPSAs, such as the dental HPSA they created in Arlandia, a low-income neighborhood straddling Arlington and Alexandria in Northern Virginia. This designation allows the Community Health Center there to attract and retain dentists using OHE's recruitment and retention programs.

UNCHARTED TERRITORY



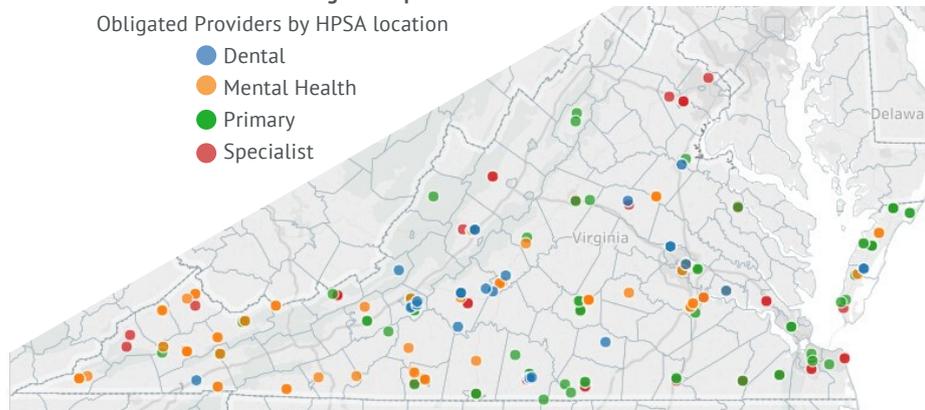
PRIMARY CARE OFFICE (PCO)

PCO's goal is to reduce health disparities by assuring the availability of quality healthcare services to low income, uninsured, isolated, vulnerable and special needs populations by fostering collaboration with similar organizations and identifying communities with the greatest unmet health care needs.

- HPSAs are eligible for certain programs and recruitment opportunities including: The State Loan Repayment Program, J-1 (Conrad 30) Waiver, National Health Service Corps promotion and support, Mary Marshall Nursing Scholarship.
- The PCO also provides administrative support to the Emergency Medical Services Scholarship fund and the Virginia Tobacco Commission State Loan Repayment program.
- **In 2019, The Virginia PCO distributed over \$900,000 in scholarships or loan repayment funds.**

Workforce Incentive Program Impact

Obligated Providers by HPSA location



DANVILLE YOUTH HEALTH EQUITY LEADERSHIP INSTITUTE (YHELI)

YHELI is an after-school program dedicated to empowering students to graduate high school on time, with an action plan for the future! The program provides students with knowledge and skills to have successful and fulfilling education and career plans, overcome barriers to education, and decrease health inequities by providing leadership development, life skills, critical thinking skills, mentoring opportunities, college trips/preparation, career planning, financial planning/management skills, and resume building.

- YHELI students perform significantly better academically compared to their peers.
- YHELI is a safe space where students can always feel heard and appreciated, which is a critical component of mental health.

UNCHARTED TERRITORY

Leveraging the strengths of our faith-based and academic networks to respond with *Urgency*

Since 2013, fatal drug overdose has been the leading method of unnatural death in VA, surpassing all other forms of unnatural death including homicide, suicide, motor vehicles accidents, and undetermined deaths.

OPIOID RESPONSE OUTREACH COORDINATOR (OROC) REVIVE! TRAININGS

REVIVE! is the Opioid Overdose and Naloxone Education (OONE) program for the Commonwealth. The VDH-OHE's Partners in Prayer and Prevention (P3) program facilitate the REVIVE! trainings to teach community members to recognize and respond to an opioid overdose emergency with the administration of naloxone (Narcan®).

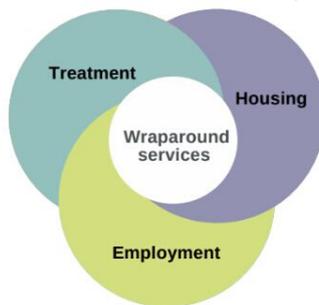
In the past 5 months, P3's response efforts have reached

8,400 persons

through training and community engagement events.

