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

Other Business

Adjourn
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.
Final Regulation
Agency Background Document

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

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  

### 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.*

<table>
<thead>
<tr>
<th>Current chapter-section number</th>
<th>New chapter-section number, if applicable</th>
<th>New requirement from previous stage</th>
<th>Updated new requirement since previous stage</th>
<th>Change, intent, rationale, and likely impact of updated requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>12VAC5-371-410</td>
<td></td>
<td>A. All construction of new buildings and additions, renovations or alterations, or repairs of existing buildings for occupancy as a nursing facility shall conform to state and local</td>
<td>This change updates the reference to Parts 1 and 2 and section 3.1 of the 2018 Guidelines for</td>
<td></td>
</tr>
</tbody>
</table>
codes, zoning and building ordinances, and the *Virginia Uniform Statewide Building Code* (13VAC5-63).

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

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, 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.

This change removes a requirement that was included in the proposed stage. The requirement is no longer necessary.
DEPARTMENT OF HEALTH

Amend regulations to revise construction standards for nursing facilities

Part V
Physical Environment

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

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

B. Architectural drawings and specifications for all new construction or for additions, alterations or renovations to any existing building, shall be dated, stamped with professional seal, and signed by the architect. The architect shall certify that the drawings and specifications were prepared to conform to building code requirements the Virginia Uniform Statewide Building Code and be consistent with Parts 1 and 2 and sections 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.

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

D. Upon completion of the construction, the nursing 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.

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

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

DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-371)


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

Prevention and Control of Influenza, MMWR 53 (RR06), Advisory Committee on Immunization Practices, Centers for Disease Control and Prevention
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.
Fast-Track Regulation
Agency Background Document

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

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

**Impact on Localities**

| Projected costs, savings, fees or revenues resulting from the regulatory change. |
| Benefits the regulatory change is designed to produce. |
| None. |
| 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. |
| Agency’s best estimate of the number of such entities that will be affected. Please include an |
| Licensed inpatient hospitals and licensed outpatient surgical hospitals. |
| 106 inpatient hospitals and 63 outpatient surgical hospitals. Three of the outpatient surgical |
| 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. |
| hospitals are estimated to meet the definition of "small business" |
| 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. |
| As all licensed hospitals are required to comply with the Code of Virginia, there are no projected costs for compliance with the regulatory change. |
| Benefits the regulatory change is designed to produce. |
| The regulatory change is designed to conform the regulations to the Code of Virginia. |

### 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:

<table>
<thead>
<tr>
<th>Current section number</th>
<th>Current requirement</th>
<th>Change, intent, rationale, and likely impact of new requirements</th>
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<tbody>
<tr>
<td>441</td>
<td>12VAC5-410-441. Obstetric service requirements; medical direction; physician consultation and coverage; nurse staffing and coverage; policies and procedures. A. 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. 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. 2. The duties and responsibilities of the medical director of obstetric services shall include but not be limited to: a. The general supervision of the quality of care provided patients admitted to the service;</td>
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b. The establishment of criteria for admission to the service;

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

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

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

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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.

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.

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.

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.

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

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

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.

H. A copy of the 24-hour on-call duty schedule, including the list of on-call consulting services shall include but not be limited to:

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physicians, shall be posted at each nurses' station in the obstetric suite and in the emergency room.

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

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.

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.

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.

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.

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.

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. 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:

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</tr>
<tr>
<td>1:4</td>
<td>Rooming-in units.</td>
</tr>
<tr>
<td>1:2</td>
<td>Intensive care units.</td>
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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.

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.

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<td>Laboring patients</td>
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<td>Coverage of epidural anesthesia</td>
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<td>1:1</td>
<td>Circulation for cesarean delivery</td>
</tr>
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<td>1:6 to 8</td>
<td>Antepartum/postpartum patients without complications</td>
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<td>1:2</td>
<td>Postoperative recovery</td>
</tr>
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<td>1:3</td>
<td>Patients with complications, but in stable condition</td>
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<td>1:4</td>
<td>Mother-newborn care</td>
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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.

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.

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.

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

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.

1. The policies and procedures shall include, but not be limited to, the following:
   
   a. Criteria for the identification and referral of high-risk obstetric patients;
   
   b. The types of birthing alternatives, if offered, by the hospital;
   
   c. The monitoring of patients during antepartum, labor, delivery, recovery and busy or crisis periods, duty schedules shall be developed in accordance with the following nurse/patient ratios:

   1. 1:1 to 2 Antepartum testing
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   3. 1:1 Patients in second stage of labor
   4. 1:1 Ill patients with complications
   5. 1:2 Oxytocin induction or augmentation of labor
   6. 1:2 Coverage of epidural anesthesia
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<td>n. Staff capability to perform cesarean sections within 30 minutes of notice;</td>
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<td></td>
<td>p. The treatment of volume shock in mothers;</td>
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<td></td>
<td>q. Training of hospital staff in discharge planning for identified substance abusing, postpartum women and their infants; and</td>
</tr>
<tr>
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<td>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:</td>
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<td>(1) Substance abuse treatment services; and</td>
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<td></td>
<td>(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.</td>
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<td>(3) The discharge planning process shall be coordinated by a health care professional and shall include, to the extent possible:</td>
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<td>(a) The father of the infant; and</td>
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<td>(b) Any family members who may participate in the follow-up care of the mother or infant.</td>
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<td>The discharge plan shall be discussed with the mother and documented in the medical record.</td>
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<td>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:</td>
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<td>a. The philosophy, goals and objectives for the use of the LDR/LDRP rooms;</td>
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<td>b. Criteria for patient eligibility to use the LDR/LDRP rooms;</td>
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<td>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</td>
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<td><strong>d.</strong></td>
<td>Patient care in LDR/LDRP rooms, including but not limited to, the following;</td>
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<td></td>
<td>(1) Defining vital signs, the intervals at which they shall be taken, and requirements for documentation; and</td>
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<td></td>
<td>(2) Observing, monitoring, and assessing the patient by a registered nurse, certified nurse midwife, or physician;</td>
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<td><strong>e.</strong></td>
<td>The types of analgesia and anesthesia to be used in LDR/LDRP rooms;</td>
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<td>Specifications of conditions of labor or delivery requiring transfer of the patient from LDR/LDRP rooms to the delivery room;</td>
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information about safe sleep environments for infants that is consistent with current information from the American Academy of Pediatrics.
room in the event that the patient is transferred to the delivery room or operating room;
k. The number of visitors allowed in the LDR/LDRP room, and their relationship to the mother; and
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.

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.

Rationale: The provision is being included to conform the regulations to the Code, as amended by Chapter 433 of the 2019 Acts of Assembly.

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.
DEPARTMENT OF HEALTH
Amend Regulations to Conform to Chapter 433 of the 2019 Acts of Assembly

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

A. 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.
   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.
   2. The duties and responsibilities of the medical director of obstetric services shall include but not be limited to:
      a. The general supervision of the quality of care provided patients admitted to the service;
      b. The establishment of criteria for admission to the service;
      c. The adherence to standards of professional practices and policies and procedures adopted by the medical staff and governing body;
      d. The development of recommendations to the medical staff on standards of professional practice and staff privileges;
      e. The identification of clinical conditions and medical or surgical procedures that require physician consultation; and
      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.

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.

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.

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

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

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.

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

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.

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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:

1. 1:1 to 2 Antepartum testing
2. 1:2 Laboring patients
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4. 1:1 Ill patients with complications
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6. 1:2 Coverage of epidural anesthesia
7. 1:1 Circulation for cesarean delivery
8. 1:6 to 8 Antepartum/postpartum patients without complications
9. 1:2 Postoperative recovery
10. 1:3 Patients with complications, but in stable condition
11. 1:4 Mother-newborn care

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.

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.

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.

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

1. The policies and procedures shall include, but not be limited to, the following:
   a. Criteria for the identification and referral of high-risk obstetric patients;
   b. The types of birthing alternatives, if offered, by the hospital;
   c. The monitoring of patients during antepartum, labor, delivery, recovery and postpartum periods with or without the use of electronic equipment;
   d. The use of equipment and personnel required for high-risk deliveries, including multiple births;
   e. The presence of family members or chosen companions during labor, delivery, recovery, and postpartum periods;
   f. The reporting, to the Department of Health, of all congenital defects;
   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;
   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;
   i. The use of specially trained paramedical and nursing personnel by the obstetrics and newborn service units;
   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;
   k. The use of anesthesia with obstetric patients;
   l. The use of radiological and electronic services, including safety precautions, for obstetric patients;
   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;
   n. Staff capability to perform cesarean sections within 30 minutes of notice;
   o. Emergency resuscitation procedures for mothers and infants;
   p. The treatment of volume shock in mothers;
   q. Training of hospital staff in discharge planning for identified substance abusing, postpartum women and their infants; and
   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:
      (1) Substance abuse treatment services; and
      (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.
      (3) The discharge planning process shall be coordinated by a health care professional and shall include, to the extent possible:
      (a) The father of the infant; and
(b) Any family members who may participate in the follow-up care of the mother or
infant.

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

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 information about safe sleep environments for
infants that is consistent with current information from the American Academy of
Pediatrics.

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:

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

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

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

d. Patient care in LDR/LDRP rooms, including but not limited to, the following;
   (1) Defining vital signs, the intervals at which they shall be taken, and requirements
       for documentation; and
   (2) Observing, monitoring, and assessing the patient by a registered nurse,
certified nurse midwife, or physician;

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

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

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

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

i. The completion of medical records;

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;

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

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.
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.
Fast-Track Regulation
Agency Background Document

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

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.


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

<table>
<thead>
<tr>
<th>For your agency: projected costs, savings, fees or revenues resulting from the regulatory change, including:</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) fund source / fund detail;</td>
</tr>
<tr>
<td>b) delineation of one-time versus on-going expenditures; and</td>
</tr>
<tr>
<td>c) whether any costs or revenue loss can be absorbed within existing resources</td>
</tr>
</tbody>
</table>

| For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures. | None |

| For all agencies: 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:

<table>
<thead>
<tr>
<th>Current section number</th>
<th>New section number, if applicable</th>
<th>Current requirement</th>
<th>Change, intent, rationale, and likely impact of new requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>330</td>
<td>N/A</td>
<td>12VAC5-391-330. Medical direction. 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</td>
<td>Change: The Board is proposing the following change: 12VAC5-391-330. Medical direction. 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</td>
</tr>
</tbody>
</table>
and medical needs of the terminally ill.

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.

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

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.

<table>
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<tr>
<th>and medical needs of the terminally ill.</th>
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</tr>
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<tr>
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<tr>
<td>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;</td>
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</tr>
<tr>
<td>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.</td>
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</tr>
</tbody>
</table>

**Intent:** This regulatory change is intended to make it easier for hospices to find suitable medical directors.

**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.
### 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:

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.

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

#### Change: The Board is proposing the following change:

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:

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.

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

1. Assessing a patient's needs and admission for service as appropriate;
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.

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

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

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

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

1. Delivering nursing services according to the hospice program's policies and standard nursing practices;
### Town Hall Agency Background Document

**Form: TH-04**

<table>
<thead>
<tr>
<th>Service Provided</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delivering nursing services according to the hospice program's policies and standard nursing practices;</td>
<td>1.</td>
</tr>
<tr>
<td>Assisting the registered nurse in performing specialized procedures;</td>
<td>2.</td>
</tr>
<tr>
<td>Assisting the patient with activities of daily living, including the teaching of self-care techniques;</td>
<td>3.</td>
</tr>
<tr>
<td>Preparing equipment and supplies for treatment that requires adherence to sterile or aseptic techniques; and</td>
<td>4.</td>
</tr>
<tr>
<td>Preparing clinical notes.</td>
<td>5.</td>
</tr>
</tbody>
</table>

### 350 N/A

#### 12VAC5-391-350. Home attendant services.

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

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;

#### Change: The Board is proposing the following change:

12VAC5-391-350. Home attendant services.

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

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;
4. Measuring and recording fluid intake and output;
5. Recording and reporting to the health care professional changes in the patient's physical condition, behavior or appearance;
6. Documenting services and observations in the medical record; and
7. Performing any other duties that the attendant is qualified to do by additional training and demonstrated competency, within state guidelines.

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.

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

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.

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.

F. Home attendants shall be able to speak, read and write English and shall meet one of the following qualifications:

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

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

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

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;

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

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.

<table>
<thead>
<tr>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>G. Hospice programs may develop a 40-hour training program for volunteers. The program shall:</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>1. Include education addressing:</td>
</tr>
<tr>
<td>a. Goals of personal care;</td>
</tr>
<tr>
<td>b. Prevention of skin breakdown;</td>
</tr>
<tr>
<td>c. Physical and biological aspects of aging;</td>
</tr>
<tr>
<td>d. Physical and emotional needs of older adults;</td>
</tr>
<tr>
<td>e. Orientation to types of physical disabilities;</td>
</tr>
</tbody>
</table>
f. Personal care and rehabilitative services;

g. Body mechanics;

h. Home management;

i. Safety and accident prevention in the home;

j. Policies and procedures regarding accidents or injuries;

k. Food, nutrition, and meal preparation;

l. Special considerations in preparation of special diets;

m. Care of the home and personal belongings; and

n. Documentation requirements for Medicaid individuals.

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

3. Issue and maintain certificates of completion containing:

   a. The instructor’s printed name and signature;

   b. The participant’s printed name; and

   c. The date of completion of the program.

**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.

**Rationale:** The reference to 2003 DMAS Personal Care Aide Training Curriculum is out of date and needs to be replaced by a current curriculum.
DMAS indicated that their requirements for personal care aide training existed within the CCC Plus Waiver Manual, on which this language is based.

**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.

| 380 | N/A | **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. |
| Change: The Board is proposing the following change: |
| **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. |
| **Intent:** The change removes a reference to a chapter of regulations that has been repealed. |
| **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. |
| **Likely Impact:** The change will reduce confusion for regulated entities regarding the specific requirements for dietary or nutritional counselors. |

| 440 | N/A | **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.  
In addition, hospice facilities shall be designed and constructed according to section 4.2 of Part 4 of the Uniform Statewide Building Code. |
| Change: The Board is proposing the following change: |
| **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.  
In addition, hospice facilities shall be designed and constructed according to section 4.2 of Part 4 of the Uniform Statewide Building Code. |
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.

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.

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.

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.

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.

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.

of Part 3 of the 2018 Guidelines for Design and Construction of 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.

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.

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.

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.

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.

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.
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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

Intent: The intent of the change is to update the reference to the appropriate guidelines for design and construction of hospice facilities.

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.

Likely Impact: The change will reduce confusion for regulated entities regarding the specific requirements for
| DIBR | N/A | DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-391)  
Personal Care Aide Training Curriculum, 2003, Department of Medical Assistance Services.  
| Change: The Board is proposing the following change:  
DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-391)  
Personal Care Aide Training Curriculum, 2003, Department of Medical Assistance Services.  
| 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. |
| 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. |
| Likely Impact: Hospice facilities will be designed and constructed according to the current version of the FGI guidelines. |
12VAC5-391-330. Medical direction.
   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 and medical needs of the terminally ill.
   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.
   C-B. The duties and responsibilities of the medical director shall include at least the following:
   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.

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

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

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

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

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

12VAC5-391-350. Home attendant services.

A. Services of the home attendants may include, but are not limited to:
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;
4. Measuring and recording fluid intake and output;
5. Recording and reporting to the health care professional changes in the patient's physical condition, behavior or appearance;
6. Documenting services and observations in the medical record; and
7. Performing any other duties that the attendant is qualified to do by additional training and demonstrated competency, within state guidelines.

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.

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

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.
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.

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

   1. Have satisfactorily completed a nursing education hospice program preparing for registered nurse licensure or practical nurse licensure;
   2. Have satisfactorily completed a nurse aide education hospice program approved by the Virginia Board of Nursing;
   3. Have certification as a nurse aide issued by the Virginia Board of Nursing;
   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; or
   5. Have satisfactorily passed a competency evaluation that meets the criteria of 42 CFR 484.36 (b); or
   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.

   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.

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

   1. Include education addressing:
      a. Goals of personal care;
      b. Prevention of skin breakdown;
      c. Physical and biological aspects of aging;
      d. Physical and emotional needs of older adults;
      e. Orientation to types of physical disabilities;
      f. Personal care and rehabilitative services;
      g. Body mechanics;
      h. Home management;
      i. Safety and accident prevention in the home;
      j. Policies and procedures regarding accidents or injuries;
      k. Food, nutrition, and meal preparation;
      l. Special considerations in preparation of special diets;
      m. Care of the home and personal belongings; and
      n. Documentation requirements for Medicaid individuals.

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

   3. Issue and maintain certificates of completion containing:
      a. The instructor's printed name and signature;
      b. The participant’s printed name; and
      c. The date of completion of the program.
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.

Part IV
Hospice Facilities

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.

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.

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.

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.

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.

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

G. 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.

H. 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.

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

J. 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.

K. 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.

L. 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.

M. The 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.

DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-391)

Personal Care Aide Training Curriculum, 2003, Department of Medical Assistance Services.

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.
Fast-Track Regulation
Agency Background Document

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

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 regulated 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**

<table>
<thead>
<tr>
<th>For your agency: 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</th>
<th>The Board does not expect any changes to costs, savings, fees or revenues as a result of the proposed regulatory change.</th>
</tr>
</thead>
<tbody>
<tr>
<td>For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.</td>
<td>The Board does not expect any cost savings by other state agencies as a result of the regulatory change. 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.</td>
</tr>
<tr>
<td>For all agencies: Benefits the regulatory change is designed to produce.</td>
<td>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.</td>
</tr>
</tbody>
</table>

**Impact on Localities**

<table>
<thead>
<tr>
<th>Projected costs, savings, fees or revenues resulting from the regulatory change.</th>
<th>There is no projected cost to localities.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benefits the regulatory change is designed to produce.</td>
<td>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.</td>
</tr>
</tbody>
</table>

**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.

<table>
<thead>
<tr>
<th>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.</th>
<th>The regulations pertain to food establishments operating in the Commonwealth.</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>Benefits the regulatory change is designed to produce.</td>
<td>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</td>
</tr>
</tbody>
</table>

**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:

<table>
<thead>
<tr>
<th>Current section number</th>
<th>New section number, if applicable</th>
<th>Current requirement</th>
<th>Change, intent, rationale, and likely impact of new requirements</th>
</tr>
</thead>
</table>

7
| 12VAC5-421-10 | Definitions | • 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
not include full spelling of term.  
- 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.