EMPOWERED COMMUNITIES OPIOID PROJECT

ECOP is a regional partnership implemented through the collaborative efforts the VDH-OHE and George Mason University. The ECOP seeks to improve public health by developing and implementing an innovative model of health promotion and management that provides needed medical and social services components to inmates who were found to be drug dependent during incarceration at the Adult Detention Center (ADC) upon their release.



HENRIETTA LACKS COMMISSION

On July 1, 2018, Virginia Governor Ralph Northam signed into law the creation of the Henrietta Lacks Commission and proclaimed September 23-29, 2018 as Henrietta Lacks Legacy Week—to coincide with the inaugural meeting of the Henrietta Lacks Commission. Some additional activities included:

- A worship service at Henrietta Lacks' church home
 - St. Matthew Baptist Church of Clover
- Lacks Legacy Lunch: A VDH lunch & learn to honor Henrietta Lacks' contributions to public health
- An evening panel about Henrietta Lacks and the Henrietta Lacks Commission
- Signing of the Henrietta Lacks Legacy Week Proclamation by State Officials

Highlighting *Resiliency*
Honoring *Legacy*

LGBTQ+ HEALTH EQUITY SYMPOSIUM

On June 27, 2019, the VDH-OHE hosted "The Fierce Urgency of NOW!: Virginia's first LGBTQ+ Health Equity Symposium". This day-long event coinciding with Pride Month was held at VCU's James Branch Cabell Library and aimed to highlight the resiliency of the LGBTQ+ community, while also taking an honest look at who has been left behind in the strides that have been made forward. Focusing on health equity, this gathering proved to be valuable for the 235 healthcare providers, public health professionals, community members, legislators, and allies who attended.



Virginia's Plan for Well-Being

2016-2020

Annual Report, 2019

Virginia Department of Health
109 Governor Street
Richmond, VA 23219
www.vdh.virginia.gov

Background

This information below serves as an annual report to *Virginia's Plan for Well-Being*, the Commonwealth of Virginia's state health improvement plan for 2016-2020. The plan has four aims:

1. Healthy, Connected Communities
2. Strong Start for Children
3. Preventive Actions
4. System of Health Care

Within this framework, the plan lays out 13 goals and 29 measures of success. This document describes the measures and status of indicators for review.

Vision: Well-Being for All Virginians

Well-Being

Measure	Percent of adults in Virginia who report positive well-being; Baseline: 68% (2016).
2019 Update	73.3% (2018)
2020 Goal	70%
Data Source	Virginia Behavioral Risk Factor Surveillance System. Virginia Department of Health.
Description	<p>The four-item Satisfaction with Life Scale (SWLS) asks respondents to indicate how much they agree with the four following statements on a scale from 1 (strongly agree) to 5 (strongly disagree): (1) "In most ways my life is close to ideal," (2) "The conditions of my life are excellent," (3) "I am satisfied with my life," and (4) "So far I have gotten the important things I want in life." Responses to the four SWLS questions are dichotomized into those indicating positive well-being (e.g., agree/strongly agree) and those indicating negative well-being (e.g., disagree/strongly disagree). For overall SWLS, adults responding agree or strongly agree to all four questions (score = 4), are considered positive. Data collection for the SWLS scale began in 2016 as part of Virginia's Behavioral Risk Factor Surveillance System.</p> <p>The Behavioral Risk Factor Surveillance System is an ongoing, annual survey of adults who are randomly called via landline or cell phone. The survey is coordinated by the Centers for Disease Control and Prevention and conducted in all 50 states. The Virginia Department of Health conducts the survey in Virginia. Responses of don't know/not sure, refused, or missing are removed from the numerator and denominator in all estimates.</p>

AIM 1 — Healthy, Connected Communities

Goal 1.1	Virginia's Families Maintain Economic Stability
1.1 A	High School Graduates Enrolled in Higher Education
Measure	Percent of Virginia high school graduates enrolled in an institute of higher education within 16 months after graduation; Baseline: 70.9% (2013).
2019 Update	77.7% (2018)
2020 Goal	75%

Data Source Virginia Postsecondary Enrollment Reports. Virginia Department of Education.