<table>
<thead>
<tr>
<th>Regulation</th>
<th>Description</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>12VAC5-421-30</td>
<td>Outlines the purpose of this chapter</td>
<td>Section amended for clarity; strikes &quot;be connected to and use&quot; as certain classifications of food establishments may be permitted without direct connections to water source (mobile food unit).</td>
</tr>
<tr>
<td>12VAC5-421-40</td>
<td>Outlines administration of regulations</td>
<td>Section amended for clarity.</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
<td>Details</td>
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</tr>
<tr>
<td>12VAC5-421-55</td>
<td>Requires at least one employee to be a certified food protection manager</td>
<td>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.</td>
</tr>
<tr>
<td>12VAC5-421-60</td>
<td>Outlines the standard of accreditation of certified food protection manager certification.</td>
<td>Requires the person in charge obtain food protection manager certification from an accredited program.</td>
</tr>
<tr>
<td>12VAC5-421-70</td>
<td>Identifies the responsibilities of the person in charge</td>
<td>Section amended for clarity, addition of regulatory citation.</td>
</tr>
<tr>
<td>12VAC5-421-80</td>
<td>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.</td>
<td>Amended to align with 2017 FDA Food Code, language added “…the last”.</td>
</tr>
<tr>
<td>12VAC5-421-100</td>
<td>Identifies when exclusions or restrictions of food employees diagnosed with certain diseases can be removed by the person in charge</td>
<td>Insert missing superscript at 1.e (2).</td>
</tr>
<tr>
<td>12VAC5-421-190</td>
<td>Outlines standard for maintenance of fingernails</td>
<td>Section amended to conform with the Virginia Register of Regulations style requirements.</td>
</tr>
<tr>
<td>Section</td>
<td>Description</td>
<td>Notes</td>
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</tr>
<tr>
<td>12VAC5-421-255</td>
<td>Requires facility to have procedures to clean up vomit or diarrheal events</td>
<td>Amends section to require written procedures regarding cleanup of vomit or diarrheal events, conforms to 2017 FDA Food Code.</td>
</tr>
<tr>
<td>12VAC5-421-260</td>
<td>Requires food served in food establishments be safe, unadulterated and honestly presented.</td>
<td>Amend superscript from “Pf” or priority foundation to “P” or priority to conform to the 2017 FDA Food Code.</td>
</tr>
<tr>
<td>12VAC5-421-270</td>
<td>Establishes criteria by which a food establishment may individually portion whole muscle, intact beef steaks in a food establishment</td>
<td>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.</td>
</tr>
<tr>
<td>12VAC5-421-295</td>
<td>Establishes the standard by which food establishments may offer for sale or services treated juice.</td>
<td>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.</td>
</tr>
<tr>
<td>12VAC5-421-300</td>
<td>Establishes the standard by which food establishments may offer for sale or service fish and molluscan shellfish</td>
<td>Amend subsection A (2) to Strike, “…by a regulatory agency of competent jurisdiction.” This amendment conforms this section to the 2017 FDA Food Code.</td>
</tr>
<tr>
<td>12VAC5-421-310</td>
<td>Requires that molluscan shellfish be obtained from an approved source.</td>
<td>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.</td>
</tr>
<tr>
<td>12VAC5-421-340</td>
<td>Outlines the appropriate temperatures to receive food products</td>
<td>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.</td>
</tr>
<tr>
<td>12VAC5-421-350</td>
<td>Outlines the standards and allowance for the use of additives to food</td>
<td>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.</td>
</tr>
<tr>
<td>12VAC5-421-400</td>
<td>Outlines packing and identification standards for shucked shellfish</td>
<td>Amends subsection A. 2 to conform with language from the National Shellfish Sanitation Program Guide.</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
<td>Amendments</td>
</tr>
<tr>
<td>------</td>
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</tr>
<tr>
<td>12VAC5-421-410</td>
<td>Outlines the criteria of shellstock identification</td>
<td>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.</td>
</tr>
<tr>
<td>12VAC5-421-440</td>
<td>Outlines requirements to maintain shellstock identification</td>
<td>Amend section to include &quot;...or shucked shellfish&quot; 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.</td>
</tr>
<tr>
<td>12VAC5-421-450</td>
<td>Outlines processes to prevent contamination from hands</td>
<td>Amend title of section to conform to 2017 FDA Food Code.</td>
</tr>
<tr>
<td>VAC12VAC5-421-470</td>
<td>Outlines the requirement for protecting food from cross-contamination during storage, preparation, holding and display.</td>
<td>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.</td>
</tr>
<tr>
<td>12VAC5-421-540</td>
<td>Outlines the requirements of food contact equipment and utensil sanitation</td>
<td>Amends section to correct cross reference; strike 12VAC5-421-1870 and add 12VAC5-421-1860. Section 1870 was repealed.</td>
</tr>
</tbody>
</table>
| 12VAC5-421-700 | Specifies the required cooking temperature and the length of time for raw animal foods | 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.  
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 &quot;Fruits and vegetables&quot;, insert &quot;Plant foods&quot;, new term encompasses both fruits and vegetables; conforms to 2017 FDA Food Code. |</p>
<table>
<thead>
<tr>
<th>Regulation</th>
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<th>Amendment Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>12VAC5-421-730</td>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>12VAC5-421-740</td>
<td>Specifies record retention for raw, marinated, raw-marinated, partially cooked, or marinated partially cooked fish.</td>
<td>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.</td>
</tr>
<tr>
<td>12VAC5-421-740</td>
<td>Specifies the proper temperature and time line to retain ready-to-eat foods and methods to date mark and dispose of food.</td>
<td>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.</td>
</tr>
<tr>
<td>12VAC5-421-830</td>
<td>Specifies the methods of compliance and time allowances for utilization of time as a public health control.</td>
<td>Amends superscript from “P” or Priority to “Pf” or priority foundation at 850.B2 and C.2.; conforms to 2017 FDA Food Code.</td>
</tr>
<tr>
<td>12VAC5-421-870</td>
<td>Outlines the requirements necessary to package foods using a reduced oxygen packaging method.</td>
<td>Amended for clarity, to correct typographical errors and to conform to the 2017 FDA Food Code.</td>
</tr>
<tr>
<td>12VAC5-421-900</td>
<td>Specifies requirements for food label information.</td>
<td>Amended for clarity, to correct typographical errors and to conform changes to the 2017 FDA Food Code.</td>
</tr>
<tr>
<td>12VAC5-421-930</td>
<td>Specifies when a consumer advisory is required for consumption of raw or undercooked animal foods and required language in disclosures.</td>
<td>Amended for clarity, to correct typographical errors and to conform to the 2017 FDA Food Code.</td>
</tr>
<tr>
<td>12VAC5-421-940</td>
<td>Specifies criteria to which food must be discarded or reconditioned.</td>
<td>Amends for clarity, to correct typographical errors and to conform to the 2017 FDA Food Code.</td>
</tr>
<tr>
<td>12VAC5-421-950</td>
<td>Outlines prohibitions to services of certain pasteurized foods.</td>
<td>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.</td>
</tr>
<tr>
<td>12VAC5-421-1180</td>
<td>Specifies scaling of food temperature measuring devices.</td>
<td>Section amended to conform to the 2017 FDA Food Code.</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
<td>Action</td>
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<td>------------------------------------------------------------------------</td>
</tr>
<tr>
<td>12VAC5-421-1190</td>
<td>Specifies scaling of ambient air and water temperature measuring devices</td>
<td>Section amended to conform to the 2017 FDA Food Code.</td>
</tr>
<tr>
<td>12VAC5-421-1300</td>
<td>Requires a variance and a HACCP plan for food establishments to use molluscan shellfish life support system display tanks.</td>
<td>Amend cross reference regulations to correct citation.</td>
</tr>
<tr>
<td>12VAC5-421-1380</td>
<td>Specifies requirements of flow pressure devices in warewashing machines</td>
<td>Insert &quot;and&quot; between section A and B. Section amended to conform to the 2017 FDA Food Code.</td>
</tr>
<tr>
<td>12VAC5-421-1520</td>
<td>Specifies requirements of temperature measuring devices for manual and mechanical warewashing</td>
<td>Insert &quot;priority foundation&quot; superscripts to section A and B to conform to 2017 FDA Food Code.</td>
</tr>
<tr>
<td>12VAC5-421-1535</td>
<td>Specifies necessity of cleaning agents and sanitizers to clean equipment and utensils</td>
<td>Section amended to correct cross-reference, Change “Article 6” to “Article 7”.</td>
</tr>
<tr>
<td>12VAC5-421-1620</td>
<td>Specifies limitations of use of warewashing sinks</td>
<td>Amend section to correct cross reference, strike “12VAC5-421-1880 et seq.” and insert “12VAC5-421-1885 et seq.”</td>
</tr>
<tr>
<td>12VAC5-421-2090</td>
<td>Requires that nondrinking water is only used if approved and only for non-culinary purposes</td>
<td>Strike “irrigation”. Amended language to conform to the 2017 FDA Food Code.</td>
</tr>
<tr>
<td>12VAC5-421-2100</td>
<td>Specifies sampling requirements of private wells.</td>
<td>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.</td>
</tr>
<tr>
<td>12VAC5-421-2270</td>
<td>Specifies circumstances for use of backflow prevention device with carbonator</td>
<td>Amend language, strike “approved”, insert “provided” to conform to 2017 FDA Food Code.</td>
</tr>
<tr>
<td>12VAC5-421-2330</td>
<td>Requires scheduling of inspection and services of water treatment devices or</td>
<td>Amend language to include timeline to retain service records and to require such records be available upon the request of the regulatory authority.</td>
</tr>
<tr>
<td>Code</td>
<td>Section Description</td>
<td>Amended Section</td>
</tr>
<tr>
<td>----------------------</td>
<td>-------------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>12VAC5-421-2350</td>
<td>Requires plumbing systems to be repaired and maintained</td>
<td>Reformat section for clarity, and conformance to the 2017 FDA Food Code.</td>
</tr>
<tr>
<td>12VAC5-421-2570</td>
<td>Requires food establishments to utilize an approved sewage disposal system.</td>
<td>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.</td>
</tr>
<tr>
<td>12VAC5-421-2720</td>
<td>Requires food establishments to cover waste handling receptacles</td>
<td>Section amended for clarity and conformance to the 2017 FDA Food Code.</td>
</tr>
<tr>
<td>12VAC5-421-2750</td>
<td>Requires cleaning and cleaning frequency of receptacles and waste handling units</td>
<td>Section amended to correct error in cross reference citation, strike “12VAC5-421-2550, insert “12VAC5-421-2540”.</td>
</tr>
<tr>
<td>12VAC5-421-3040</td>
<td>Outlines restrictions of use of sinks for food preparation and utensil washing</td>
<td>Section amended to conform to 2017 FDA Food Code, specifically formatting.</td>
</tr>
<tr>
<td>12VAC5-421-3360</td>
<td>Outlines conditions of use of poisonous or toxic materials in food establishments</td>
<td>Section amended to conform to 2017 FDA Food Code.</td>
</tr>
<tr>
<td>12VAC5-421-3390</td>
<td>Outlines the criteria for the use of chemicals when washing fruits and vegetables</td>
<td>Section, including title, amended to conform to 2017 FDA Food Code.</td>
</tr>
<tr>
<td>12VAC5-421-3410</td>
<td>Establishes requirements for the use of drying agents used in conjunction with sanitation.</td>
<td>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.</td>
</tr>
<tr>
<td>12VAC5-421-3510</td>
<td>General provision of the applicability of this chapter as it pertains to public health protection</td>
<td>Section amended to conform to 2017 FDA Food Code.</td>
</tr>
<tr>
<td>12VAC5-421-3570</td>
<td>Outlines criteria for the submission of a variance</td>
<td>Section amended for clarity.</td>
</tr>
<tr>
<td>12VAC5-421-3580</td>
<td>Outlines the variance evaluation process by the commissioner</td>
<td>Section amended to correct error in cross referenced regulation, add “section C” to 12VAC5-421-3570.</td>
</tr>
<tr>
<td>12VAC5-421-3620</td>
<td>Outlines when a HACCP plan is required</td>
<td>Section amended for clarity.</td>
</tr>
<tr>
<td>12VAC5-421-3630</td>
<td>Outlines the content requirements of a HACCP</td>
<td>Section amended to conform to 2017 FDA Food Code.</td>
</tr>
<tr>
<td>Section</td>
<td>Description</td>
<td>Notes</td>
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</tr>
<tr>
<td>12VAC5-421-3660</td>
<td>Establishes the requirements pertaining to obtaining and maintaining a food establishment permit</td>
<td>Language added to clarify expiration dates of permits, not to exceed twelve months from date of issuance.</td>
</tr>
<tr>
<td>12VAC5-421-3670</td>
<td>Outline the application procedure for a food establishment permit</td>
<td>Amends section to expand on general application procedures and the disposition of applications after one year.</td>
</tr>
<tr>
<td>12VAC5-421-3690</td>
<td>Outlines with the qualifications and responsibilities of applicants</td>
<td>Section amended for clarity.</td>
</tr>
<tr>
<td>12VAC5-421-3710</td>
<td>Establishes a requirement to submit plans for new, converted, or remodeled food establishments</td>
<td>Section amended to clarify cross reference and conformance to 2017 FDA Food Code.</td>
</tr>
<tr>
<td>12VAC5-421-3720</td>
<td>Establishes process to renew a permit or issue a new permit.</td>
<td>Amends section to include the requirement to notify the department of change of legal ownership of a food establishment.</td>
</tr>
<tr>
<td>12VAC5-421-3750</td>
<td>Establishes responsibilities for permit holders which includes reporting and operating requirements</td>
<td>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.</td>
</tr>
<tr>
<td>12VAC5-421-3770</td>
<td>Outlines process of summary suspension of permit, include notification to permit holder</td>
<td>Amended for clarity and to adhere to current administrative process.</td>
</tr>
<tr>
<td>12VAC5-421-3780</td>
<td>Establishes when the director may revoke a permit.</td>
<td>Section amended for clarity.</td>
</tr>
<tr>
<td>12VAC5-421-3800</td>
<td>Establishes inspection frequency for food establishments</td>
<td>Section amended for clarity, additional cross reference added to conform to the 2017 FDA Food Code.</td>
</tr>
<tr>
<td>12VAC5-421-3815</td>
<td>Establishes standard for competency of environmental health specialists.</td>
<td>Section amended to comply with 1VAC7-10-140.D.</td>
</tr>
<tr>
<td>12VAC5-421-3830</td>
<td>Outlines process for staff to follow when access to a food establishment is denied.</td>
<td>Section amended to correct error in regulatory cross reference, Strike “12VAC5-421-3750.F” insert “12VAC5-421-3750.6” and amended for clarity.</td>
</tr>
<tr>
<td>12VAC5-421-3850</td>
<td>Outlines process of applying to circuit court to obtain inspection warrant if denied access to a food establishment</td>
<td>Strike “or his designee”, commissioner’s authority to elect a designee is in statute.</td>
</tr>
<tr>
<td>12VAC5-421-3860</td>
<td>Outlines the information required for an inspection form.</td>
<td>Amended to conform to current administrative practices, insert item “core” as these items are currently documented on inspection form.</td>
</tr>
<tr>
<td>Current chapter-section number</td>
<td>New chapter-section number, if applicable</td>
<td>Current requirement</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>------------------------------------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>12VAC5-421-3550</td>
<td>Establishes the Food Service Advisory Committee (FSAC) which provides policy and program advise to the Commissioner</td>
<td>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</td>
</tr>
</tbody>
</table>

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:
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.

<table>
<thead>
<tr>
<th>New chapter-section number</th>
<th>New requirements</th>
<th>Other regulations and law that apply</th>
<th>Intent and likely impact of new requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>12VAC5-421-3960</td>
<td>12VAC5-421-3961 to 12VAC5-421-3966 Outlines process when impounding food</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-4035</td>
<td>Outlines operational requirements for facilities that otherwise are exempt from the requirement of a permit that choose to be regulated</td>
<td>Section repealed, strike allowance for food establishments who would otherwise be exempt from permitting from voluntarily obtaining a permit.</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>New chapter-section number</th>
<th>New requirements</th>
<th>Other regulations and law that apply</th>
<th>Intent and likely impact of new requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>12VAC5-421-235</td>
<td>Outlines the permissible use of bandages, finger cots, or finger stalls</td>
<td>N/A</td>
<td>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.</td>
</tr>
<tr>
<td>12VAC5-421-2140</td>
<td>Specifies the types of approved source from which food establishments must obtain water.</td>
<td>N/A</td>
<td>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.</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
<td>Notes</td>
<td></td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-3595</td>
<td>Requires permit holders, who apply for a variance or HACCP Plan to comply with the approved variance and/or HACCP Plan.</td>
<td>N/A Section added to conform to 2017 FDA Food Code. No impact foreseeable.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-3961</td>
<td>Requires staff, when impounding food products, to provide a written order outlining the reason for the impoundment</td>
<td>N/A Section added to conform to 2017 FDA Food Code, expands on section 12VAC5-421-3960. No impact on regulated community.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-3962</td>
<td>Outlines language required on impoundment/hold orders of food products</td>
<td>N/A Section added to conform to 2017 FDA Food Code, expands on section 12VAC5-421-3960. No impact on regulated community.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-3963</td>
<td>Outlines procedures for staff to properly label food under a hold order and label language</td>
<td>N/A Section added to conform to 2017 FDA Food Code, expands on section 12VAC5-421-3960. No impact on regulated community.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-3964</td>
<td>Requires permit holders not to move, use, or sell food under a hold order</td>
<td>N/A Section added to conform to 2017 FDA Food Code, expands on section 12VAC5-421-3960. No impact on regulated community.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-3965</td>
<td>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</td>
<td>N/A Section added to conform to 2017 FDA Food Code, expands on section 12VAC5-421-3960. No impact on regulated community.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-3966</td>
<td>Outlines when staff may order a permit holder to comply with regulations or destroy or denature food and due process rights of permit holder</td>
<td>N/A Section added to conform to 2017 FDA Food Code, expands on section 12VAC5-421-3960. No impact on regulated community.</td>
<td></td>
</tr>
</tbody>
</table>
12VAC5-421-10. Definitions.

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

“Board”
“Commissioner”
“Department”

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

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

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

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

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

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

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

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

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

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

"a_w" means water activity that is a measure of the free moisture in a food, is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature, and is indicated by the symbol a_w.
"Balut" means an embryo inside a fertile egg that has been incubated for a period sufficient for the embryo to reach a specific stage of development after which it is removed from incubation before hatching.

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

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

"Board" means the State Board of Health.

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

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

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

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

"Catering operation" does not include:
1. A private chef or cook who, as the employee of a consumer, prepares food solely in the consumer's home.
2. Delivery service of food by an approved and permitted food establishment to an end consumer.

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

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

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

"Commingle" means:
1. To combine shellstock harvested on different days or from different growing areas as identified on the tag or label; or
2. To combine shucked shellfish from containers with different container codes or different shucking dates.

"Comminuted" means reduced in size by methods including chopping, flaking, grinding, or mincing. "Comminuted" includes (i) fish or meat products that are reduced in size and restructured or reformulated such as gefilte fish, gyros, ground beef, and sausage and (ii) a mixture of two or more types of meat that have been reduced in size and combined, such as sausages made from two or more meats.
"Commissary" means a catering establishment, food establishment, or any other place in which food, food containers, or supplies are kept, handled, prepared, packaged, or stored for distribution to satellite operations.

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

"Commonwealth" means the Commonwealth of Virginia.

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

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

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

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

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

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

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

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

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

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

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

"Department" means the Virginia Department of Health.

"Director" means the district or local health director.

"Disclosure" means a written statement that clearly identifies the animal derived foods that are, or can be ordered, raw, undercooked, or without otherwise being processed to eliminate
pathogens in their entirety, or items that contain an ingredient that is raw, undercooked, or without otherwise being processed to eliminate pathogens.

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

"Easily cleanable" means a characteristic of a surface that:
1. Allows effective removal of soil by normal cleaning methods;
2. Is dependent on the material, design, construction, and installation of the surface; and
3. Varies with the likelihood of the surface’s role in introducing pathogenic or toxigenic agents or other contaminants into food based on the surface’s approved placement, purpose, and use.

"Easily cleanable" includes a tiered application of the criteria that qualify the surface as easily cleanable as specified above to different situations in which varying degrees of cleanability are required such as:
1. The appropriateness of stainless steel for a food preparation surface as opposed to the lack of need for stainless steel to be used for floors or for tables used for consumer dining; or
2. The need for a different degree of cleanability for a utilitarian attachment or accessory in the kitchen as opposed to a decorative attachment or accessory in the consumer dining area.

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

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

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

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

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

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

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

"°F" means degrees Fahrenheit.
"FDA" means the U.S. Food and Drug Administration.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"Injected" means manipulating meat to which a solution has been introduced into its interior by processes such that are referred to as "injecting," "pump marinating," or "stitch pumping."
"Intact Meat" means a cut of whole muscle(s) meat that has not undergone comminution, injection, mechanical tenderization, or reconstruction.

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

"Kitchenware" means food preparation and storage utensils.

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

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

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

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

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

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

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

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

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

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

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

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

"Permit holder" means the entity person that is legally responsible for the operation of the food establishment such as the owner, the owner's agent, or other person, and possesses a valid permit to operate a food establishment.
"Person" means an association, a corporation, individual, partnership, other legal entity, government, or governmental subdivision or agency.

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

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

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

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

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

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

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

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

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

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

"Premises" means the physical facility, its contents, and the contiguous land or property under the control of the permit holder; or the physical facility, its contents, and the land or property which
are under the control of the permit holder and may impact food establishment personnel, facilities, or operations, if a food establishment is only one component of a larger operation such as a health care facility, hotel, motel, school, recreational camp, or prison.

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

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

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

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

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

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

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

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

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

"Ready-to-eat food" includes:

1. Raw animal food that is cooked as specified under 12VAC5-421-700, or 12VAC5-421-710 or frozen as specified under 12VAC5-421-730;
2. Raw fruits and vegetables that are washed as specified under 12VAC5-421-510;
3. Fruits and vegetables that are cooked for hot holding as specified under 12VAC5-421-720;
4. All time/temperature control for safety food that is cooked to the temperature and time required for the specific food under 12VAC5-421-700Part III, Article 4 (12VAC5-421-700 et seq.) and cooled as specified in 12VAC5-421-800;

5. Plant food for which further washing, cooking, or other processing is not required for food safety, and from which rinds, peels, husks, or shells, if naturally present, are removed;

6. Substances derived from plants such as spices, seasonings, and sugar;

7. A bakery item such as bread, cakes, pies, fillings, or icing for which further cooking is not required for food safety;

8. The following products that are produced in accordance with USDA guidelines and that have received a lethality treatment for pathogens: dry, fermented sausages, such as dry salami or pepperoni; salt-cured meat and poultry products, such as prosciutto ham, country cured ham, and Parma ham; and dried meat and poultry products, such as jerky or beef sticks; and


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

1. Vacuum packaging, in which air is removed from a package of food and the package is hermetically sealed so that a vacuum remains inside the package;

2. Modified atmosphere packaging, in which the atmosphere of a package of food is modified so that its composition is different from air, but the atmosphere may change over time due to the permeability of the packaging material or the respiration of the food. Modified atmosphere packaging includes reduction in the proportion of oxygen, total replacement of oxygen, or an increase in the proportion of other gases such as carbon dioxide or nitrogen;

3. Controlled atmosphere packaging, in which the atmosphere of a package of food is modified so that until the package is opened, its composition is different from air, and continuous control of that atmosphere is maintained, such as by using oxygen scavengers or a combination of total replacement oxygen, nonrespiring food, and impermeable packaging material;

4. Cook chill packaging, in which cooked food is hot filled into impermeable bags that have the air expelled and are then sealed or crimped closed. The bagged food is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens; or

5. Sous vide packaging, in which raw or partially cooked food is vacuum packaged in an impermeable bag, cooked in the bag, rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.

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

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

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

"Reservice" "Re-service" means the transfer of food that is unused and returned by a consumer after being served or sold and in the possession of the consumer, to another person.
"Restrict" means to limit the activities of a food employee so that there is no risk of transmitting a disease that is transmissible through food and the food employee does not work with exposed food, clean equipment, utensils, linens, and unwrapped single-service or single-use articles.

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

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

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

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

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

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

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

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

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

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

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

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

"Shucked shellfish" means molluscan shellfish that have one or both shells removed.
"Single-service articles" means tableware, carry-out utensils, and other items such as bags, containers, placemats, stirrers, straws, toothpicks, and wrappers that are designed and constructed for one time, one person use after which they are intended for discard.

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

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

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

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

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

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

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

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

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

<table>
<thead>
<tr>
<th>A_w values</th>
<th>pH values</th>
<th>4.6 or less</th>
<th>&gt;4.6 - 5.6</th>
<th>&gt;5.6</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤0.92</td>
<td>non-TCS food*</td>
<td>non-TCS food</td>
<td>non-TCS food</td>
<td></td>
</tr>
<tr>
<td>&gt;0.92 - 0.95</td>
<td>non-TCS food</td>
<td>non-TCS food</td>
<td>PA**</td>
<td></td>
</tr>
</tbody>
</table>

Table A. Interaction of pH and A_w for control of spores in food heat treated to destroy vegetative cells and subsequently packaged.
Table B. Interaction of pH and A\textsubscript{w} for control of vegetative cells and spores in food not heat treated or heat treated but not packaged.

<table>
<thead>
<tr>
<th>A\textsubscript{w} values</th>
<th>pH values</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt; 4.2</td>
<td>4.2 - 4.6</td>
<td>&gt; 4.6 - 5.0</td>
<td>&gt; 5.0</td>
</tr>
<tr>
<td>&lt; 0.88</td>
<td>non-TCS food*</td>
<td>non-TCS food</td>
<td>non-TCS food</td>
<td>non-TCS food</td>
</tr>
<tr>
<td>0.88 - 0.90</td>
<td>non-TCS food</td>
<td>non-TCS food</td>
<td>non-TCS food</td>
<td>PA**</td>
</tr>
<tr>
<td>&gt; 0.90 - 0.92</td>
<td>non-TCS food</td>
<td>non-TCS food</td>
<td>PA</td>
<td>PA</td>
</tr>
<tr>
<td>&gt; 0.92</td>
<td>non-TCS food</td>
<td>PA</td>
<td>PA</td>
<td>PA</td>
</tr>
</tbody>
</table>

*TCS food means time/temperature control for safety food
**PA means product assessment required

2. TCS food does not include:

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;

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;

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

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:

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

(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

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

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.

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

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

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

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

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

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

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

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

12VAC5-421-30. Purpose.

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

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

12VAC5-421-40. Administration of regulation.

This chapter is administered by the following:

1. The State Board of Health, hereinafter referred to as the board, has responsibility
to promulgate, amend and repeal regulations necessary to protect the public health.
2. The State Health Commissioner, hereinafter referred to as the commissioner,
   commissioner is the chief executive officer of the State Department of Health department.
The commissioner has the authority to act within the scope of regulations promulgated by
the board and for the board when it is not in session.

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

12VAC5-421-55. Certified food protection manager.
A. At least one employee with supervisory and management responsibility and the authority
to direct and control food preparation and service shall be a certified food
protection manager, demonstrating proficiency of required knowledge and
information through passing a test that is part of an accredited program.
B. This section does not apply to food establishments that serve only non-temperature
controlled food and food establishments where food handling does not exceed reheating, cold holding, and hot holding of commercially processed and packaged ready-
to-eat foods, that store and prepare food only to the extent that they reheat or cold hold
commercially processed, fully cooked time/temperature control for safety foods. Food
establishments exempt from the certified food protection manager requirement may not cool
time/temperature control for safety foods.
C. For purposes of enforcement, this section will take effect on July 1, 2018.

12VAC5-421-60. Demonstration of knowledge.
Based on the risks of foodborne illness inherent to the food operation, during inspections and
upon request the person in charge shall demonstrate to the regulatory authority department
knowledge of foodborne disease prevention, and the requirements of this chapter. The person in
charge shall demonstrate this knowledge by:

1. Complying with this chapter by having no violations of priority items during the current
inspection;
2. Being a certified food protection manager who has shown proficiency of required
information through passing a test that is part of an accredited program; or
3. Responding correctly to the environmental health specialist’s questions as they relate
to the specific food operation. The areas of operation may include:

A. Describing the relationship between the prevention of foodborne disease and the
personal hygiene of a food employee;
B. Explaining the responsibility of the person in charge for preventing the transmission
of foodborne disease by a food employee who has a disease or medical condition that
may cause foodborne disease;
C. Describing the symptoms associated with the diseases that are transmissible
through food;
D. Explaining the significance of the relationship between maintaining the time and
temperature of time/temperature control for safety food and the prevention of
foodborne illness;
E. Explaining the hazards involved in the consumption of raw or undercooked meat,
poultry, eggs, and fish;
F. Stating the required food temperatures and times for safe cooking of
time/temperature control for safety food including meat, poultry, eggs, and fish;
G. Stating the required temperatures and times for the safe refrigerated storage, hot
holding, cooling, and reheating of time/temperature control for safety food;
h. Describing the relationship between the prevention of foodborne illness and the management and control of the following:
(1) Cross contamination; (2) Hand contact with ready-to-eat foods; (3) Handwashing; and
(4) Maintaining the food establishment in a clean condition and in good repair;
i. Describing the foods identified as major food allergens and the symptoms that a major food allergen could cause in a sensitive individual who has an allergic reaction;
j. Explaining the relationship between food safety and providing equipment that is:
(1) Sufficient in number and capacity; and
(2) Properly designed, constructed, located, installed, operated, maintained, and cleaned;
k. Explaining correct procedures for cleaning and sanitizing utensils and food-contact surfaces of equipment;
l. Identifying the source of water used and measures taken to ensure that the water supply remains protected from contamination such as providing protection from backflow and precluding the creation of cross connections;
m. Identifying poisonous or toxic materials in the food establishment and the procedures necessary to ensure that they are safely stored, dispensed, used, and disposed of according to law;
n. Identifying critical control points in the operation from purchasing through sale or service that when not controlled may contribute to the transmission of foodborne illness and explaining steps taken to ensure that the points are controlled in accordance with the requirements of this chapter;
o. Explaining the details of how the person in charge and food employees comply with a HACCP plan if such a plan is required by the law, this chapter, or a voluntary agreement between the regulatory authority department and the food establishment;
p. Explaining the responsibilities, rights, and authorities assigned by this chapter to the:
(1) Food employee; (2) Conditional employee; (3) Person in charge; and
(4) Regulatory authority department;
q. Explaining how the person in charge, food employees, and conditional employees comply with reporting responsibilities and the exclusion or restriction of food employees.

12VAC5-421-70. Duties of person in charge.
The person in charge shall ensure that:
1. Food establishment operations are not conducted in a private home or in a room used as living or sleeping quarters as specified under 12VAC5-421-2990;
2. Persons unnecessary to the food establishment operation are not allowed in the food preparation, food storage, or warewashing areas, except that brief visits and tours may be authorized by the person in charge if steps are taken to ensure that exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles are protected from contamination;
3. Employees and other persons such as delivery and maintenance persons and pesticide applicators entering the food preparation, food storage, and warewashing areas comply with this chapter;\textsuperscript{Pf}

4. Employees are effectively cleaning their hands, by routinely monitoring the employees' handwashing;\textsuperscript{Pf}

5. Employees are visibly observing foods as they are received to determine that they are from approved sources, delivered at the required temperatures, protected from contamination, unadulterated, and accurately presented, by routinely monitoring the employees' observations and periodically evaluating foods upon their receipt;\textsuperscript{Pf}

6. Employees are verifying that foods delivered to the food establishment during non-operating hours are from approved sources and are placed into appropriate storage locations such that they are maintained at the required temperatures, protected from contamination, unadulterated, and accurately presented;\textsuperscript{Pf}

7. Employees are properly cooking time/temperature control for safety food, being particularly careful in cooking those foods known to cause severe foodborne illness and death, such as eggs and comminuted meats, through daily oversight of the employees' routine monitoring of the cooking temperatures using appropriate temperature measuring devices properly scaled and calibrated as specified under 12VAC5-421-1180 and 12VAC5-421-1730 B;\textsuperscript{Pf}

8. Employees are using proper methods to rapidly cool time/temperature control for safety food that is not held hot or is not for consumption within four hours, through daily oversight of the employees' routine monitoring of food temperatures during cooling;\textsuperscript{Pf}

9. Employees are properly maintaining the temperatures of time/temperature control for safety food during hot and cold holding through daily oversight of the employees routine monitoring of food temperatures;\textsuperscript{Pf}

10. Consumers who order raw or partially cooked ready-to-eat foods of animal origin are informed as specified under 12VAC5-421-930 that the food is not cooked sufficiently to ensure its safety;\textsuperscript{Pf}

11. Employees are properly sanitizing cleaned multiuse equipment and utensils before they are reused, through routine monitoring of solution temperature and exposure time for hot water sanitizing, and chemical concentration, pH, temperature, and exposure time for chemical sanitizing;\textsuperscript{Pf}

12. Consumers are notified that clean tableware is to be used when they return to self-service areas such as salad bars and buffets as specified in 12VAC5-421-590;\textsuperscript{Pf}

13. Except when approval is obtained from the regulatory authority department as specified in 12VAC5-421-450 E, employees are preventing cross-contamination of ready-to-eat food with bare hands by properly using suitable utensils such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment;\textsuperscript{Pf}

14. Employees are properly trained in food safety, including food allergy awareness, as it relates to their assigned duties;\textsuperscript{Pf}

15. Food employees and conditional employees are informed in a verifiable manner of their responsibility to report in accordance with law, to the person in charge, information about their health and activities as they relate to diseases that are transmissible through food, as specified under 12VAC5-421-80;\textsuperscript{Pf} and

16. Written procedures and plans, where specified by this chapter and as developed by the food establishment, are maintained and implemented as required;\textsuperscript{Pf}
Article 2
Employee Health

12VAC5-421-80. Responsibility of permit holder, person in charge, and conditional employees.

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

1. Has any of the following symptoms:
   a. Vomiting;
   b. Diarrhea;
   c. Jaundice;
   d. Sore throat with fever; or
   e. A lesion containing pus such as a boil or infected wound that is open or draining and is:
      (1) On the hands or wrists, unless an impermeable cover such as a finger cot or stall protects the lesion and a single-use glove is worn over the impermeable cover;
      (2) On exposed portions of the arms, unless the lesion is protected by an impermeable cover; or
      (3) On other parts of the body, unless the lesion is covered by a dry, durable, tight-fitting bandage;

2. Has an illness diagnosed by a health practitioner due to:
   a. Norovirus;
   b. Hepatitis A virus;
   c. Shigella spp.;
   d. Shiga toxin-producing Escherichia coli;
   e. Typhoid fever (caused by Salmonella typhi); or
   f. Salmonella (nontyphoidal);

3. Had typhoid Typhoid fever, diagnosed by a health practitioner, within the past three months, without having received antibiotic therapy, as determined by a health practitioner;

4. Has been exposed to, or is the suspected source of, a confirmed disease outbreak, because the food employee or conditional employee consumed or prepared food implicated in the outbreak, or consumed food at an event prepared by a person who is infected or ill with:
   a. Norovirus within the past 48 hours of the last exposure;
   b. Shiga toxin-producing Escherichia coli, or Shigella spp. within the past three days of the last exposure;
   c. Typhoid fever (caused by Salmonella typhi) within the past 14 days of the last exposure; or
   d. Hepatitis A virus within the past 30 days of the last exposure; or

5. Has been exposed by attending or working in a setting where there is a confirmed disease outbreak, or living in the same household as, and has knowledge about an
individual who works or attends a setting where there is a confirmed disease outbreak, or
living in the same household as, and has knowledge about, and an individual diagnosed
with an illness caused by:

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

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

1. Jaundiced;
2. Diagnosed with an illness due to a pathogen as specified under subdivisions A 2 a
   through f of this section.

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

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

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

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

E. A food employee or conditional employee shall report to the person in charge the
   information as specified under subsection A of this section.

F. A food employee shall:

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

12VAC5-421-90. Exclusions and restrictions.

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

1. Except when the symptom is from a noninfectious condition, exclude a food employee
   if the food employee is:
2. Exclude a food employee who is:
   a. Jaundiced and the onset of jaundice occurred within the last seven calendar days, unless the food employee provides to the person in charge written medical documentation from a health practitioner specifying that the jaundice is not caused by Hepatitis A virus or other fecal- or orally transmitted infection;
   b. Diagnosed with an infection from Hepatitis A virus within 14 calendar days from the onset of any illness symptoms, or within seven calendar days of the onset of jaundice;
   or
   c. Diagnosed with an infection from Hepatitis A virus without developing symptoms.

3. Exclude a food employee who is diagnosed with typhoid fever, or reports having had typhoid fever within the past three months as specified in 12VAC5-421-80 A 3.

4. If a food employee is diagnosed with an infection from Norovirus and is asymptomatic:
   a. Exclude the food employee who works in a food establishment serving a highly susceptible population;
   or
   b. Restrict the food employee who works in a food establishment not serving a highly susceptible population.

5. If a food employee is diagnosed with an infection from Shigella spp. and is asymptomatic:
   a. Exclude the food employee who works in a food establishment serving a highly susceptible population;
   or
   b. Restrict the food employee who works in a food establishment not serving a highly susceptible population.

6. If a food employee is diagnosed with an infection from Shiga toxin-producing Escherichia coli, and is asymptomatic:
   a. Exclude the food employee who works in a food establishment serving a highly susceptible population;
   or
   b. Restrict the food employee who works in a food establishment not serving a highly susceptible population.

7. If a food employee is diagnosed with an infection from Salmonella (nontyphoidal) and is asymptomatic, restrict the food employee who works in a food establishment:
   a. Serving a highly susceptible population;
   or
   b. Not serving a highly susceptible population.

8. If a food employee is ill with symptoms of acute onset of sore throat with fever:
   a. Exclude the food employee who works in a food establishment serving a highly susceptible population;
   or
   b. Restrict the food employee who works in a food establishment not serving a highly susceptible population.