Description The percent of Virginia high school graduates who:

1. Graduated within five years of entering high school,
2. Earned a standard or advanced studies diploma, and
3. Were enrolled in an institute of higher education within 16 months of graduation.

This measure follows a cohort of students who entered ninth grade in the same year.

1.1 B [Cost-Burdened Households](#)

Measure Percent of cost-burdened households in Virginia (more than 30% of monthly income spent on housing costs); Baseline: 31.4% (2013).

2019 Update 28.5% (2017)

2020 Goal 29.0%

Data Source American Community Survey. U.S. Census Bureau.

Description This measure is calculated by dividing the number of Virginians that spent more than 30% of their monthly income on rent, mortgage, or housing without a mortgage by the number of occupied housing units in Virginia. The numerator is housing cost as a proportion of total income in a given year. The data are from the American Community Survey 1-Year Estimates. This is a point-in-time annual survey.

1.1 C [Consumer Opportunity Index Score](#)

The Health Opportunity Index (HOI) is being recalculated. In lieu of the consumer opportunity index score, we calculated the Townsend Material Deprivation Index Score as a measure of economic stability.

1.1 [Townsend Material Deprivation Index Score](#)

Measure Townsend Material Deprivation Index score in Virginia; Baseline: 3.98 (2009-2013).

2019 Update 3.94 (2013-2017)

2020 Goal 3.93

Data Source The Virginia Department of Health created the Townsend Index utilizing the following data sources: U.S. Census, American Community Survey, and 5-Year Estimates.

Description The Townsend deprivation index is a measure of material deprivation, which is one of the indices of the Virginia Health Opportunity Index. Townsend Index is calculated using a combination of four census variables at census tract level:

1. **Unemployment:** Percentage of all people who are economically active who are unemployed.
2. **Overcrowding:** Percentage of households that are overcrowded, Persons per room is a measure of how many people are in the house per room, any number over 1 is classed as overcrowded as that would mean there is more than one person per room.
3. **Non-car Ownership:** Percentage of households that do not own a car or van.
4. **Non-home Ownership:** Percentage of households that are not owner-occupied

The value represents the geometric mean of all the above listed four variables. This is necessary because poor performance in any dimension is directly reflected in the geometric mean. In other words, a high unemployment in one dimension is not linearly compensated for anymore by low percentage in another dimension. The geometric mean reduces the level of substitutability between dimensions and at the same time ensures that a 1 percent increase in the percent of, say, unemployment has the same impact on the final value as a 1 percent increase in the Overcrowding. Thus, as a basis for comparisons of best indicators, this method is also more respectful of the intrinsic differences across the dimensions than a simple average. The state score represents the median county score.

1.2 D **Economic Opportunity Index Score**

The Health Opportunity Index (HOI) is being recalculated. In lieu of the economic opportunity index score, we calculated the Gini Income Inequality Index Score as a measure of economic stability.

1.2 **Gini Income Inequality Index Score**

Measure Gini Income Inequality Index score in Virginia; Baseline: 38.9 (2009-2013).

2019 Update 39.9 (2013-2017)

2020 Goal 38.9

Data Source The Virginia Department of Health utilizes the U.S. Census American Community Survey Data on income dispersion

Description The Gini Index is a summary measure of income inequality. The Gini coefficient incorporates the detailed shares data into a single statistic, which summarizes the dispersion of income across the entire income distribution.

The Gini coefficient ranges from zero, indicating perfect equality (where everyone receives an equal share), to 100, perfect inequality (where only one recipient or group of recipients receives all the income). The Gini Index indicator is calculated at the census-tract level and the median is selected.

Goal 1.2 **Virginia’s Communities Collaborate to Improve the Population’s Health**

1.2 **Districts with Collaborative Community Health Improvement Processes**

Measure Percent of Virginia health planning districts that have established an on-going collaborative community health improvement process; Baseline: 43.0% (2015).