9. If a food employee is infected with a skin lesion containing pus such as a boil or infected wound that is open or draining and not properly covered as specified under 12VAC5-421-80 A 1 e, restrict the food employee.
421-80 A 4 or 5, restrict the food employee who works in a food establishment serving a
highly susceptible population.\textsuperscript{p}

\textbf{12VAC5-421-100. Removal, adjustment, or retention of exclusions and restrictions.}

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

1. Except when a food employee is diagnosed with \textit{typhoid Typhoid} fever or an infection
from Hepatitis A virus:

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

(1) Is asymptomatic for at least 24 hours;\textsuperscript{p} or

(2) Provides to the person in charge written medical documentation from a health
practitioner that states the symptom is from a noninfectious condition.\textsuperscript{p}

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

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

(2) Retain the exclusion for the food employee, who is asymptomatic for at least 24
hours and works in a food establishment that serves a highly susceptible population,
until the conditions for reinstatement as specified in subdivision 4 a or b of this section
are met.\textsuperscript{p}

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

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

(2) Retain the exclusion for the food employee, who is asymptomatic for at least 24
hours and works in a food establishment that serves a highly susceptible population,
until the conditions for reinstatement as specified in subdivision 5 a or b, or 5 a and 1

\textsuperscript{c} (1) of this section are met.\textsuperscript{p}

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

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

(2) Retain the exclusion for the food employee, who is asymptomatic for at least 24
hours and works in a food establishment that serves a highly susceptible population,
until the conditions for reinstatement as specified in subdivision 6 a or b are met.\textsuperscript{p}

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

(1) Restrict the food employee who is asymptomatic for at least 30 days until conditions
for reinstatement as specified under subdivision 7 a or 7 b of this section are met;\textsuperscript{p} or

(2) Retain the exclusion for the food employee who is symptomatic, until conditions for
reinstatement as specified under subdivision 7 a or 7 b of this section are met.\textsuperscript{p}
2. Reinstate a food employee who was excluded as specified under subdivision 2 of 12VAC5-421-90 if the person in charge obtains approval from the regulatory authority department and one of the following conditions is met:
   a. The food employee has been jaundiced for more than seven calendar days;\(^p\)
   b. The anicteric food employee has been symptomatic with symptoms other than jaundice for more than 14 calendar days;\(^p\) or
   c. The food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of a Hepatitis A virus infection.\(^p\)

3. Reinstate a food employee who was excluded as specified under subdivision 3 of 12VAC5-421-90 if:
   a. The person in charge obtains approval from the regulatory authority department;\(^p\)
      and
   b. The food employee provides to the person in charge written medical documentation from a health practitioner that states the employee is free from Typhoid fever.\(^p\)

4. Reinstate a food employee who was excluded as specified under subdivision 1 b or 4 a of 12VAC5-421-90, who was restricted under subdivision 4 b of 12VAC5-421-90 if the person in charge obtains approval from the regulatory authority department and one of the following conditions is met:
   a. The excluded or restricted food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of a Norovirus infection;\(^p\)
      and
   b. The food employee was excluded or restricted after symptoms of vomiting or diarrhea resolved, and more than 48 hours have passed since the food employee became symptomatic;\(^p\) or
   c. The food employee was excluded or restricted and did not develop symptoms and more than 48 hours have passed since the food employee was diagnosed.\(^p\)

5. Reinstate a food employee who was excluded as specified under subdivision 1 b or 5 a of 12VAC5-421-90 or who was restricted under subdivision 5 b of 12VAC5-421-90 if the person in charge obtains approval from the regulatory authority department and one of the following conditions is met:
   a. The excluded or restricted food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of a Shigella spp. infection based on test results showing two consecutive negative stool specimen cultures that are taken:
      (1) Not earlier than 48 hours after discontinuance of antibiotics;\(^p\) and
      (2) At least 24 hours apart;\(^p\)
   b. The food employee was excluded or restricted after symptoms of vomiting or diarrhea resolved, and more than seven calendar days have passed since the food employee became asymptomatic;\(^p\) or
   c. The food employee was excluded or restricted and did not develop symptoms and more than seven calendar days have passed since the food employee was diagnosed.\(^p\)

6. Reinstate a food employee who was excluded or restricted as specified under subdivision 1 b or 6 a of 12VAC5-421-90 or who was restricted under subdivision 6 b of 12VAC5-421-90 if the person in charge obtains approval from the regulatory authority department and one of the following conditions is met:
a. The excluded or restricted food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of an infection from Shiga toxin-producing Escherichia coli based on test results that show two consecutive negative stool specimen cultures that are taken:

(1) Not earlier than 48 hours after the discontinuance of antibiotics; and
(2) At least 24 hours apart;

b. The food employee was excluded or restricted after symptoms of vomiting or diarrhea resolved and more than seven calendar days have passed since the employee became asymptomatic; or
c. The food employee was excluded or restricted and did not develop symptoms and more than seven days have passed since the employee was diagnosed.

7. Reinstate a food employee who was excluded as specified under subsection 1 ab of 12VAC5-421-90 or who was restricted as specified under subsection 7 of 12VAC5-421-90 if the person in charge obtains approval from the regulatory authority and one of the following conditions is met:

a. The excluded or restricted food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of a Salmonella (nontyphoidal) infection based on test results showing two consecutive negative stool specimen cultures that are taken:

(1) Not earlier than 48 hours after discontinuance of antibiotics; and
(2) At least 24 hours apart;

b. The food employee was restricted after symptoms of vomiting or diarrhea resolved, and more than 30 days have passed since the food employee became asymptomatic; or

c. The food employee was excluded or restricted and did not develop symptoms and more than 30 days have passed since the food employee was diagnosed.

8. Reinstate a food employee who was excluded or restricted as specified under subdivision 8 a or b of 12VAC5-421-90 if the food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee meets one of the following conditions:

a. Has received antibiotic therapy for Streptococcus pyogenes infection for more than 24 hours;

b. Has at least one negative throat specimen culture for Streptococcus pyogenes infection; or

c. Is otherwise determined by a health practitioner to be free of Streptococcus pyogenes infection.

9. Reinstate a food employee who was restricted as specified under subdivision 9 of 12VAC5-421-90 if the skin, infected wound, cut, or pustular boil is properly covered with one of the following:

a. An impermeable cover such as a finger cot or stall and a single-use glove over the impermeable cover if the infected wound or pustular boil is on the hand, finger, or wrist;

b. An impermeable cover on the arm if the infected wound or pustular boil is on the arm; or

c. A dry, durable, tight-fitting bandage if the infected wound or pustular boil is on another part of the body.
10. Reinstate a food employee who was restricted as specified under subdivision 10 of 12VAC5-421-90 and was exposed to one of the following pathogens as specified under 12VAC5-421-80 A 4 or 5:
   a. Norovirus and one of the following conditions is met:
      (1) More than 48 hours have passed since the last day the food employee was potentially exposed;\(^p\) or
      (2) More than 48 hours have passed since the food employee’s household contact became asymptomatic.\(^p\)
   b. Shigella spp. or Shiga toxin-producing Escherichia coli and one of the following conditions is met:
      (1) More than three calendar days have passed since the last day the food employee was potentially exposed;\(^p\) or
      (2) More than three calendar days have passed since the food employee’s household contact became asymptomatic.\(^p\)
   c. Typhoid fever (caused by Salmonella typhi) and one of the following conditions is met:
      (1) More than 14 calendar days have passed since the last day the food employee was potentially exposed;\(^p\) or
      (2) More than 14 calendar days have passed since the food employee’s household contact became asymptomatic.\(^p\)
   d. Hepatitis A virus and one of the following conditions is met:
      (1) The food employee is immune to Hepatitis A virus infection because of prior illness from Hepatitis A;\(^p\)
      (2) The food employee is immune to Hepatitis A virus infection because of vaccination against Hepatitis A;\(^p\)
      (3) The food employee is immune to Hepatitis A virus infection because of IgG administration;\(^p\)
      (4) More than 30 calendar days have passed since the last time the food employee was potentially exposed;\(^p\)
      (5) More than 30 calendar days have passed since the food employee’s household contact became jaundiced;\(^p\) or
      (6) The food employee does not use an alternative procedure that allows bare hand contact with ready-to-eat food until at least 30 days after the potential exposure, as specified in subdivisions 10 d (4) and (5) of this section, and the food employee receives additional training about:
         (a) Hepatitis A symptoms and preventing the transmission of infection;\(^p\)
         (b) Proper handwashing procedures;\(^p\) and
         (c) Protecting ready-to-eat food from contamination introduced by bare hand contact.\(^p\)

12VAC5-421-180. Hand antiseptics.
A. A hand antiseptic used as a topical application, a hand antiseptic solution used as a hand dip, or a hand antiseptic soap shall:
   1. Comply with one of the following:
(U.S. Food and Drug Administration) as an approved drug based on safety and effectiveness,\textsuperscript{Pt} or

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

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

a. A threshold of regulation exemption under 21 CFR 170.39;\textsuperscript{Pt}

b. 21 CFR Part 178, as regulated for use as a food additive with conditions of safe use;\textsuperscript{Pt}

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

d. A prior sanction listed under 21 CFR 181;\textsuperscript{Pt} or

e. A Food Contact Notification that is effective;\textsuperscript{Pt} and

3. Be applied only to hands that are cleaned as specified under 12VAC5-421-140.\textsuperscript{Pt}

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

1. Followed by thorough hand rinsing in clean water before hand contact with food or by the use of gloves;\textsuperscript{Pt} or

2. Limited to situations that involve no direct contact with food by the bare hands.\textsuperscript{Pt}

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

12VAC5-421-190. Maintenance of fingernails.

A. Food employees shall keep their fingernails trimmed, filed, and maintained so the edges and surfaces are cleanable and not rough.\textsuperscript{Pt}

B. Unless wearing intact gloves in good repair, a food employee shall not wear fingernail polish or artificial nails when working with exposed food.\textsuperscript{Pt}

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

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

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

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

Part III

Food

Article 1

Characteristics

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

Food shall be safe,\textsuperscript{2} and unadulterated, and, as specified in 12VAC5-421-890, honestly presented.\textsuperscript{Pt}

\textsuperscript{2}
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.\(^p\)

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 under 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;\(^p\) 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;\(^p\) 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;\(^p\)

   b. Prepared so they remain intact;\(^p\)

   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.\(^p\)

F. Meat and poultry that are not a ready-to-eat food and are 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 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;\(^p\) 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
2. Approved for sale or service by a regulatory agency of competent jurisdiction.  

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

12VAC5-421-310. Molluscan shellfish.

A. Molluscan shellfish shall be obtained from sources according to law and the requirements specified in the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish, 2013 Revision, (U.S. Food and Drug Administration).  

B. Molluscan shellfish shall be from sources that are listed in the "Interstate Certified Shellfish Shippers List," updated monthly (U.S. Food and Drug Administration).


A. Except as specified in subsection B of this section, refrigerated, time/temperature control for safety food shall be at a temperature of 41°F (5°C) or below when received.  

B. If a temperature other than 41°F (5°C) for a time/temperature control for safety food is specified in law governing its distribution, such as laws governing milk and molluscan shellfish, the food may be received at the specified temperature.  

C. Raw shell eggs shall be received in refrigerated equipment that maintains an ambient air temperature of 45°F (7°C) or less.

D. Time/temperature control for safety food that is cooked to a temperature and for a time specified under 12VAC5-421-700, 12VAC5-421-710, and 12VAC5-421-720 and received hot shall be at a temperature of 135°F (57°C) or above.  

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

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

12VAC5-421-350. Additives.

Food shall not contain unapproved food additives or additives that exceed amounts allowed specified in 21 CFR Parts 170-180 relating to food additives; generally recognized as safe (GRAS) or prior sanctioned substances that exceed amounts allowed in 21 CFR Parts 181-186; substances that exceed amounts specified in 9 CFR 424.21(b), Subpart C; or pesticide residues that exceed provisions specified in 40 CFR Part 180 and exceptions.

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

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

1. Name, address, and certification number of the shucker, packer, or repacker of the molluscan shellfish;  

2. The "sell by" or "best if used by" date for packages with a capacity of less than one-half gallon (1.89 L) 64 fluid ounces (1.89L) or the date shucked for packages with a capacity of one-half gallon (1.89 L) 64 fluid ounces (1.89L) or more.  

B. A package of raw shucked shellfish that does not bear a label or that bears a label which does not contain all the information as specified under subsection A of this section shall be subject to a hold order, as allowed by law, or seizure and destruction in accordance with 21 CFR 1240.60(d), Subpart D.


A. Shellstock shall be obtained in containers bearing legible source identification tags or labels that are affixed by a dealer that depurates, ships, or reships the shellstock, as specified in the National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish,
1258 2013-2017 Revision (U.S. Food and Drug Administration) and that include the following information:

1. The dealer's name and address, and the certification number assigned by the shellfish control authority.

2. The original shipper's certification number assigned by the shellfish control authority.

3. The harvest date, or if depurated, the date of depuration processing, or if wet stored, the original harvest date and the final harvest date.

4. If wet stored or depurated, the wet storage or depuration cycle or lot number. The wet storage lot number shall begin with the letter "w."

5. The harvest area, including the initials of the state or, as applicable, country of harvest.

6. The type and quantity of shellstock.

7. The following statement in bold, capitalized type: "THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE FOR 90 DAYS." THIS TAG (OR LABEL) IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE, IN CHRONOLOGICAL ORDER, FOR 90 DAYS. “RETAILERS: DATE WHEN LAST SHELLFISH FROM THIS CONTAINER SOLD OR SERVED (INSERT DATE); and

8. All shellstock intended for raw consumption shall include a consumer advisory using the statement from 12VAC5-421-930 C, or an equivalent statement.

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

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

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

B. The date when the last shellstock from the container is sold or served shall be recorded on the tag or label.

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

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

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

a. Preserving source identification by using a recordkeeping system as specified under subdivision C 1 of this section, and

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

Article 3

12VAC5-421-450. Protection from Contamination from hands.

A. Food employees shall wash their hands as specified under 12VAC5-421-140.
B. Except when washing fruits and vegetables as specified under 12VAC5-421-510 or as specified in subsections D and E of this section, food employees shall not contact exposed, ready-to-eat food with their bare hands and shall use suitable utensils such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment.\textsuperscript{P}

C. Food employees shall minimize bare hand and arm contact with exposed food that is not in a ready-to-eat form.\textsuperscript{P}

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

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

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

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

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

2. Written procedures are maintained in the food establishment and made available to the regulatory authority department upon request that include:
   a. For each bare hand contact procedure, a listing of the specific ready-to-eat foods that are touched by bare hands;
   b. Diagrams and other information showing that handwashing facilities, installed, located, equipped, and maintained as specified under 12VAC5-421-2230, 12VAC5-421-2280, 12VAC5-421-2310, 12VAC5-421-3020, 12VAC5-421-3030, and 12VAC5-421-3045 are in an easily accessible location and in close proximity to the work station where the bare hand contact procedure is conducted;

3. A written employee health policy that details how the food establishment complies with 12VAC5-421-80, 12VAC5-421-90, and 12VAC5-421-100 including:
   a. Documentation that the food employees and conditional employees acknowledge that they are informed to report information about their health and activities as they relate to gastrointestinal symptoms and diseases that are transmittable through food as specified under 12VAC5-421-80 A;
   b. Documentation that food employees and conditional employees acknowledge their responsibilities as specified under 12VAC5-421-80 E and F; and
   c. Documentation that the person in charge acknowledges the responsibilities as specified under 12VAC5-421-80 B, C, and D, and 12VAC5-421-90 and 12VAC5-421-100;

4. Documentation that the food employees acknowledge that they have received training in:
   a. The risks of contacting the specific ready-to-eat foods with their bare hands;
   b. Proper handwashing as specified under 12VAC5-421-140;
   c. When to wash their hands as specified under 12VAC5-421-160;
   d. Where to wash their hands as specified under 12VAC5-421-170;
   e. Proper fingernail maintenance as specified under 12VAC5-421-190;
   f. Prohibition of jewelry as specified under 12VAC5-421-200; and
5. Documentation that hands are washed before food preparation and as necessary to prevent cross-contamination by food employees as specified under 12VAC5-421-130 through 12VAC5-421-170 during all hours of operation when the specific ready-to-eat foods are prepared;

6. Documentation that food employees contacting ready-to-eat food with bare hands use two or more of the following control measures to provide additional safeguards to hazards associated with bare hand contact:
   a. Double handwashing;
   b. Nail brushes;
   c. A hand antiseptic after handwashing as specified under 12VAC5-421-180;
   d. Incentive programs such as paid sick leave that assist or encourage food employees not to work when they are ill; or
   e. Other control measures approved by the regulatory authority department; and

7. Documentation that corrective action is taken when subdivisions 1 through 6 of this subsection are not followed.

12VAC5-421-470. Packaged and unpackaged food - separation, packaging, and segregation.

A. Food shall be protected from cross contamination by:

1. Except as specified in subdivision 1 eg of this subsection, separating raw animal foods during storage, preparation, holding, and display from:
   a. Raw ready-to-eat food including other raw animal food such as fish for sushi or molluscan shellfish, or other raw ready-to-eat food such as fruits and vegetables;
   b. Cooked ready-to-eat food;
   c. Fruits and vegetables before they are washed;
   d. Frozen, commercially processed, and packaged raw animal food may be stored or displayed with or above frozen, commercially processed and packaged, ready-to-eat food;

2. Except when combined as ingredients, separating types of raw animal foods from each other such as beef, fish, lamb, pork, and poultry during storage, preparation, holding, and display by:
   a. Using separate equipment for each type;
   b. Arranging each type of food in equipment so that cross contamination of one type with another is prevented;
   c. Preparing each type of food at different times or in separate areas;

3. Cleaning equipment and utensils as specified under 12VAC5-421-1780 A and sanitizing as specified under 12VAC5-421-1900;

4. Except as specified in subsection B of this section and 12VAC5-421-810 B 2, storing the food in packages, covered containers, or wrappings;

5. Cleaning hermetically sealed containers of food of visible soil before opening;

6. Protecting food containers that are received packaged together in a case or overwrap from cuts when the case or overwrap is opened;

7. Storing damaged, spoiled, or recalled food being held in the food establishment as specified under 12VAC5-421-3150; and
8. Separating fruits and vegetables, before they are washed as specified under 12VAC5-421-510 from ready-to-eat food.

B. Subdivision A 4 of this section does not apply to:
   1. Whole, uncut, raw fruits and vegetables and nuts in the shell that require peeling or hulling before consumption;
   2. Primal cuts, quarters, or sides of raw meat or slab bacon that are hung on clean, sanitized hooks or placed on clean, sanitized racks;
   3. Whole, uncut, processed meats such as country hams, and smoked or cured sausages that are placed on clean, sanitized racks;
   4. Food being cooled as specified under 12VAC5-421-810 B 2; or
   5. Shellstock.

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

   Food shall only contact surfaces of:
   1. Equipment and utensils that are cleaned as specified under 12VAC5-421-1770 through 12VAC5-421-1870 and sanitized as specified under 12VAC5-421-1885, 12VAC5-421-1890 and 12VAC5-421-1900;¹
   2. Single-service and single-use articles;¹ or
   3. Linens, such as cloth napkins, as specified under 12VAC5-421-560 that are laundered as specified under 12VAC5-421-1920 C.¹

12VAC5-421-660. Condiments; protection.

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

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

Article 4

Destruction of Organisms of Public Health Concern

12VAC5-421-700. Raw animal foods.

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

   1. 145°F (63°C) or above for 15 seconds for:¹
      a. Raw eggs that are broken and prepared in response to a consumer's order and for immediate service;¹ and
      b. Except as specified under subdivisions A 2 and 3 and subsections B and C of this section, fish and intact meat, including game animals commercially raised for food and game animals under a voluntary inspection program as specified under 12VAC5-421-330 A 1;¹

   2. 155°F (68°C) for 4517 seconds or the temperature specified in the following chart that corresponds to the holding time for ratites and, mechanically tenderized meats, and injected meats; the following if they are comminuted: fish, meat, game animals commercially raised for food and game animals under a voluntary inspection program as
specified under 12VAC5-421-330 A 1; and raw eggs that are not prepared as specified under subdivision 1 a of this subsection.

<table>
<thead>
<tr>
<th>Temperature °F (°C)</th>
<th>Minimum Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>145 (63)</td>
<td>3 minutes</td>
</tr>
<tr>
<td>150 (66)</td>
<td>1 minute</td>
</tr>
<tr>
<td>158 (70)</td>
<td>&lt;1 second (instantaneous)</td>
</tr>
</tbody>
</table>

; or

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

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

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

<table>
<thead>
<tr>
<th>Temperature °F (°C)</th>
<th>Time 1 in Minutes</th>
<th>Time 1 in Seconds</th>
</tr>
</thead>
<tbody>
<tr>
<td>130 (54.4)</td>
<td>112</td>
<td>134</td>
</tr>
<tr>
<td>131 (55.0)</td>
<td>89</td>
<td>85</td>
</tr>
<tr>
<td>133 (56.1)</td>
<td>56</td>
<td>54</td>
</tr>
<tr>
<td>135 (57.2)</td>
<td>36</td>
<td>34</td>
</tr>
<tr>
<td>136 (57.8)</td>
<td>28</td>
<td>22</td>
</tr>
<tr>
<td>138 (58.9)</td>
<td>18</td>
<td>14</td>
</tr>
<tr>
<td>140 (60.0)</td>
<td>12</td>
<td>0</td>
</tr>
<tr>
<td>142 (61.1)</td>
<td>8</td>
<td>-</td>
</tr>
<tr>
<td>144 (62.2)</td>
<td>5</td>
<td>-</td>
</tr>
<tr>
<td>145 (62.8)</td>
<td>4</td>
<td>-</td>
</tr>
</tbody>
</table>

1 Holding time may include postoven heat rise.

; and

1. In an oven that is preheated to the temperature specified for the roast's weight in the following chart and that is held at that temperature, and

2. If cooked in an oven, use an oven that is preheated to the temperature specified for the roast's weight in the following chart and that is held at that temperature.

<table>
<thead>
<tr>
<th>Oven Type</th>
<th>Oven Temperature Based on Roast Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 10 lbs (4.5 kg)</td>
<td>10 lbs (4.5 kg) or more</td>
</tr>
</tbody>
</table>
2. As specified in the following chart, to heat all parts of the food to a temperature and for the holding time that corresponds to that temperature.⁴

<table>
<thead>
<tr>
<th>Temperature °F (°C)</th>
<th>Time in Minutes</th>
<th>Temperature °F (°C)</th>
<th>Time in Seconds</th>
</tr>
</thead>
<tbody>
<tr>
<td>130 (54.4)</td>
<td>112</td>
<td>147 (63.9)</td>
<td>134</td>
</tr>
<tr>
<td>131 (55.0)</td>
<td>89</td>
<td>149 (65.0)</td>
<td>85</td>
</tr>
<tr>
<td>133 (56.1)</td>
<td>56</td>
<td>151 (66.1)</td>
<td>54</td>
</tr>
<tr>
<td>135 (57.2)</td>
<td>36</td>
<td>153 (67.2)</td>
<td>34</td>
</tr>
<tr>
<td>136 (57.8)</td>
<td>29</td>
<td>155 (68.3)</td>
<td>22</td>
</tr>
<tr>
<td>138 (59.9)</td>
<td>18</td>
<td>157 (69.4)</td>
<td>14</td>
</tr>
<tr>
<td>140 (60.0)</td>
<td>12</td>
<td>158 (70.0)</td>
<td>0</td>
</tr>
<tr>
<td>142 (61.1)</td>
<td>8</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>144 (62.2)</td>
<td>5</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>145 (62.8)</td>
<td>4</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

⁴Holding time may include postoven heat rise.

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

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

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

1. As specified under subdivisions 3 a and b of 12VAC5-421-950 the food establishment serves a population that is not a highly susceptible population;
2. The food, if served or offered for service by consumer selection from a children's menu, does not contain comminuted meat;¹⁵ and
3. The consumer is informed as specified under 12VAC5-421-930 that to ensure its safety, the food should be cooked as specified under subsection A or B of this section; or
4. The regulatory authority department grants a variance from subsection A or B of this section as specified in 12VAC5-421-3570 based on a HACCP plan that:
   a. Is submitted by the permit holder and approved as specified under 12VAC5-421-
      3570;
   b. Documents scientific data or other information that shows that a lesser time and
      temperature regimen results in a safe food; and
   c. Verifies that equipment and procedures for food preparation and training of food
      employees at the food establishment meet the conditions of the variance.

12VAC5-421-720. Plant food cooking for hot holding.
Fruits and vegetables. Plant foods that are cooked for hot holding shall be cooked to a
minimum temperature of 135°F (57°C).

12VAC5-421-725. Noncontinuous cooking.
Raw animal foods that are cooked using a noncontinuous cooking process shall be:
   1. Subject to an initial heating process that is no longer than 60 minutes in duration;
   2. Immediately after initial heating, cooled according to the time and temperature
      requirements specified for cooked time/temperature control for safety food under 12VAC5-
      421-800 A;
   3. After cooling, held frozen or cold, as specified for time/temperature control for safety
      food under 12VAC5-421-820 A 2;
   4. Prior to sale or service, cooked using a process that heats all parts of the food to a
      temperature and for a time as designated in 12VAC5-421-700 A, B, and C;
   5. Cooled according to the time and temperature parameters specified for cooked
      time/temperature control for safety food under 12VAC5-421-800 A if not either hot held as
      specified under 12VAC5-421-820 A 1, served immediately, or held using time as a public
      health control as specified under 12VAC5-421-850 after complete cooling; and
   6. Prepared and stored according to written procedures that:
      a. Have obtained prior approval from the regulatory authority department;
      b. Are maintained in the food establishment and are made available to the regulatory
         authority department upon request;
      c. Describe how the requirements specified under subdivisions 1 through 5 of this
         section are to be monitored and documented by the permit holder and the corrective
         actions to be taken if the requirements are not met;
      d. Describe how the foods, after initial heating, but prior to complete cooking, are to
         be marked or otherwise identified as foods that must be cooked as specified under
         subdivision 4 of this section prior to being offered for sale or service; and
      e. Describe how the foods, after initial heating but prior to cooking as specified in
         subdivision 4 of this section, are to be separated from ready-to-eat foods as specified
         under 12VAC5-421-470 A.

12VAC5-421-730. Parasite destruction.
A. Except as specified in subsection B of this section, before service or sale in ready-to-eat
   form, raw, raw-marinated, partially cooked or marinated-partially cooked fish shall be:
   1. Frozen and stored at a temperature of -4°F (-20°C) or below for a minimum of 168 hours
      (seven days) in a freezer;
   2. Frozen at -31°F (-35°C) or below until solid and stored at -31°F (-35°C) or below for a
      minimum of 15 hours; or
3. Frozen at -31°F (-35°C) or below until solid and stored at -4°F (-20°C) or below for a minimum of 24 hours.

B. Subsection A of this section does not apply to:

1. Molluscan shellfish, including the shucked adductor muscle of scallops;
2. A scallop product consisting only of the shucked adductor muscle;
3. Tuna of the species Thunnus alalunga, Thunnus albacares (Yellowfin tuna), Thunnus atlanticus, Thunnus maccoyii (Bluefin tuna, Southern), Thunnus obesus (Bigeye tuna), or Thunnus thynnus (Bluefin tuna, Northern);
4. Aquacultured fish, such as salmon, that:
   a. If raised in open water, are raised in net-pens; or
   b. Are raised in land-based operations such as ponds or tanks; and
   c. Are fed formulated feed, such as pellets, that contains no live parasites infective to the aquacultured fish, or
5. Fish eggs that have been removed from the skein and rinsed.

12VAC5-421-740. Records, creation and retention.

A. Except as specified in 12VAC5-421-730 B and subsection B of this section, if raw, marinated, raw-marinaded, partially cooked, or marinated-partially cooked fish are served or sold in ready-to-eat form, the person in charge shall record the freezing temperature and time to which the fish are subjected and shall retain the records at the food establishment for 90 calendar days beyond the time of service or sale of the fish.

B. If the fish are frozen by a supplier, a written agreement or statement from the supplier stipulating that the fish supplied are frozen to a temperature and for a time specified under 12VAC5-421-730 may substitute for the records specified under subsection A of this section.

C. If raw, raw-marinaded, partially cooked, or marinated-partially cooked fish are served or sold in ready-to-eat form, and the fish are raised and fed as specified in 12VAC5-421-730 B 34, a written agreement or statement from the supplier or aquaculturist stipulating that the fish were raised and fed as specified in 12VAC5-421-730 B 34 shall be obtained by the person in charge and retained in the records of the food establishment for 90 calendar days beyond the time of service or sale of the fish.

12VAC5-421-760. Reheating for hot holding.

A. Except as specified under subsections B, C, and E of this section, time/temperature control for safety food that is cooked, cooled, and reheated for hot holding shall be reheated so that all parts of the food reach at least 165°F (74°C) for 15 seconds.

B. Except as specified under subsection C of this section, time/temperature control for safety food reheated in a microwave oven for hot holding shall be reheated so that all parts of the food reach a temperature of at least 165°F (74°C) and the food is rotated or stirred, covered, and allowed to stand covered two minutes after reheating.

C. Ready-to-eat time/temperature control for safety food that has been commercially processed and packaged in a food processing plant that is inspected by the regulatory authority department that has jurisdiction over the plant shall be heated to a temperature of at least 135°F (57°C) when being reheated for hot holding.

D. Reheating for hot holding as specified under subsections A, B, and C of this section shall be done rapidly and the time the food is between 41°F (5°C) and the temperatures specified under subsections A, B, and C of this section may not exceed two hours.
E. Remaining unsliced portions of meat roasts that are cooked as specified under 12VAC5-421-700 B may be reheated for hot holding using the oven parameters and minimum time and temperature conditions specified under 12VAC5-421-700 B.

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

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

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

1. The day the original container is opened in the food establishment shall be counted as day 1;
2. The day or date marked by the food establishment shall not exceed a manufacturer’s “use by” date if the manufacturer determined the “use by” date based on food safety.

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

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

1. Using a method approved by the regulatory authority department for refrigerated, ready-to-eat time/temperature control for safety food that is frequently rewrapped, such as lunchmeat or a roast, or for which date marking is impractical, such as soft-serve mix or milk in a dispensing machine;
2. Marking the date or day of preparation, with a procedure to discard the food on or before the last date or day by which the food must be consumed on the premises, sold, or discarded as specified in subsection A of this section;
3. Marking the date or day the original container is opened in a food establishment, with a procedure to discard the food on or before the last date or day by which the food must be consumed on the premises, sold, or discarded as specified under subsection B of this section; or
4. Using calendar dates, days of the week, color-coded marks, or other effective marking methods, provided that the marking system is disclosed to the regulatory authority department upon request.

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

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

G. Subsection B of this section does not apply to the following foods prepared and packaged by a food processing plant inspected by a regulatory authority:
1. Deli salads, such as ham salad, seafood salad, chicken salad, egg salad, pasta salad, potato salad, and macaroni salad, manufactured in accordance with 21 CFR Part 110;
2. Hard cheeses containing not more than 39% moisture as defined in 21 CFR Part 133, such as cheddar, gruyere, parmesan and reggiano, and romano;
3. Semi-soft cheese containing more than 39% moisture, but not more than 50% moisture, as defined in 21 CFR Part 133, such as blue, edam, gorgonzola, gouda, and monterey jack;
4. Cultured dairy products as defined in 21 CFR Part 131, such as yogurt, sour cream, and buttermilk;
5. Preserved fish products, such as pickled herring and dried or salted cod, and other acidified fish products as defined in 21 CFR Part 114;
6. Shelf stable, dry fermented sausages, such as pepperoni and Genoa salami; and
7. Shelf stable salt-cured products such as prosciutto and Parma (ham).

12VAC5-421-850. Time as a public health control.
A. Except as specified under subsection D of this section, if time without temperature control is used as the public health control for a working supply of time/temperature control for safety food before cooking or for ready-to-eat time/temperature control for safety food that is displayed or held for sale or service, written procedures shall be prepared in advance, maintained in the food establishment, and made available to the regulatory authority upon request that specify:
1. Methods of compliance with subdivisions B 1, 2, and 3 or C 1 through 5 of this section;
2. Methods of compliance with 12VAC5-421-800 for food that is prepared, cooked, and refrigerated before time is used as a public health control.
B. If time without temperature control is used as the public health control up to a maximum of four hours:
1. The food shall have an initial temperature of 41°F (5°C) or less when removed from cold holding temperature control or 135°F (57°C) or greater when removed from hot holding temperature control;
2. The food shall be marked or otherwise identified to indicate the time that is four hours past the point in time when the food is removed from temperature control;
3. The food shall be cooked and served, served at any temperature if ready-to-eat, or discarded, within four hours from the point in time when the food is removed from temperature control;
4. The food in unmarked containers or packages, or marked to exceed a four-hour limit shall be discarded.
C. If time without temperature control is used as the public health control up to a maximum of six hours:
1. The food shall have an initial temperature of 41°F (5°C) or less when removed from temperature control and the food temperature may not exceed 70°F (21°C) within a maximum time period of six hours;
2. The food shall be monitored to ensure the warmest portion of the food does not exceed 70°F (21°C) during the six-hour period, unless an ambient air temperature is maintained that ensures the food does not exceed 70°F (21°C) during the six-hour holding period;
3. The food shall be marked or otherwise identified to indicate.
a. The time when the food is removed from 41°F (5°C) or less cold-holding temperature control,\textsuperscript{P} and

b. The time that is six hours past the point in time when the food is removed from 41°F (5°C) or less cold-holding temperature control;\textsuperscript{P}

4. The food shall be:

a. Discarded if the temperature of the foods exceeds 70°F (21°C);\textsuperscript{P} or

b. Cooked and served, served at any temperature if ready-to-eat, or discarded within a maximum of six hours from the point in time when the food is removed from 41°F (5°C) or less cold-holding temperature control;\textsuperscript{P} and

5. The food in unmarked containers or packages, or marked with a time that exceeds the six-hour limit shall be discarded.\textsuperscript{P}

D. A food establishment that serves a highly susceptible population may not use time as specified under subsection A, B, or C of this section as the public health control for raw eggs.

12VAC5-421-860. Variance requirement.

A food establishment shall obtain a variance from the regulatory authority department as specified in 12VAC5-421-3570 and 12VAC5-421-3580 before.\textsuperscript{P}

1. Smoking food as a method of food preservation rather than as a method of flavor enhancement;\textsuperscript{P}

2. Curing food;\textsuperscript{P}

3. Using food additives or adding components such as vinegar:\textsuperscript{P}
   a. As a method of food preservation rather than as a method of flavor enhancement;\textsuperscript{P}
   or
   b. To render a food so that it is not a time/temperature control for safety food;\textsuperscript{P}

4. Packaging time/temperature control for safety food using a reduced oxygen packaging method except where the growth of and toxin formation by Clostridium botulinum and the growth of Listeria monocytogenes are controlled as specified under 12VAC5-421-870;\textsuperscript{P}

5. Operating a molluscan shellfish life-support system display tank used to store or display shellfish that are offered for human consumption;\textsuperscript{P}

6. Custom processing animals that are for personal use as food and not for sale or service in a food establishment;\textsuperscript{P}

7. Sprouting seeds or beans;\textsuperscript{P} or

8. Preparing food by another method that is determined by the regulatory authority department to require a variance.\textsuperscript{P}

12VAC5-421-870. Reduced oxygen packaging without a variance, criteria.

A. Except for a food establishment that obtains a variance as specified under 12VAC5-421-860, a food establishment that packages time/temperature control for safety food using a reduced oxygen packaging method shall control the growth and toxin formation of Clostridium botulinum and the growth of Listeria monocytogenes.\textsuperscript{P}

B. Except as specified under subsection F of this section, a food establishment that packages time/temperature control for safety food using a reduced oxygen method shall have implement a HACCP plan that contains the following information specified under subdivisions 3 and 4 of 12VAC5-421-3630 and that:\textsuperscript{P}

1. Identifies food to be packaged;\textsuperscript{P}
2. Except as specified in subsections C through E of this section and as specified in subsection D of this section, requires that the packaged food shall be maintained at 41°F (5°C) or less and meet at least one of the following criteria:\(^\text{Pt}\)

a. Has an \(A_w\) of 0.91 or less;\(^\text{Pt}\)

b. Has a pH of 4.6 or less;\(^\text{Pt}\)

c. Is a meat or poultry product cured at a food processing plant regulated by the USDA using substances specified in 9 CFR 424.21 and is received in an intact package;\(^\text{Pt}\)

d. Is a food with a high level of competing organisms such as raw meat, raw poultry, or raw vegetables;\(^\text{Pt}\)

3. Describes how the package shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to:\(^\text{Pt}\)

a. Maintain food at 41°F (5°C) or below;\(^\text{Pt}\)

b. Discard the food if within 30 calendar days of its packaging it is not served for on-premises consumption, or consumed if served or sold for off-premises consumption;\(^\text{Pt}\)

4. Limits the refrigerated shelf life to no more than 30 calendar days from packaging to consumption, except the time the product is maintained frozen, or the original manufacturer's "sell by" or "use by" date, whichever occurs first;\(^\text{Pt}\)

5. Includes operational procedures that:

a. Prohibit contacting ready-to-eat food with bare hands as specified in 12VAC5-421-450 B;\(^\text{Pt}\)

b. Identify a designated work area and the method by which:\(^\text{Pt}\)

(1) Physical barriers or methods of separation of raw foods and ready-to-eat foods minimize cross contamination;\(^\text{Pt}\)

(2) Access to the processing equipment is limited to responsible trained personnel familiar with the potential hazards of the operation;\(^\text{Pt}\)

c. Delineate cleaning and sanitization procedures for food contact surfaces;\(^\text{Pt}\)

6. Describes the training program that ensures that the individual responsible for the reduced oxygen packaging operation understands the:\(^\text{Pt}\)

a. Concepts required for safe operation;\(^\text{Pt}\)

b. Equipment and facilities;\(^\text{Pt}\)

c. Procedures specified under subdivision B 5 of this section and subdivisions 3 and 4 of 12VAC5-421-3630;\(^\text{Pt}\)

7. Is provided to the regulatory authority department prior to implementation as specified under 12VAC5-421-3620 B.

C. Except for fish that is frozen before, during, and after packaging and bears a label indicating that it is to be kept frozen until time of use, a food establishment may not package fish using a reduced oxygen packaging method.\(^\text{Pt}\)

D. Except as specified in subsections C and F of this section, a food establishment that packages time/temperature control for safety food using a cook-chill or sous-vide process shall:

1. Provide to the regulatory authority department prior to implementation a HACCP plan that contains the information as specified under subdivisions 3 and 4 of 12VAC5-421-3630;\(^\text{Pt}\)

2. Ensure the food is:
a. Prepared and consumed on the premises, or prepared and consumed off the premises but within the same business entity with no distribution or sale of the bagged product to another business entity or the consumer;

b. Cooked to heat all parts of the food to a temperature and for a time as specified under subsections A, B, and C of 12VAC5-421-700;

c. Protected from contamination before and after cooking as specified in 12VAC5-421-450 through 12VAC5-421-765;

d. Placed in a package with an oxygen barrier and sealed before cooking, or placed in a package and sealed immediately after cooking, and before reaching a temperature below 135°F (57°C);

e. Cooled to 41°F (5°C) in the sealed package as specified under 12VAC5-421-800, and:
(1) Cooled to 34°F (1°C) within 48 hours of reaching 41°F (5°C) and held at that temperature until consumed or discarded within 30 days after the date of packaging;
(2) Held at 41°F (5°C) or less for no more than seven days, at which time the food must be consumed or discarded;
or
(3) Held frozen with no shelf-life restriction while frozen until consumed or used;

f. Held in a refrigeration unit that is equipped with an electronic system that continuously monitors time and temperature and is visually examined for proper operation twice daily;

g. If transported off site to a satellite location of the same business entity, equipped with verifiable electronic monitoring devices to ensure that times and temperatures are monitored during transportation, and

h. Labeled with the product name and the date packaged, and

3. Maintain the records required to confirm that cooling and cold holding refrigeration time/temperature parameters are required as part of the HACCP plan, are maintained and are:

a. Made available to the regulatory authority upon request, and

b. Held for six months, and

4. Implement written operational procedures as specified under subdivision B 5 of this section and a training program as specified under subdivision B 6 of this section.