2019 Update 97% (2018)

2020 Goal 100%

Data Source Virginia Department of Health.

Description The measure is calculated by dividing the number of health districts in Virginia that report that a collaborative community health improvement process is established in their health planning district divided by 35 (total number of health planning districts).

AIM 2 — Strong Start for Children

Goal 2.1 Virginians Plan Their Pregnancies

2.1 Teen Pregnancy Rate

Measure Teen pregnancy rate per 1,000 females, ages 15 to 19 years, in Virginia; Baseline: 27.9 (2013).

2019 Update 19.7 (2017)

2020 Goal 25.1

Data Source Virginia Vital Records and Health Statistics Electronic Birth Certificates, Fetal Death Certificates, Induced Termination of Pregnancy Certificates. Virginia Department of Health.

Description This metric is created using live birth data from the electronic birth certificate as reported by birth facilities, Induced Termination of Pregnancy (ITOP) data as reported by ITOP facilities, fetal death data as reported by medical providers and the number of female teens (15-19 years of age) from the National Center for Health Statistics population estimates.

Goal 2.2 Virginia's Children Are Prepared to Succeed in Kindergarten

2.2 A Kindergartens Not Meeting Phonological Awareness Literacy (PALS-K) Benchmark

Measure Percent of children in Virginia who do not meet the PALS-K benchmarks in the fall of kindergarten and require literacy intervention; Baseline: 12.7% (2014-2015).

2019 Update 17% (2018-2019)

2020 Goal 12.2%

Data Source Phonological Awareness Literacy Screening – Kindergarten Results. Virginia Department of Education.

Description The Phonological Awareness Literacy Screening – Kindergarten (PALS-K) is conducted in the fall of each school year and identifies kindergarten students who are at risk for reading difficulties. The tool measures children's knowledge of several literacy fundamentals: phonological awareness, alphabet recognition, concept of word, knowledge of letter sounds, and spelling. The PALS-K is an assessment of literacy readiness and is not a comprehensive measure of school readiness. PALS-K is the state-provided screening tool for Virginia's Early Intervention Reading Initiative (EIRI) and is used by 99% of school divisions in the state on a voluntary basis.

2.2 B Third Graders Passing Reading Standards of Learning (SOL) Assessment

Measure Percent of third graders in Virginia who pass the Standards of Learning third grade reading assessment; Baseline: 69.0% (2014-2015).

2019 Update 71% (2018-2019)

2020 Goal 80.0%

Data Source Virginia Standards of Learning Results. Virginia Department of Education.

Description The Standards of Learning (SOL) for Virginia Public Schools establish minimum expectations for what students should know and be able to do at the end of each grade. All items on SOL tests are reviewed by Virginia classroom teachers for accuracy and fairness, and teachers also assist the state Board of Education in setting proficiency standards for the tests.

Goal 2.3 **The Racial Disparity in Virginia’s Infant Mortality Rate is Eliminated**

2.3 **Infant Mortality Rate by Race**

Measure Black infant mortality rate in Virginia per 1,000 live births by race; Baseline: 12.2 (2013).

2019 Update 9.6 (2018)

2020 Goal 5.2

Data Source Virginia Vital Records and Health Statistics Electronic Birth Certificates and Electronic Death Certificates. Virginia Department of Health.

Description Virginia’s infant mortality rate is calculated by dividing the number of deaths of children under one year of age by the number of live births to mothers living in the state. The resulting number is multiplied by 1,000 to compute the rate.

AIM 3 — Preventive Actions

Goal 3.1 **Virginians Follow a Healthy Diet and Live Actively**

1.1 A **Adults Not Participating in Physical Activity**

Measure Percent of Virginia adults 18 years and older who do not participate in any physical activity during the past 30 days; Baseline: 23.5% (2014).

2019 Update 22% (2018)

2020 Goal 20.0%

Data Source Virginia Behavioral Risk Factor Surveillance System. Virginia Department of Health.