E. Except as specified under subsection F of this section, a food establishment that packages cheese using a reduced oxygen packaging method shall:

1. Limit the cheeses packaged to those that are commercially manufactured in a food processing plant with no ingredients added in the food establishment and that meet the Standards of Identity as specified in 21 CFR 133.150, 21 CFR 133.169, or 21 CFR 133.187;

2. Have a HACCP plan that contains the information specified in subdivisions 3 and 4 of 12VAC5-421-3630 and as specified under subdivisions B 1, B 3 a, B 5, and B 6 of this section;

3. Label the package on the principal display panel with a "use by" date that does not exceed 30 days from its packaging or the original manufacturer's "sell by" or "use by" date, whichever occurs first, and

4. Discard the reduced oxygen packaged cheese if it is not sold for off-premises consumption or consumed within 30 calendar days of its packaging.
A. HACCP plan is not required when a food establishment uses a reduced oxygen packaging method to package time/temperature control for safety food that is always:

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

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

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

B. Label information shall include:

1. The common name of the food, or absent a common name, an adequately descriptive identity statement;
2. If made from two or more ingredients, a list of ingredients and sub-ingredients in descending order of predominance by weight, including a declaration of artificial colors, artificial flavors, and chemical preservatives, if contained in the food;
3. An accurate declaration of the net quantity of contents;
4. The name and place of business of the manufacturer, packer, or distributor; and
5. The name of the food source for each major food allergen contained in the food unless the food source is already part of the common or usual name of the respective ingredient;
7. For any salmonid fish containing canthaxanthin or astaxanthin as a color additive, the labeling of the bulk fish container, including a list of ingredients, displayed on the retail container or by other written means, such as a counter card, that discloses the use of canthaxanthin or astaxanthin.

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

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

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

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

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

A. Except as specified in 12VAC5-421-700 C and D 4 and under 12VAC5-421-950 3, if an animal food such as beef, eggs, fish, lamb, pork, poultry, or shellfish is served or sold raw, undercooked, or without otherwise being processed to eliminate pathogens, either in ready-to-eat form or as an ingredient in another ready-to-eat food, the permit holder shall inform consumers of the significantly increased risk of consuming such foods by way of a disclosure and reminder, as specified in subsections B and C of this section, using brochures, deli case or menu advisories, label statements, table tents, placards, or other effective written means.
B. Disclosure shall include:
1. A description of the animal-derived foods, such as "oysters on the half shell (raw oysters)," "raw-egg Caesar salad," and "hamburgers (can be cooked to order)"; or
2. Identification of the animal-derived foods by asterisking them to a footnote that states that the items are served raw or undercooked, or contain (or may contain) raw or undercooked ingredients.

C. Reminder shall include asterisking the animal-derived foods requiring disclosure to a footnote that states:
1. "Regarding the safety of these items, written information is available upon request";
2. "Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness";
3. "Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions."

12VAC5-421-940. Discarding or Reconditioning unsafe, adulterated, or contaminated food.
A. A food that is unsafe, adulterated, or not honestly presented as specified in 12VAC5-421-260 from an approved source as specified under 12VAC5-421-270 through 12VAC5-421-330 shall be discarded or reconditioned according to an approved procedure, rendered unusable and discarded.
B. Food that is not from an approved source as specified under 12VAC5-421-270 through 12VAC5-421-330 shall be discarded.

B-C. Ready-to-eat food that may have been contaminated by an employee who has been restricted or excluded as specified under 12VAC5-421-90 shall be rendered unusable and discarded.
C-D. Food that is contaminated by food employees, consumers, or other persons through contact with their hands, bodily discharges, such as nasal or oral discharges, or other means shall be rendered unusable and discarded.

12VAC5-421-950. Pasteurized foods, prohibited reservice, and prohibited food.
In a food establishment that serves a highly susceptible population:

1. The following criteria apply to juice:
   a. For the purposes of this paragraph only, children who are age nine or less and receive food in a school, day care setting, or similar facility that provides custodial care are included as highly susceptible populations;
   b. Prepackaged juice or a prepackaged beverage containing juice that bears a warning label as specified in 21 CFR 101.17(g) (Juices that have not been specifically processed to prevent, reduce or eliminate the presence of pathogens) or a packaged juice or beverage containing juice that bears a warning label as specified under subdivision 2 of 12VAC5-421-765 may not be served or offered for sale; and
   c. Unpackaged juice that is prepared on the premises for service or sale in a ready-to-eat form shall be processed under a HACCP plan that contains the information specified in subdivisions 23 through 5 of 12VAC5-421-3630 and as specified in 21 CFR 120.24.
2. Pasteurized eggs or egg products shall be substituted for raw eggs in the preparation of:
   a. Foods such as Caesar salad, hollandaise or béarnaise sauce, mayonnaise, meringue, eggnog, ice cream, and egg-fortified beverages; and
   b. Except as specified in subdivision 6 of this section, recipes in which more than one egg is broken and the eggs are combined.

3. The following foods shall not be served or offered for sale in a ready-to-eat form:
   a. Raw animal foods such as raw fish, raw-marinated fish, raw molluscan shellfish, and steak tartare;
   b. A partially cooked animal food such as lightly cooked fish, rare meat, soft-cooked eggs that are made from raw eggs, and meringue; and
   c. Raw seed sprouts.

4. Food employees shall not contact ready-to-eat food as specified in 12VAC5-421-450 B and E.

5. Time only, as the public health control as specified under 12VAC5-421-850 D, may not be used for raw eggs.

6. Subdivision 2 b of this section does not apply if:
   a. The raw eggs are combined immediately before cooking for one consumer’s serving at a single meal, cooked as specified under 12VAC5-421-700 A 1, and served immediately, such as an omelet, soufflé, or scrambled eggs;
   b. The raw eggs are combined as an ingredient immediately before baking and the eggs are thoroughly cooked to a ready-to-eat form, such as a cake, muffin, or bread; or
   c. The preparation of the food is conducted under a HACCP plan that:
      (1) Identifies the food to be prepared;
      (2) Prohibits contacting ready-to-eat food with bare hands;
      (3) Includes specifications and practices that ensure:
         (a) Salmonella Enteritidis growth is controlled before and after cooking; and
         (b) Salmonella Enteritidis is destroyed by cooking the eggs according to the temperature and time specified in 12VAC5-421-700 A 2;
      (4) Contains the information specified under subdivision 4 of 12VAC5-421-3630 including procedures that:
         (a) Control cross contamination of ready-to-eat food with raw eggs; and
         (b) Delineate cleaning and sanitization procedures for food-contact surfaces; and
      (5) Describes the training program that ensures that the food employee responsible for the preparation of the food understands the procedures to be used.

7. Except as specified in subdivision 8 of this section, food may be re-served as specified under 12VAC5-421-680 B 1 and 2.

8. Foods may not be re-served under the following conditions:
   a. Any food served to patients or clients who are under contact precautions in medical isolation or quarantine, or protective environment isolation may not be re-served to others outside.
   b. Packages of food from any patients, clients, or other consumers should not be re-served to persons in protective environment isolation.
12VAC5-421-1180. Temperature measuring devices; food.
A. Food temperature measuring devices that are scaled only in Fahrenheit or Celsius shall be scaled in 2°F increments and accurate to ±2°F in the intended range of use.\textsuperscript{P}
B. Food temperature measuring devices that are scaled only in Fahrenheit and Celsius shall be scaled in 2°F increments and accurate to ±2°F in the intended range of use.\textsuperscript{P}

12VAC5-421-1190. Temperature measuring devices; ambient air and water.
A. Ambient air and water temperature measuring devices that are scaled in Fahrenheit and Celsius shall be designed to be easily readable and scaled in 3°F increments and accurate to ±3°F in the intended range of use.\textsuperscript{P}
B. Ambient air and water temperature measuring devices that are scaled only in Celsius shall be scaled in 1.5°C increments and accurate to ±3°F in the intended range of use.\textsuperscript{P}

12VAC5-421-1300. Molluscan shellfish tanks.
A. Except as specified under subsection B of this section, molluscan shellfish life support system display tanks shall not be used to store or display shellfish that are offered for human consumption and shall be conspicuously marked so that it is obvious to consumers that the shellfish are for display only.\textsuperscript{P}
B. Molluscan shellfish life-support system display tanks that are used to store and display shellfish that are offered for human consumption shall be operated and maintained in accordance with a variance granted by the regulatory authority as specified in 12VAC5-421-3570 and a HACCP plan that:
1. Is submitted by the permit holder and approved as specified under 12VAC5-421-3580; \textsuperscript{P}
2. Ensures that:
   a. Water used with fish other than molluscan shellfish does not flow into the molluscan tank; \textsuperscript{P}
   b. The safety and quality of the shellfish as they were received are not compromised by the use of the tank; \textsuperscript{P}
   c. The identity of the source of the shellstock is retained as specified under 12VAC5-421-440. \textsuperscript{P}

12VAC5-421-1380. Warewashing machines, flow pressure device.
A. Warewashing machines that provide a fresh hot water sanitizing rinse shall be equipped with a pressure gauge or similar device such as a transducer that measures and displays the water pressure in the supply line immediately before entering the warewashing machine; and
B. If the flow pressure measuring device is upstream of the fresh hot water sanitizing rinse control valve, the device shall be mounted in a one-fourth inch or 6.4 millimeter Iron Pipe Size (IPS) valve.
C. Subsections A and B of this section do not apply to a machine that uses only a pumped or recirculated sanitizing rinse.
D. Subsections A and B of this section shall not apply to home model dishwashers used in bed and breakfast operations serving 18 or fewer guests.

12VAC5-421-1520. Temperature measuring devices, manual and mechanical warewashing.
A. In manual warewashing operations, a temperature measuring device shall be provided and readily accessible for frequently measuring the washing and sanitizing temperatures.\textsuperscript{P}
B. In hot water mechanical warewashing operations, an irreversible registering temperature indicator shall be provided and readily accessible for measuring the utensil surface temperature.

12VAC5-421-1535. Cleaning agents and sanitizers, availability.
A. Cleaning agents that are used to clean equipment and utensils as specified under Article 6 (12VAC5-421-1770 et seq.) of this part shall be provided and available for use during all hours of operation.
B. Except for chemical sanitizers that are generated on site at the time of use, chemical sanitizers that are used to sanitize equipment and utensils as specified under Article 6 shall be provided and available for use during all hours of operation.

12VAC5-421-1550. Fixed equipment, spacing or sealing.
A. Equipment that is fixed because it is not easily movable shall be installed so that it is:
1. Spaced to allow access for cleaning along the sides, behind, and above the equipment;
2. Spaced from adjoining equipment, walls, and ceilings a distance of not more than 1/32 inch or 1 millimeter; or
3. Sealed to adjoining equipment or walls, if the equipment is exposed to spillage or seepage.
B. Counter-mounted equipment that is not easily movable shall be installed to allow cleaning of the equipment and areas underneath and around the equipment by being:
1. Sealed to the table; or
2. Elevated on legs as specified under 12VAC5-421-1560 D.

12VAC5-421-1620. Warewashing sinks, use limitation.
A. A warewashing sink shall not be used for handwashing.
B. If a warewashing sink is used to wash wiping cloths, wash produce, or thaw food, the sink shall be cleaned as specified under 12VAC5-421-1600 before and after each time it is used to wash wiping cloths or wash produce or thaw food. Sinks used to wash or thaw food shall be sanitized as specified under Article 7 (12VAC5-421-1880 et seq.) (12VAC5-421-1885 et seq.) of this part before and after using the sink to wash produce or thaw food.

A. A chemical sanitizer used in a sanitizing solution for a manual or mechanical operation at contact times specified under subdivision 3 of 12VAC5-421-1900 shall be listed in 40 CFR 180.940, shall meet the criteria as specified under 12VAC5-421-3380, shall be used in accordance with the EPA-registered label use instructions, and shall be used as follows:
1. A chlorine solution shall have a minimum temperature based on the concentration and pH of the solution as listed in the following chart:
2. An iodine solution shall have a:
   a. Minimum temperature of 68°F (20°C);^p
   b. pH of 5.0 or less or a pH no higher than the level for which the manufacturer
      specifies the solution is effective;^p and
   c. Concentration between 12.5 mg/L (ppm) and 25 mg/L (ppm);^p

3. A quaternary ammonium compound solution shall:
   a. Have a minimum temperature of 75°F (24°C);^p
   b. Have a concentration as specified under 40 CFR 180.940 12VAC5-421-3380 and
      as indicated by the manufacturer’s use directions included in the labeling;^p and
   c. Be used only in water with 500 mg/L hardness or less or in water having a hardness
      no greater than specified by the manufacturer’s label;^p

4. If another solution of a chemical specified under subdivisions 1, 2 and 3 of this section
   is used, the permit holder shall demonstrate to the regulatory authority department that
   the solution achieves sanitization and the use of the solution shall be approved;^p

5. If a chemical sanitizer other than chlorine, iodine, or a quaternary ammonium compound
   is used, it shall be applied in accordance with the EPA-registered label use instructions;^p
   and

6. If a chemical sanitizer is generated by a device located on site at the food establishment
   it shall be used as specified in subdivisions 1 through 4 of this section and shall be
   produced by a device that:
   a. Complies with regulation as specified in §§ 2(q)(1) and 12 of the Federal Insecticide,
      Fungicide and Rodenticide Act (FIFRA);^p
   b. Complies with 40 CFR 152.500 and 40 CFR 156.10;^p
   c. Displays the EPA device manufacturing facility registration number on the device;^p
      and
   d. Is operated and maintained in accordance with manufacturer’s instructions.~}

12VAC5-421-1920. Laundering frequency for linens, cloth gloves, napkins, and wiping
   cloths.
   A. Linens that do not come in direct contact with food shall be laundered between operations
      if they become wet, sticky, or visibly soiled.
   B. Cloth gloves used as specified in 12VAC5-421-580 D shall be laundered before being used
      with a different type of raw animal food such as beef, fish, lamb, pork, and poultry.
   C. Linens and napkins that are used as specified under 12VAC5-421-560 and cloth napkins
      shall be laundered between each use.
   D. Wet wiping cloths shall be laundered daily.
   E. Dry wiping cloths shall be laundered as necessary to prevent contamination of food and
      clean serving utensils.

12VAC5-421-2090. Nonpotable water.
   A. A nonpotable water supply shall be used only if its use is approved by the regulatory
      authority.~}
   B. Nonpotable water shall be used only for nonculinary purposes such as air conditioning,
      nonfood equipment cooling, and fire protection,~}

12VAC5-421-2100. Sampling.
   Water from a private well shall be sampled and tested at least annually for nitrate and total
   coliform.~}

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^p regulatory authority department
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1. If nitrate, which is reported as "N" on the test results, exceeds 10 mg/L (ppm), the owner shall notify the regulatory authority within 24 hours from when the owner is notified of the nitrate positive test result.

2. If a sample is total coliform positive, the positive culture medium shall be further analyzed to determine if E. coli is present. The owner shall notify the regulatory authority within two calendar days from when the owner is notified of the coliform positive test result.

3. If E. coli is present, the owner shall notify the regulatory authority within 24 hours from when the owner is notified of the E. coli positive test result.

12VAC5-421-2110. Sample report.
All sample reports for the private well shall be retained on file in the food establishment for a minimum of five years and be made available to the regulatory authority upon request.

12VAC5-421-2140. [Reserved] Water System.
Water shall be received from the source through the use of:
1. An approved public water main; or
2. One or more of the following that shall be constructed, maintained, and operated according to law:
   a. Nonpublic water main, water pumps, pipes, hoses, connections, and other appurtenances;
   b. Water transport vehicles; or
   c. Water containers.

12VAC5-421-2270. Backflow prevention device, carbonator.
A. If not provided with an air gap as specified under 12VAC5-421-2200, a double dual check valve with an intermediate vent preceded by a screen of not less than 100 mesh to 1 inch (100 mesh to 25.4mm) shall be installed upstream from a carbonating device and downstream from any copper in the water supply line.
B. A dual check valve attached to the carbonator need not be of the vented type if an air gap or vented backflow prevention device has been otherwise approved as specified under subsection A of this section.

12VAC5-421-2330. Scheduling inspection and service for a water system device.
A device such as a water treatment device or backflow preventer shall be scheduled for inspection and service, in accordance with manufacturer's instructions and as necessary to prevent device failure based on local water conditions, and records demonstrating inspection and service shall be maintained by the person in charge for a minimum of five years and made available to the department upon request.

12VAC5-421-2350. System maintained in good repair.
A plumbing system shall be (i) repaired according to law and (ii) maintained in good repair.

12VAC5-421-2505. Establishment Drainage System.
Food establishment drainage systems, including grease traps, that convey sewage shall be designed and installed as specified under 12 VAC5-421-2180 A.
12VAC5-421-2570. Approved sewage disposal system.

Sewage shall be disposed through an approved facility that is:

1. A public sewage treatment plant; or
2. An individual sewage disposal system that is sized, constructed, maintained, and operated according to the State Board of Health’s regulations promulgated pursuant to Chapter 6 (§ 32.1-163 et seq.) of Title 32 of the Code of Virginia, including 12VAC5-610 (Sewage Handling and Disposal Regulations), 12VAC5-613, and 12VAC5-640 (Regulations for Alternative Onsite Sewage Systems), or otherwise according to law.

12VAC5-421-2720. Covering receptacles.

Receptacles and waste handling units for refuse, recyclables, and returnables shall be kept covered:

1. Inside the food establishment if the receptacles and units:
   a. Contain food residue and are not in continuous use or
   b. After they are filled; and
2. With tight-fitting lids or doors if kept outside the food establishment.

12VAC5-421-2750. Cleaning receptacles.

A. Receptacles and waste handling units for refuse, recyclables, and returnables shall be thoroughly cleaned in a way that does not contaminate food, equipment, utensils, linens, or single-service and single-use articles, and waste water shall be disposed of as specified under 12VAC5-421-2550.

B. Soiled receptacles and waste handling units for refuse, recyclables, and returnables shall be cleaned at a frequency necessary to prevent them from developing a buildup of soil or becoming attractants for insects and rodents.

12VAC5-421-3040. Handwashing aids and devices, use restrictions.

A sink used for food preparation or utensil washing, or a service sink or curbed cleaning facility used for the disposal of mop water or similar wastes, shall not be provided with the handwashing aids and devices required for a handwashing sink as specified under 12VAC5-421-3020 and 12VAC5-421-3030, and 12VAC5-421-2650 C.

12VAC5-421-3310. Prohibiting animals.

A. Except as specified in subsections B and C of this section, live animals shall not be allowed on the premises of a food establishment.