Description The percent of Virginia adults 18 years and older who reported that they did not participate in any physical activity other than their regular job during the past 30 days. The Behavioral Risk Factor Surveillance System (BRFSS) is an ongoing, annual survey of adults who are randomly called via landline or cell phone. The survey is coordinated by the Centers for Disease Control and Prevention (CDC) and conducted in all 50 states. The Virginia Department of Health conducts the survey in Virginia. The information is self-reported and not observed or measured. Responses of don’t know/not sure, refused, or missing were removed from the numerator and denominator in all estimates.

3.1 B **Adults Who Are Overweight or Obese**

Measure Percent of Virginia adults 18 years and older who are overweight or obese; Baseline: 64.7% (2014).

2019 Update 66.3% (2018)

2020 Goal 63.0%

Data Source Virginia Behavioral Risk Factor Surveillance System. Virginia Department of Health.

Description The percent of Virginia adults 18 years and older who reported a body mass index (BMI) greater than 25. The Behavioral Risk Factor Surveillance System (BRFSS) is an ongoing, annual survey of adults who are randomly called via landline or cell phone. The survey asks respondents what their height and weight are. BMI is then calculated based on reported height and weight. The

survey is coordinated by the Centers for Disease Control and Prevention (CDC) and conducted in all 50 states. The Virginia Department of Health conducts the survey in Virginia. Responses of don't know/not sure, refused, or missing were removed from the numerator and denominator in all estimates.

3.1 C [Households That Are Food Insecure](#)

Measure Percent of Virginia households that are food insecure for some part of the year. Baseline: 11.9% (2013).

2019 Update 10.2% (2017)

2020 Goal 10.0%

Data Source *Map the Meal Gap* utilized the Current Population Survey, and American Community Survey from the U.S. Census Bureau.

Description Feeding America's *Map the Meal Gap* analyzes the relationship between food insecurity and indicators of food insecurity, and child food insecurity (poverty, unemployment, median income, etc.) at the state level.

Goal 3.2 [Virginia Prevents Nicotine Dependency](#)

3.2 [Adults Using Tobacco](#)

Measure Percent of Virginia adults aged 18 years and older who report using tobacco. Baseline: 21.9% (2014).

2019 Update 17.3% (2018)

2020 Goal 12.0%

Data Source Virginia Behavioral Risk Factor Surveillance System. Virginia Department of Health.

Description The percent of Virginia adults 18 years and older who report that they have smoked at least 100 cigarettes in their lifetime and currently smoke tobacco on at least some days, use chewing tobacco, use snuff and/or use snus. The Behavioral Risk Factor Surveillance System (BRFSS) is an ongoing, annual survey of adults who are randomly called via landline or cell phone. The survey is coordinated by the Centers for Disease Control and Prevention (CDC) and conducted in all 50 states. The Virginia Department of Health conducts the survey in Virginia. The information is self-reported and not observed or measured. Responses of don't know/not sure, refused, or missing were removed from the numerator and denominator in all estimates.

Goal 3.3 [Virginians Are Protected Against Vaccine-Preventable Diseases](#)

3.3 A [Adults Vaccinated Against Influenza](#)

Measure Percent of Virginia adults 18 years and older who received an annual influenza vaccine. Baseline: 48.2% (2014-2015).

2019 Update 50.6% (2018-2019)

2020 Goal 70%

Data Source National Immunization Survey. Centers for Disease Control and Prevention.

Description The percent of Virginians 18 years of age and older who received an annual influenza vaccine. The Centers for Disease Control and Prevention analyzed the National Immunization Survey-Flu

and the Behavioral Risk Factor Surveillance System to estimate national and state level flu vaccination coverage. Influenza vaccination status is based on self-reported data and not validated with medical records.

3.3 B **Adolescents Vaccinated Against HPV**

Measure Percent of girls aged 13-17 in Virginia who receives three doses of HPV vaccine and percent of boys aged 13-17 in Virginia who receive three doses of HPV vaccine. Girls Baseline: 35.9% (2014), Boys Baseline: 22.5% (2014).

This measure has been updated for the 2018 Annual Report to reflect changes in CDC methodology. The above measure is no longer used. The updated measure is below:

Percent of girls ages 13-17/Percent of boys age 13-17 in Virginia who are “up to date” (UTD) in the HPV vaccine series. This can be met with two or three doses, depending on the age of initiation of the vaccine series. Girls UTD baseline (2016): 41.1%; Boys UTD Baseline (2016): 37.4%

2019 Update Girls (UTD): 59.1% (2018), Boys (UTD): 50.8% (2018)

2020 Goal Girls and Boys: 80.0%

Data Source National Immunization Survey-Teen. Centers for Disease Control and Prevention.

Description The percent of Virginia adolescents aged 13-17 (girls and boys reported separately) who received three doses of human papillomavirus (HPV) vaccine (two doses are recommended as of 2016). The National Immunization Survey-Teen (NIS-Teen) is an ongoing, annual survey of children, whose parents/guardians are randomly called via landline or cell phone. The survey is coordinated by the Centers for Disease Control and Prevention and conducted in all 50 states. Doses of vaccines administered are verified by providers through a mailed survey to the girls’ immunization providers.

Goal 3.4 Cancers Are Prevented or Diagnosed at the Earliest Stage Possible

3.4 **Adults Screened for Colorectal Cancer**

Measure Percent of Virginia adults aged 50 to 75 years who receive colorectal cancer screening. Baseline: 69.1% (2014).

2019 Update 70.1% (2018)

2020 Goal 85.0%

Data Source Virginia Behavioral Risk Factor Surveillance System. Virginia Department of Health.

Description The percent of Virginia adults, ages 50 to 75 years, who report receiving a colorectal cancer screening test based on the most recent guidelines (fecal occult blood test, proctoscopy, colonoscopy, or sigmoidoscopy). The Behavioral Risk Factor Surveillance System (BRFSS) is an ongoing, annual survey of adults who are randomly called via landline or cell phone. The survey

is coordinated by the Centers for Disease Control and Prevention (CDC) and conducted in all 50 states. The Virginia Department of Health conducts the survey in Virginia. The information is self-reported and not observed or measured. Responses of don't know/not sure, refused, or missing were removed from the numerator and denominator in all estimates. Data collected in even years: 2014, 2016, 2018, etc.

Goal 3.5 **Virginians Have Life-Long Wellness**

3.5 A **Disability-Free Life Expectancy**

Measure Average years of disability-free life expectancy for Virginians; Baseline: 66.1 (2013).

2019 Update 67.9 (2017)

2020 Goal 67.3

Data Source U.S. Census Intercensal Population File Vintage 2014, Virginia Vital Records and Health Statistics Electronic Death Certificates, and the American Community Survey. Virginia Department of Health.

Description Disability-free life expectancy (DFLE) was calculated for Virginia census tracts by adding the estimates of the proportion of individuals with disabilities by tract and age group to the abridged life table estimates of mortality and population used for creating life expectancy (LE) estimates. The life table with the proportion of disabled individuals was the input for the analysis using the Chiang II methodology with Silcock's adjustment for calculation of LE and Sullivan's methods for DFLE. The disabled population proportion was defined for this study as answering yes to any one of the six disability questions (2009-2013 aggregate) in the American Community Survey. Significant consideration was given to disability chosen, small area analysis problems, and how to share the analysis for best impact. At the tract level, data censorship was considered when unusual population distributions were encountered. Minimum population size requirements were met to reduce large standard errors. DFLE estimates were added to a multiple linear regression model with social determinants of health as the explanatory variables.

3.5 B **Adults with Adverse Childhood Experiences**

Measure Percent of adults in Virginia who report at least one (1) adverse childhood experience; Baseline: 60.4% (2016).

2019 Update 60.7% (2018)

2020 Goal 45%

Data Source Virginia Behavioral Risk Factor Surveillance System. Virginia Department of Health.