B. Live animals may be allowed in the following situations if the contamination of food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles cannot result:

1. Edible fish or decorative fish in aquariums, shellfish or crustacea on ice or under refrigeration, and shellfish and crustacea in display tank systems;
2. Patrol dogs accompanying police or security officers in offices and dining, sales, and storage areas, and sentry dogs running loose in outside fenced areas;
3. In areas that are not used for food preparation and that are usually open for customers, such as dining and sales areas, service animals that are controlled by the disabled employee or person if a health or safety hazard will not result from the presence or activities of the service animal;
4. Pets in the common dining areas of institutional care facilities such as nursing homes, assisted living facilities, group homes, residential care facilities, and bed and breakfast 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
2143 5. In areas that are not used for food preparation, storage, sales, display, or dining, in
2144 which there are caged animals or animals that are similarly restricted, such as in a variety
2145 store that sells pets or a tourist park that displays animals; and
2146
2147 6. Dogs in outdoor dining areas if:
2148 a. The outdoor dining area is not fully enclosed with floor to ceiling walls and is not
2149 considered a part of the interior physical facility;
2150 b. The outdoor dining area is equipped with an entrance that is separate from the main
2151 entrance to the food establishment and the separate entrance serves as the sole
2152 means of entry for patrons accompanied by dogs;
2153 c. A sign stating that dogs are allowed in the outdoor dining area is posted at each
2154 entrance to the outdoor dining area in such a manner as to be clearly observable by
2155 the public;
2156 d. A sign within the outdoor dining area stating the requirements as specified in
2157 subdivisions 6 e, 6 f, and 6 g of this subsection is provided in such a manner as to be
2158 clearly observable by the public;
2159 e. Food and water provided to dogs is served using equipment that is not used for
2160 service of food to persons or is served in single-use articles;
2161 f. Dogs are not allowed on chairs, seats, benches, or tables;
2162 g. Dogs are kept on a leash or within a pet carrier and under the control of an adult at
2163 all times; and
2164 h. Establishment provides effective means for cleaning up dog vomitus and fecal
2165 matter.
2166
2167 C. Live or dead fish bait may be stored if contamination of food; clean equipment, utensils,
2168 and linens; and unwrapped single-service and single-use articles cannot result.
2169
2170 D. In bed and breakfast operations serving 18 or fewer guests, live animals shall be allowed
2171 in the facility but shall not be fed using the same equipment or utensils that are used to feed
2172 humans.
2173
2174 12VAC5-421-3360. Conditions of use.
2175 Poisonous or toxic materials shall be:
2176 1. Used according to:
2177 a. Law and this chapter;
2178 b. Manufacturer's use directions included in labeling, and, for a pesticide,
2179 manufacturer's label instructions that state that use is allowed in a food establishment;
2180 c. The conditions of certification, if certification is required, for use of the pest control
2181 materials; and
2182 d. Additional conditions that may be established by the regulatory authority.
2183
2184 2. Applied so that:
2185 a. A hazard to employees or other persons is not constituted; and
b. Contamination including toxic residues due to drip, drain, fog, splash, or spray on food, equipment, utensils, linens, and single-service and single-use articles is prevented, and for a restricted-use pesticide, this is achieved by:

(1) Removing the items, covering the items with impermeable covers, or taking other appropriate preventive actions; and

(2) Cleaning and sanitizing equipment and utensils after the application.

3. A restricted use pesticide shall be applied only by an applicator certified as defined in 7 USC § 136(e) (Federal Insecticide, Fungicide and Rodenticide Act), or a person under the direct supervision of a certified applicator.


A. Chemicals, including those generated on site, used to wash or peel raw, whole fruits and vegetables or used in the treatment, storage, and processing of fruits and vegetables shall:

1. Be an approved food additive listed for this intended use in 21 CFR Part 173 or

2. Be generally recognized as safe (GRAS) for this intended use or

3. Be the subject of an effective food contact notification for this intended use (only effective for the manufacturer or supplier identified in the notification) or

4. Meet the requirements in the 40 CFR Part 156.

B. Ozone as an antimicrobial agent used in the treatment, storage, and processing of fruits and vegetables in a food establishment shall meet the requirements specified in 21 CFR Part 173.368.

12VAC5-421-3410. Drying agents, criteria.

Drying agents used in conjunction with sanitization shall:

1. Contain only components that are listed as one of the following:

   a. Generally recognized as safe (GRAS) for use in food as specified in 21 CFR Part 182 or 21 CFR Part 184 or

   b. Generally recognized as safe (GRAS) for the intended use as specified in 21 CFR Part 186 or

   c. Generally recognized as safe (GRAS) for the intended use as determined by experts qualified in scientific training and experience to evaluate the safety of substances added, directly or indirectly, to food as described in 21 CFR 170.30 or

   d. Subject of an effective Food Contact Notification as described in the Federal Food Drug and Cosmetic Act (FFDCA) § 409(h) or

   e. Approved for use as a drying agent under a prior sanction specified in 21 CFR Part 181 as specified in the Federal Food Drug and Cosmetic Act (FFDCA) § 201(s)(4) or

   f. Specifically regulated as an indirect food additive for use as a drying agent as specified in 21 CFR Parts 175 to 178 or

   g. Approved for use as a drying agent under the threshold of regulation process established by 21 CFR 170.39 or
2. When sanitization is with chemicals, the approval required under subdivision 1 e or g of this section or the regulation as an indirect food additive required under subdivision 1 f of this section, shall be specifically for use with chemical sanitizing solutions.  

Part VIII
Compliance and Enforcement

Article 1
Applicability of Chapter

12VAC5-421-3510. Public health protection.

A. The regulatory authority department shall apply this regulation chapter to promote its underlying purpose, as specified in 12VAC5-421-30, of safeguarding public health and ensuring that food is safe, and unadulterated and honestly presented when offered to the consumer.

B. In enforcing the provisions of this regulation, the regulatory authority department shall assess existing facilities or equipment that were in use before March 1, 2002, the effective date of this chapter, based on the following considerations:

1. Whether the facilities or equipment are in good repair and capable of being maintained in a sanitary condition;

2. Whether food-contact surfaces comply with 12VAC5-421-960 through 12VAC5-421-1060; and

3. Whether the capacities of cooling, heating, and holding equipment are sufficient to comply with 12VAC5-421-1450.

12VAC5-421-3520. Preventing health hazards, provision for conditions not addressed.

A. If necessary to protect against public health hazards or nuisances, the regulatory authority department may impose specific requirements in addition to the requirements contained in this regulation that are authorized by law.

B. The regulatory authority department shall document the conditions that necessitate the imposition of additional requirements and the underlying public health rationale. The documentation shall be provided to the permit applicant or permit holder and a copy shall be maintained in the regulatory authority's department's file for the food establishment.

12VAC5-421-3550. Food Service Advisory Committee. (Repealed.)

The commissioner shall appoint a Food Service Advisory Committee (FSAC). He shall appoint to the FSAC as many members as he wishes, but a minimum of one individual each from the following: Department of Agriculture and Consumer Services, Department of Housing and Community Development, Department of Social Services, Virginia Hospitality and Travel Association, Virginia Retail Merchants Association, public at large, Virginia Public Health Association, Virginia Environmental Health Association, Virginia Caterers Association, Virginia Food Dealers Association, a consumer and/or civic organization representative, and an environmental health specialist.

Ex-officio members shall be the Director of the Division of Food and General Environmental Services and the Director of Health Facilities Regulation.

Appointed members of the FSAC shall serve at the discretion of the commissioner and shall make recommendation to the commissioner regarding food service policies, procedures and other food program operations. The FSAC shall meet at least annually.

12VAC5-421-3560. Exemptions to regulations. (Repealed.)

A. The following are exempt from this chapter as defined in §§ 35.1-25 and 35.1-26 of the Code of Virginia.

1. Boarding houses that do not accommodate transients;
2. Cafeterias operated by industrial plants for employees only;

3. Churches, fraternal, school and social organizations and volunteer fire departments and rescue squads which hold dinners and bazaars of not more than one time per week and not in excess of two days duration at which food prepared in homes of members or in the kitchen of the church or organization and is offered for sale to the public;

4. Grocery stores, including the delicatessen that is a part of a grocery store, selling exclusively for off-premises consumption and places manufacturing or selling packaged or canned goods;

5. Churches that serve meals for their members as a regular part of their religious observance;

6. Convenience stores or gas stations that are subject to the State Board of Agriculture and Consumer Services’ Retail Food Establishment Regulations (2VAC5-585) or any regulations subsequently adopted and that (i) have 15 or fewer seats at which food is served to the public on the premises of the convenience store or gas station and (ii) are not associated with a national or regional restaurant chain. Notwithstanding this exemption, such convenience stores or gas stations shall remain responsible for collecting any applicable local meals tax; and

7. Any bed and breakfast operation that prepares food for and offers food to guests, regardless of the time the food is prepared and offered, if (i) the premises of the bed and breakfast operation is a home that is owner occupied or owner-agent occupied, (ii) the bed and breakfast operation prepares food for and offers food to transient guests of the bed and breakfast only, (iii) the number of guests served by the bed and breakfast operation does not exceed 18 on any single day, and (iv) guests for whom food is prepared and to whom food is offered are informed by statements contained in published advertisements, mailed brochures, and placards posted at the registration area that the food is prepared in a kitchen that is not licensed as a restaurant and is not subject to regulations governing restaurants.

B. The governing body of any county, city or town may provide by ordinance that this chapter shall not apply to food booths at fairs and youth athletic activities if such booths are promoted or sponsored by any political subdivision of the Commonwealth or by any charitable nonprofit organization or group thereof. The ordinance shall provide that the director of the county, city, or town in which the fair and youth athletic activities are held, or a qualified person designated by the director, shall exercise such supervision of the sale of food as the ordinance may prescribe.

12VAC5-421-3570. Variances.

A. The commissioner or his designee may grant a variance to this chapter by following the appropriate procedures set forth in this section and 12VAC5-421-3580.

B. The commissioner or his designee may grant a variance if he finds that the hardship imposed, which may be economic, outweighs the benefits that may be received by the public and that granting such a variance does not subject the public to unreasonable health risks or environmental pollution.

C. Any owner or permit holder who seeks a variance shall apply in writing within the time period specified in 12VAC5-421-4000. The request shall be sent to the local health department. The application shall include:

1. A citation to the regulation from which a variance is requested;

2. The nature and duration of the variance requested;

3. Any relevant analytical results including result of relevant tests conducted pursuant to the requirements of these regulations;
4. Statements or evidence which establishes that the public health, welfare and environment would not be adversely affected if the variance were granted;

5. Suggested conditions that might be imposed on the granting of a variance that would limit the detrimental impact on the public health and welfare;

6. A HACCP plan if required as specified under 12VAC5-421-3620 A that includes the information specified under 12VAC5-421-3630 as it is relevant to the variance requested.

7. Other information believed pertinent by the applicant; and

8. Such other information as the district or local health department or commissioner may require.

12VAC5-421-3580. Evaluation of a variance application.

A. The commissioner shall act on any variance request submitted pursuant to 12VAC5-421-3570 B C within 60 days of receipt of the request.

B. In evaluating a variance application, the commissioner shall consider such factors as the following:

1. The effect that such a variance would have on the operation of the food establishment.

2. The cost and other economic considerations imposed by this requirement;

3. The effect that such a variance would have on protection of the public health, safety, welfare and the environment;

4. Such other factors as the commissioner, deputy commissioner, or director of the office of environmental health services may deem appropriate.

12VAC5-421-3595. Conformance with Approved Procedures.

If the commissioner or his designee grants a variance as specified in 12VAC5-421-3570, or a HACCP Plan is otherwise required as specified under 12VAC5-421-3620, the permit holder shall:

1. Comply with the HACCP plans and procedures that are submitted as specified under 12VAC5-421-3630 and approved as a basis for the variance;

2. Maintain and provide to the department, upon request, records specified under 12VAC5-421-3630 4 and 5 c that demonstrate that the following are routinely employed:

   a. Procedures for monitoring the critical control points;

   b. Monitoring of the critical control points;

   c. Verification of the effectiveness of the operation or process; and

   d. Necessary corrective actions if there is failure at the critical control point.

Article 2

Plan Submission and Approval

12VAC5-421-3600. Facility and operating plans.

A permit applicant or permit holder shall submit to the regulatory authority properly prepared plans and specifications for review and approval before:

1. The construction of a food establishment;

2. The conversion of an existing structure for use as a food establishment or

3. The remodeling of a food establishment or a change of type of food establishment or food operation as specified under subdivision 3 of 12VAC-421-3700 if the regulatory authority determines that plans and specifications are necessary to ensure compliance with this chapter.
12VAC5-421-3610. Contents of the plans and specifications.

The plans and specifications for a food establishment, including a food establishment specified under 12VAC5-421-3620, shall include, as required by the regulatory authority department based on the type of operation, type of food preparation, and foods prepared, the following information to demonstrate conformance with the provisions of this chapter:

1. Intended menu;
2. Anticipated volume of food to be stored, prepared, and sold or served;
3. Proposed layout, mechanical schematics, construction materials, and finish schedules;
4. Proposed equipment types, manufacturers, model numbers, locations, dimensions, performance capacities, and installation specifications;
5. Evidence that standard procedures ensuring compliance with the requirements of this chapter are developed or are being developed; and
6. Other information that may be required by the regulatory authority department for the proper review of the proposed construction, conversion or modification, and procedures for operating a food establishment.

12VAC5-421-3620. When a HACCP plan is required.

A. Before engaging in an activity that requires a HACCP plan, a permit applicant or permit holder shall submit to the regulatory authority department for approval a properly prepared HACCP plan as specified under 12VAC5-421-3630 and the relevant provisions of this chapter if:

1. Submission of a HACCP plan is required according to law;
2. A variance is required as specified under 12VAC421-700 D 4, 12VAC5-421-860, 12VAC5-421-1300 B, or 12VAC5-421-700 D 4; or
3. The regulatory authority department determines that a food preparation or processing method requires a variance based on a plan submittal specified under 12VAC5-421-3610, an inspectional finding, or a variance request.

B. Before engaging in reduced oxygen packaging without a variance as specified under 12VAC5-421-870, a permit applicant or permit holder shall submit a properly prepared HACCP plan to the regulatory authority department.

12VAC5-421-3630. Contents of a HACCP plan.

For a food establishment that is required under 12VAC5-421-3620 to have a HACCP plan, the permit applicant or permit holder shall submit to the regulatory authority department a properly prepared HACCP plan that includes:

1. General information such as the name of the permit applicant or permit holder, the food establishment address, and contact information;
2. A categorization of the types of time/temperature control for safety food that is to be controlled under the HACCP plan;
3. A flow diagram or chart for each specific food or category type that identifies:
   a. Each step in the process,
   b. The hazards and controls for each step in the flow diagram or chart,
   c. The steps that are critical control points,
   d. The ingredients, materials, and equipment used in the preparation of that food, and
   e. Formulations or recipes that delineate methods and procedural control measures that address the food safety concerns involved;
4. A critical control point summary for each specific food or category type that clearly identifies:

   a. Each critical control point;\(^\text{Pt}\)
   b. The critical limits for each critical control point;\(^\text{Pt}\)
   c. The method and frequency for monitoring and controlling each critical control point by the food employee designated by the person in charge;\(^\text{Pt}\)
   d. The method and frequency for the person in charge to routinely verify that the food employee is following standard operating procedures and monitoring critical control points;\(^\text{Pt}\)
   e. Action to be taken by the person in charge if the critical limits for each critical control point are not met;\(^\text{Pt}\) and
   f. Records to be maintained by the person in charge to demonstrate that the HACCP plan is properly operated and managed;\(^\text{Pt}\)

5. Supporting documents such as:

   a. Food employee and supervisory training plan addressing food safety issues;\(^\text{Pt}\)
   b. Copies of blank records forms that are necessary to implement the HACCP plan;\(^\text{Pt}\)
   c. Additional scientific data or other information, as required by the regulatory authority department supporting the determination that food safety is not compromised by the proposal;\(^\text{Pt}\) and

6. Any other information required by the regulatory authority department.


The regulatory authority department shall treat as confidential in accordance with law, information that meets the criteria specified in law for a trade secret and is contained on inspection report forms and in the plans and specifications submitted as specified under 12VAC5-421-3610 and 12VAC5-421-3630.

12VAC5-421-3650. Preoperational inspections.

The regulatory authority department shall conduct one or more preoperational inspections to verify that the food establishment is constructed and equipped in accordance with the approved plans and approved modifications of those plans, has established standard operating procedures as specified under subdivision 5 of 12VAC5-421-3610 and is in compliance with law and this chapter.

Article 3
Permit to Operate

12VAC5-421-3660. Permits.

A. No person shall own, establish, conduct, maintain, manage, or operate any food establishment in this Commonwealth unless the food establishment is permitted as provided in this section. All permits shall be in the name of the owner or lessee. Permits shall not be issued to newly constructed or extensively remodeled food establishments until a certificate of occupancy has been issued by the Building Official. Only a person who complies with the requirements of this part shall be entitled to receive or retain such a permit.

B. Permits issued shall not be transferable from one person to another or from one location to another. A new owner shall be required to make a written application for a permit. The application forms are obtainable at all local health departments.

C. Any person operating a food establishment with a valid permit who desires to expand or modify the establishment, shall notify the director of the local health department in the jurisdiction where the food establishment is located, and the director of the local health department shall determine whether
such expansion, modification, or reclassification is in compliance with the applicable sections of this chapter.

D. The permit shall be posted in every food establishment in a place where it is readily observable by the public transacting business with the establishment.

E. Permits shall expire annually otherwise not to exceed twelve months from the date of issuance.

12VAC5-421-3670. Application procedure, submission before proposed opening.

A. An applicant seeking to operate a nontemporary food establishment shall submit an application for a permit at least 30 calendar days before the date planned for opening a food establishment or at least 30 calendar days before the expiration date of the current permit for an existing facility.

B. An applicant seeking to operate a temporary food establishment shall submit an application for a permit at least 10 calendar days before the date planned for opening the temporary food establishment.

C. Any applicant who fails to complete the application process within 12 months of receipt of the application by the local health department's office may be required to submit a new application and plan.

12VAC5-421-3680. Form of submission.

A person desiring to operate a food establishment shall submit to the regulatory authority a written application for a permit on a form provided by the regulatory authority.

12VAC5-421-3690. Qualifications and responsibilities of applicants.

To qualify for a permit, an applicant shall:

1. Be an owner of the food establishment or an officer of the legal ownership;
2. Comply with the requirements of this regulation chapter; and
3. As specified under 12VAC5-421-3820, agree to allow access to the food establishment and to provide required information.

12VAC5-421-3700. Contents of the application.

The application shall include:

1. The name, mailing address, telephone number, and signature of the person applying for the permit and the name, mailing address, and location of the food establishment;
2. Information specifying whether the food establishment is owned by an association, corporation, individual, partnership, or other legal entity;
3. A statement specifying whether the food establishment:
   a. Is mobile or stationary and temporary or permanent; and
   b. Is an operation that includes one or more of the following:
      (1) Prepares, offers for sale, or serves time/temperature control for safety food:
         a. Only to order upon a consumer's request;
         b. In advance in quantities based on projected consumer demand and discards food that is not sold or served at an approved frequency; or
         c. Using time as the public health control as specified under 12VAC5-421-850;
      (2) Prepares time/temperature control for safety food in advance using a food preparation method that involves two or more steps which may include combining time/temperature control for safety food ingredients; cooking; cooling; reheating; hot or cold holding; freezing; or thawing;
(3) Prepares food as specified under subdivision 3 b (2) of this section for delivery to
and consumption at a location off the premises of the food establishment where it is
prepared;
(4) Prepares food as specified under subdivision 3 b (2) of this section for service to a
highly susceptible population;
(5) Prepares only food that is not time/temperature control for safety food; or
(6) Does not prepare, but offers for sale only prepackaged food that is not
time/temperature control for safety food;

4. The name, title, address, and telephone number of the person directly responsible for
the food establishment;

5. The name, title, address, and telephone number of the person who functions as the
immediate supervisor of the person specified under subdivision 4 of this section such as
the zone, district, or regional supervisor;

6. The names, titles, and addresses of:
   a. The persons comprising the legal ownership as specified under subdivision 2 of this
   section including the owners and officers; and
   b. The local resident agent if one is required based on the type of legal ownership;

7. A statement signed by the applicant that:
   a. Attest to the accuracy of the information provided in the application; and
   b. Affirms that the applicant will:
      (1) Comply with this chapter; and
      (2) Allow the regulatory authority department access to the establishment as specified
under 12VAC5-421-3820 and to the records specified under 12VAC5-421-440 and
12VAC5-421-2330 and subdivision 4 of 12VAC5-421-3630; and

8. Other information required by the regulatory authority department.

12VAC5-421-3710. New, converted, or remodeled establishments.