Description Adverse childhood experiences (ACEs) include verbal, physical, or sexual abuse, as well as family dysfunction (e.g., an incarcerated, mentally ill, or substance-abusing family member; domestic violence; or absence of a parent because of divorce or separation). The ACE score is a measure of cumulative exposure to particular adverse childhood conditions. Exposure to any single ACE condition is counted as one point. If an adult experienced none of the conditions in childhood, the ACE score is zero. Points are totaled for a final ACE score. The Behavioral Risk Factor Surveillance System is an ongoing, annual survey of adults who are randomly called via landline or cell phone. The survey is coordinated by the Centers for Disease Control and Prevention

(CDC) and conducted in all 50 states. The Virginia Department of Health conducts the survey in Virginia. Responses of don't know/not sure, refused, or missing were removed from the numerator and denominator in all estimates.

AIM 4 — System of Health Care

Goal 4.1 **Virginia Has a Strong Primary Care System Linked to Behavioral Health Care, Oral Health Care, and Community Support Systems**

4.1 A **Adults with a Regular Health Care Provider**

Measure Percent of adults 18 years and older who have a regular health care provider; Baseline: 69.3% (2014).

2019 Update 71.0% (2018)

2020 Goal 85.0%

Data Source Virginia Behavioral Risk Factor Surveillance System. Virginia Department of Health.

Description The percent of Virginia adults who report that they have at least one personal healthcare provider for ongoing care. The Behavioral Risk Factor Surveillance System is an ongoing, annual survey of adults who are randomly called via landline or cell phone. The survey is coordinated by the Centers for Disease Control and Prevention and conducted in all 50 states. The Virginia Department of Health conducts the survey in Virginia. The information is self-reported and not observed or measured. Responses of don't know/not sure, refused, or missing were removed from the numerator and denominator in all estimates.

4.1 B **Avoidable Hospital Stays**

Measure Rate of avoidable hospital stays for ambulatory care sensitive conditions in Virginia per 100,000 persons; Baseline: 1,294 (2013).

2019 Update 1,330 (2017)

2020 Goal 1,100

Data Source Virginia Inpatient Hospitalization. Virginia Health Information.

Description The measure is the Agency for Healthcare Research and Quality's Prevention Quality Overall Composite (PQI #90) in Virginia. It includes hospitalizations that could have been prevented through high quality outpatient care, including uncontrolled diabetes, short-term diabetes complications, long-term diabetes complications (including amputated limbs), chronic obstructive pulmonary disease, high blood pressure, heart failure, chest pain, adult asthma, dehydration, pneumonia, and urinary tract infections. The number of hospital stays is provided for every 100,000 people who reside in that area.

4.1 C **Avoidable Cardiovascular Disease Deaths**

Measure Rate of avoidable deaths from heart disease, stroke, or hypertensive disease in Virginia per 100,000 persons; Baseline: 59.97 (2013).

2019 Update 47.07 (2018)

2020 Goal 40.0

Data Source	Virginia Vital Records and Health Statistics Electronic Death Certificates. Virginia Department of Health.
Description	Deaths included were those caused by cardiovascular disease, including chronic rheumatic heart disease (ICD 10 codes I05-I09), hypertension (ICD codes I10, I12, I15), ischemic heart disease (ICD 10 codes I20-I25), and cerebrovascular disease (ICD 10 codes I60-I69). An age-adjusted formula for population was used, truncating the years over 75, and then reformatting to the new million population for those age ranges.

4.1 D [Adult Mental Health and Substance Abuse Hospitalizations](#)

Measure	Rate of adult mental health and substance abuse hospitalizations in Virginia per 100,000 adults; Baseline: 668.50 (2013).
2019 Update	795.3 (2017)
2020 Goal	635.1
Data Source	Virginia Inpatient Hospitalization. Virginia Health Information.
Description	Diagnosis codes to include for mental health and substance abuse hospitalizations were selected based on criteria developed by the Healthcare Cost and Utilization Project. The case definition used excluded discharges related to maternity stays and individuals under the age of 18. Population denominators were derived from midyear Census estimates provided by the National Center for Health Statistics.

4.1 E [Adults Whose Poor Health Kept Them from Usual Activities](#)

Measure	Percent of adults 18 years and older in Virginia who reported having one or more days of poor health that kept them from doing their usual activities; Baseline: 19.5% (2014).
2019 Update	23.3% (2018)
2020 Goal	18.0%
Data Source	Virginia Behavioral Risk Factor Surveillance System. Virginia Department of Health.
Description	Percent of Virginia adults who reported having one or more days of poor health (physical health or mental health) and reported that poor health kept them from doing usual activities. The Behavioral Risk Factor Surveillance System (BRFSS) is an ongoing, annual survey of adults, who are randomly called via landline or cell phone. The survey is coordinated by the Centers for Disease Control and Prevention (CDC) and conducted in all 50 states. The Virginia Department of Health conducts the survey in Virginia. The information is self-reported and not observed or measured. Responses of don't know/not sure, refused, or missing were removed from the numerator and denominator in all estimates.

Goal 4.2 [Virginia's Health IT System Connects People, Services and Information to Support Optimal Health Outcomes](#)

4.2 A [Providers with Electronic Health Records](#)

Measure	Percent of health care providers in Virginia who have implemented a certified electronic health record; Baseline: 70.6% (2014).
2019 Update	86.0% (2017)

2020 Goal	90.0%
Data Source	National Electronic Health Records Survey. Centers for Disease Control and Prevention.
Description	Data are from the National Electronic Health Records Survey (NEHRS). NEHRS, which is conducted by the National Center for Health Statistics and sponsored by the Office of the National Coordinator for Health Information Technology, is a nationally representative mixed mode survey of office-based physicians that collects information on physician and practice characteristics, including the adoption and use of EHR systems. Using a physician database, email addresses of sampled physicians were identified. Sampled physicians that did not have an email match were asked to complete the survey by mail or phone. Among those with email addresses, respondents were randomly assigned to one of four groups: an invitation to take the web survey through email, US mail, both, or no web survey option. Nonresponse to the web survey resulted in 3 mailings of the questionnaire followed by phone contacts.

4.2 B [Entities Connected to Health Information Exchange](#)

Measure	Number of entities in Virginia connected through Connect Virginia HIE Inc., the electronic health information exchange, and the national e-Health Exchange; Baseline: 3,800 (2015).
2019 Update	5,107 (2018)
2020 Goal	7,600
Data Source	Connect Virginia HIE, Inc.
Description	Connect Virginia HIE, Inc. is the statewide health information exchange (HIE) for the Commonwealth of Virginia. The HIE uses secure, electronic, internet-based technology to allow medical information to be exchanged by participating entities. Connect Virginia reports the number of entities in Virginia connected on a quarterly basis.

4.2 C [Health Districts with Electronic Health Records](#)

Measure	Number of Virginia’s local public health districts that have electronic health records and connect to Connect Virginia, Virginia’s Health Information Exchange; Baseline: 0 (2015).
2019 Update	0 (2018)
2020 Goal	35
Data Source	Virginia Department of Health.
Description	Count of Virginia’s local public health districts (total of 35) that have electronic health records and connect to Connect Virginia, Virginia’s Health Information Exchange.

Goal 4.3 [Health Care-Associated Infections Are Prevented and Controlled in Virginia](#)

4.3 [Hospitals Meeting State Goal for Prevention of *C. difficile* Infections](#)

Measure	Percent of hospitals in Virginia meeting the state goal for prevention of hospital-onset <i>Clostridium difficile</i> infections; Baseline: 64.9% (2015).
2019 Update	87.2% (2018)
2020 Goal	100.0%

Data Source National Healthcare Safety Network. Centers for Disease Control and Prevention.

Description The percent of Virginia hospitals that meet the state goal for prevention of hospital-onset *C. difficile* laboratory-identified events. The state goal is a standardized infection ratio ≤ 0.7 , which aligns with the goal of the Department of Health and Human Services National Healthcare-Associated Infections Action Plan.

BRFSS Data Trend - Influenza Vaccination