For food establishments that are required to submit plans as specified under 12VAC5-421-
3600 the regulatory authority department shall issue a permit to the applicant after:

1. A properly completed application is submitted;
2. Any required fee is submitted;
3. The required plans, specifications, and information are reviewed and approved; and
4. A preoperational inspection as specified in 12VAC5-421-3650 shows that the
   establishment is built or remodeled in accordance with the approved plans and
   specifications and that the establishment is in compliance with this chapter.

12VAC5-421-3720. Existing establishments, permit renewal, and change of ownership, or
termination.

A. The regulatory authority department may renew a permit for an existing food establishment
   or may issue a permit to a new owner of an existing food establishment after a properly completed
   application is submitted, reviewed, and approved, any fees are paid, and an inspection shows
   that the establishment is in compliance with this chapter.

B. An existing food establishment shall notify the department in writing of a change of legal
   ownership or when business operations have terminated. Such notice shall be submitted, in
   writing, to the department at least 30 days prior to the legal ownership transfer or termination of
   business operation.
12VAC5-421-3730. Denial of application for permit, notice.

If an application for a permit to operate is denied, the regulatory authority department shall provide the applicant with a notice that includes:

1. The specific reasons and chapter citations for the permit denial;
2. The actions, if any, that the applicant must take to qualify for a permit; and
3. Advisement of the applicant's right of appeal and the process and time frames for appeal that are provided in law.

12VAC5-421-3740. Responsibilities of the regulatory authority department.

A. At the time a permit is first issued, the regulatory authority department shall provide to the permit holder a copy (or opportunity to obtain a copy) of this chapter so that the permit holder is notified of the compliance requirements and the conditions of retention, as specified under 12VAC5-421-3750, that are applicable to the permit.

B. Failure to provide the information specified in subsection A of this section does not prevent the regulatory authority department from taking authorized action or seeking remedies if the permit holder fails to comply with this chapter or an order, warning, or directive of the regulatory authority department.

12VAC5-421-3750. Responsibilities of the permit holder.

Upon acceptance of the permit issued in order to retain a permit issued by the regulatory authority department, the permit holder in order to retain the permit shall:

1. Post the permit in a location in the food establishment that is conspicuous to consumers;
2. Comply with the provisions of this chapter including the conditions of a granted variance as specified under 12VAC5-421-3590 and 12VAC5-421-3595, and approved plans as specified under 12VAC5-421-3610;
3. If a food establishment is required under 12VAC5-421-3620 to operate under a HACCP plan, comply with the plan as specified under 12VAC5-421-3620;
4. Immediately contact the regulatory authority department to report an illness of a food employee or conditional employee as specified under 12VAC5-421-80 B;
5. Immediately discontinue operations and notify the regulatory authority department if an imminent health hazard may exist as specified under 12VAC5-421-3910;
6. Allow representatives of the regulatory authority department access to the food establishment as specified under 12VAC5-421-3820;
7. Replace existing facilities and equipment specified in 12VAC5-421-3510 with facilities and equipment that comply with this chapter if:
   a. The regulatory authority department directs the replacement because the facilities and equipment constitute a public health hazard or nuisance or no longer comply with the criteria upon which the facilities and equipment were accepted;
   b. The regulatory authority department directs the replacement of the facilities and equipment because of a change of ownership; or
   c. The facilities and equipment are replaced in the normal course of operation;
8. Comply with directives of the regulatory authority department including time frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives issued by the regulatory authority department in regard to the permit holder's food establishment or in response to community emergencies;
9. Accept notices issued and served by the regulatory authority department according to law; and
10. Be subject to the administrative, civil, injunctive, and criminal remedies authorized in law for failure to comply with this chapter or a directive of the regulatory authority department, including time frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives.

11. Notify customers that a copy of the most recent establishment inspection report is available upon request by:
   a. Posting a sign or placard in a location in the food establishment that is conspicuous to customers; or
   b. By another method acceptable to the department.

12VAC5-421-3770. Summary suspension of a permit.

The director may summarily suspend a permit to operate a restaurant food establishment if the director finds the continued operation constitutes a substantial and imminent threat to the public health, except the director may summarily suspend the permit of a temporary restaurant as addressed under 12VAC5-421-3870. Upon receipt of such notice that a permit is suspended, the permit holder shall cease food operations immediately and begin corrective action.

Whenever a permit is suspended, the holder of the permit or the person in charge shall be notified in writing by certified mail or by hand delivery. Upon receipt of notice that the permit is immediately suspended, the former permit holder shall be given an opportunity for an informal fact-finding conference in accordance with § 2.2-4019 of the Code of Virginia. The request for an informal fact-finding conference shall be in writing. The written request shall be filed with the local department by the former holder of the permit. If written request for an informal fact-finding conference is not filed within 10 working days, the suspension is sustained. Each holder of a suspended permit shall be afforded an opportunity for an informal fact-finding conference, within three working days of receipt of a request for the informal fact-finding conference. The director may end the suspension at any time if the reasons for the suspension no longer exist.

12VAC5-421-3780. Revocation of a permit.

The director may, after providing an opportunity for conducting an informal fact-finding conference in accordance with § 2.2-4019 of the Code of Virginia, revoke a permit for flagrant or continuing violation of any of the requirements of this part.

12VAC5-421-3800. Periodic inspection.

Food establishments shall be inspected by the designee of the director department. Inspections of the food establishments shall be performed as often as necessary for the enforcement of this part in accordance with the following:

1. Except as specified in subdivisions 2 and 3 of this section, the regulatory authority department shall inspect a food establishment at least once every six months.

2. The regulatory authority department may increase the interval between inspections beyond six months if:
   a. The food establishment is fully operating under an approved and validated HACCP plan as specified under 12VAC5-421-3595 and 12VAC5-421-3630;
   b. The food establishment is assigned a less frequent inspection frequency based on an established risk-based inspection schedule uniformly applied throughout the Commonwealth and updated annually upon reissuance of the annual permit; or
   c. The establishment's operation involves only coffee service and other unpackaged or prepackaged food that is not time/temperature control for safety food, such as carbonated beverages and snack food such as chips, nuts, popcorn, and pretzels.
3. The regulatory authority department shall inspect a temporary food establishment during its permit period, unless the Virginia Department of Health develops a written risk-based plan for adjusting the frequency of inspections of temporary food establishments that is uniformly applied throughout the Commonwealth.


Within the parameters specified in 12VAC5-421-3800, the regulatory authority department shall prioritize, and conduct, more frequent inspections based upon its assessment of a food establishment's history of compliance with this chapter and the establishment's potential as a vector of foodborne illness by evaluating:

1. Past performance for nonconformance with this chapter or HACCP plan requirements that are priority items or priority foundation items;
2. Past performance for numerous or repeat violations of this chapter or HACCP plan requirements that are core items;
3. Past performance for complaints investigated and found to be valid;
4. The hazards associated with the particular foods that are prepared, stored, or served;
5. The type of operation including the methods and extent of food storage, preparation, and service;
6. The number of people served; and
7. Whether the population served is a highly susceptible population.

12VAC5-421-3815. Competency of environmental health specialists.

A. An authorized representative of the commissioner who inspects a food establishment or conducts plan review for compliance with this chapter shall have the knowledge, skills, and ability to adequately perform the required duties. For the purposes of this section, competency shall be demonstrated when an environmental health specialist meets the training and standardization requirements as determined by the department specified in the Virginia Department of Health Procedures for Certification and Standardization of Retail Food Protection Staff, 2014, (VDH, Division of Food and Environmental Services).

B. The regulatory authority department shall ensure that authorized representatives who inspect a food establishment or conduct plan review for compliance with this chapter have access to training and continuing education as needed to properly identify violations and apply this chapter.

12VAC5-421-3820. Access allowed at reasonable times after due notice.

After the regulatory authority department presents official credentials and provides notice of the purpose of, and intent to conduct, an inspection, the person in charge shall allow the regulatory authority department to determine if the food establishment is in compliance with this chapter by allowing access to the establishment, allowing inspection, and providing information and records specified in this chapter and to which the regulatory authority department is entitled according to law, during the food establishment's hours of operation and other reasonable times.

12VAC5-421-3830. Refusal, notification of right to access, and final request for access.

If a person denies access to the regulatory authority department, the regulatory authority department shall:

1. Inform the person that:
   a. The permit holder is required to allow access to the regulatory authority department as specified under 12VAC5-421-3820,
   b. Access is a condition of the acceptance and retention of a food establishment permit to operate as specified under 12VAC5-421-3750 F6, and
c. If access is denied, the commissioner or his designee may apply to an appropriate circuit court for an inspection warrant authorizing such inspection, testing, or taking samples for testing as provided in Chapter 24 (§ 19.2-393 et seq.) of Title 19.2 of the Code of Virginia; and

2. Make a final request for access.

12VAC5-421-3840. Refusal, reporting.

If after the regulatory authority department presents credentials and provides notice as specified under 12VAC5-421-3820, explains the authority upon which access is requested, and makes a final request for access as specified in 12VAC5-421-3830, the person in charge continues to refuse access, the regulatory authority department shall provide details of the denial of access on an inspection report form.

12VAC5-421-3850. Inspection warrants.

If denied access to a food establishment for an authorized purpose and after complying with 12VAC5-421-3830, the commissioner or his designee may apply to an appropriate circuit court for an inspection warrant authorizing such inspection, testing, or taking samples for testing as provided in Chapter 24 (§ 19.2-393 et seq.) of Title 19.2 of the Code of Virginia.

12VAC5-421-3860. Documenting information and observations.

The regulatory authority department shall document on an inspection report form:

1. Administrative information about the food establishment’s legal identity, street and mailing addresses, type of establishment and operation as specified under 12VAC5-421-3700, inspection date, and other information such as type of water supply and sewage disposal, status of the permit, and personnel certificates that may be required; and

2. Specific factual observations of violative conditions or other deviations from this chapter that require correction by the permit holder including:

   a. Failure of the person in charge to demonstrate the knowledge of foodborne illness prevention, application of HACCP principles, and the requirements of this chapter specified under 12VAC5-421-60;

   b. Failure of food employees, conditional employees, and the person in charge to report a disease or medical condition as specified under 12VAC5-421-80 B and D;

   c. Nonconformance with priority items or priority foundation, or core items of this chapter;

   d. Failure of the appropriate food employees to demonstrate their knowledge of, and ability to perform in accordance with, the procedural, monitoring, verification, and corrective action practices required by the regulatory authority department as specified under 12VAC5-421-60;

   e. Failure of the person in charge to provide records required by the regulatory authority department for determining conformance with a HACCP plan as specified under subdivision 4 f of 12VAC5-421-3630; and

   f. Nonconformance with critical limits of a HACCP plan.

12VAC5-421-3870. Specifying time frame for corrections.

The regulatory authority department shall specify on the inspection report form the time frame for correction of the violations as specified under 12VAC5-421-3910, 12VAC5-421-3930, and 12VAC5-421-3950. In the case of temporary food establishments, all violations shall be corrected within a maximum of 24 hours or the permit shall be suspended. The establishment shall immediately cease food service operations until authorized to resume by the director.
12VAC5-421-3880. Issuing report and obtaining acknowledgment of receipt.

At the conclusion of the inspection and according to law, the regulatory authority department shall provide a copy of the completed inspection report and the notice to correct violations to the permit holder or to the person in charge, and request a signed acknowledgment of receipt.

12VAC5-421-3890. Refusal to sign acknowledgment.

The regulatory authority department shall:

1. Inform a person who declines to sign an acknowledgment of receipt of inspectional findings as specified in 12VAC5-421-3880 that:
   a. An acknowledgment of receipt is not an agreement with findings,
   b. Refusal to sign an acknowledgment of receipt will not affect the permit holder's obligation to correct the violations noted in the inspection report within the time frames specified, and
   c. A refusal to sign an acknowledgment of receipt is noted in the inspection report and conveyed to the regulatory authority department's historical record for the food establishment; and
2. Make a final request that the person in charge sign an acknowledgment receipt of inspectional findings.

12VAC5-421-3900. Public records.

Except as specified in 12VAC5-421-3640, the regulatory authority department shall treat the inspection report as a public record and shall make it available for disclosure to a person who requests it as provided in law.

12VAC5-421-3910. Imminent health hazard, ceasing operations and reporting.

A. Except as specified in subsection B and C of this section, a permit holder shall immediately discontinue operations and notify the regulatory authority department if an imminent health hazard may exist because of an emergency such as a fire, flood, extended interruption of electrical or water service, sewage backup, misuse of poisonous or toxic materials, onset of an apparent foodborne illness outbreak, gross insanitary occurrence or condition, or other circumstance that may endanger public health.

B. A permit holder need not discontinue operations in an area of an establishment that is unaffected by the imminent health hazard.

C. Considering the nature of the potential hazard involved and the complexity of the corrective action needed, the department may agree to continuing operations in the event of an extended interruption of electrical or water service if:
   1. A written emergency operating plan has been approved by the department;
   2. Immediate corrective action is taken to eliminate, prevent, or control any food safety risk and imminent health hazard associated with the electrical or water service interruption; and
   3. The department is informed upon implementation of the written emergency operating plan.

12VAC5-421-3920. Resumption of operations.

If operations are discontinued as specified under 12VAC5-421-3910 or otherwise according to law, the permit holder shall obtain approval from the regulatory authority department before resuming operations.
12VAC5-421-3930. Timely correction.

A. Except as specified in subsection B of this section, a permit holder shall at the time of inspection correct a priority item or priority foundation item in this chapter and implement corrective actions for a HACCP plan provision that is not in compliance with its critical limit.\(^\text{II}\)

B. Considering the nature of the potential hazard involved and the complexity of the corrective action needed, the regulatory authority\(^{\text{department}}\) may agree to or specify a longer timeframe, not to exceed:

1. 72 hours after the inspection for the permit holder to correct priority items; or
2. 10 calendar days after the inspection for the permit holder to correct priority foundation items or HACCP plan deviations.

C. In the case of temporary food establishments, priority items shall be corrected within a maximum of 24 hours after inspection.

12VAC5-421-3940. Verification and documentation of correction.

A. After observing at the time of inspection a correction of a priority item, or priority foundation item, or a HACCP plan deviation, the regulatory authority\(^{\text{department}}\) shall enter the observation and information about the corrective action on the inspection report.

B. As specified under 12VAC5-421-3930 B, after receiving notification that the permit holder has corrected a priority item, or priority foundation item, or a HACCP plan deviation, or at the end of the specified period of time, the regulatory authority\(^{\text{department}}\) shall verify correction, document the information on an inspection report, and enter the report in the regulatory authority\(^{\text{department}}\) records.

12VAC5-421-3950. Core item, timeframe for correction.

A. Except as specified in subsection B of this section, the permit holder shall correct core items by a date and time agreed to or specified by the regulatory authority\(^{\text{department}}\) but no later than 90 calendar days after the inspection.

B. The regulatory authority\(^{\text{department}}\) may approve a compliance schedule that extends beyond the time limits specified under subsection A of this section if a written schedule of compliance is submitted by the permit holder and no health hazard exists or will result from allowing an extended schedule for compliance.

12VAC5-421-3960. Examination for condemnation of food. (Repealed.)

Food may be examined or sampled by the department as often as necessary for enforcement of this chapter. Also, the department may, upon written notice to the owner or permit holder or person in charge impound any food which it believes is in violation of Part III (12VAC5-421-260 et seq.) or any other section of this chapter. The department shall tag, label, or otherwise identify any food subject to impoundment. No food under conditions specified in the impoundment shall be used, served or moved from the establishment. The department shall permit storage of the food under conditions specified in the impoundment unless storage is not possible without risk to the public health in which case immediate destruction shall be accomplished by the owner or permit holder or person in charge. The impoundment shall state that a request for an informal fact-finding conference may be filed within 10 days and that if no conference is requested, the food shall be destroyed by the owner or permit holder or person in charge. The department shall hold an informal fact-finding conference if so requested, and on the basis of evidence produced at the hearing, the impoundment may be vacated, or the owner or permit holder or person in charge of the food may be directed in writing by the director to denature or destroy such food or to bring it into compliance with the provisions of this chapter.
Upon written notice to the owner, permit holder, or person in charge, the department may place a hold order on food that:

1. Originated from an unapproved source;
2. May be unsafe, adulterated, or not honestly presented; or
3. Is not otherwise in compliance with this chapter.

The hold order notice shall:

1. State food subject to the order may not be used, sold, moved from the food establishment, or destroyed without a written release of the order from the department;
2. State the specific reasons for placing the food under the hold order with reference to the applicable provisions of this chapter and the hazard or adverse effect created by the observed condition;
3. Sufficiently identify the food subject to the hold order by the common name, the label information, a container description, quantity, department's tag or identification information, and location; and
4. Notify the permit holder of the right to request an informal fact-finding conference pursuant to the Virginia Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia) within ten calendar days of receipt of the hold order notice. Otherwise, the food under the hold order shall be destroyed by the owner, permit holder, or the person in charge.

A. The department shall securely place an official tag or label on the food or containers or otherwise conspicuously identity food subject to the holder order.

B. The tag or label used to identify a food that is subject of a hold order shall include a summary of the provisions specified in 12VAC5-421-3962 and shall be signed and dated by the department.

C. Only the department may remove hold order tags, labels, or other identification from food subject to a hold order.

A. Except as specified in subsection B of this section, food placed under a hold order may not be used, sold, served, or moved from the food establishment.

B. The department may allow the permit holder to store the food in an area of the food establishment if the food is protected from subsequent deterioration.

A. Any appeal of a hold order must be made in writing and received by the department within ten calendar days of receipt of the hold order.

B. The department shall issue a notice of release from a hold order and shall remove hold tags, labels, or other identification from the food if the hold order is lifted.

The department may order the permit holder to bring food under a hold order into compliance with this chapter or to destroy or denature food if:

1. Following an informal fact-finding conference held pursuant to the Virginia Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia) the director affirms the hold order; or
2. The permit holder fails to file an appeal within ten calendar days of receipt of the hold order notice.

\[12\text{VAC5-421-3970. }\text{Enforcement of regulation.}\]

A. This chapter shall be enforced by the State Board of Health and the State Health Commissioner, as executive officer of the board.

B. The directors are appointed by the board and commissioner as duly designated officers and are responsible for the implementation and enforcement of this chapter.

C. All food establishments shall operate in compliance with the requirements set forth in this chapter and shall not operate without a valid permit.

D. The commissioner shall be vested with all the authority of the board when it is not in session, subject to such rules and regulations as may be prescribed by the board.

E. Pursuant to the authority granted in §§ 32.1-26 and 35.1-6 of the Code of Virginia, the commissioner may issue orders to require any owner or permit holder or other person to comply with the provisions of this chapter. The order may require the following:

1. The immediate cessation and correction of the violation;
2. Appropriate remedial action to ensure that the violation does not continue or recur;
3. The submission of a plan to prevent future violations;
4. The submission of an application for a variance; and
5. Any other corrective action deemed necessary for proper compliance with the regulations.

F. The commissioner may act as the agent of the board to enforce all effective orders and this chapter. Should any owner or permit holder fail to comply with any effective order or this chapter, the commissioner may:

1. Institute a proceeding to revoke the owner's or permit holder's permit in accordance with 12VAC5-421-3780;
2. Request the attorney for the Commonwealth to bring a criminal action;
3. Request the Attorney General to bring an action for civil penalty, injunction, or other appropriate remedy; or
4. Do any combination of the above.

G. Nothing contained in this section shall be interpreted to require the commissioner to issue an order prior to seeking enforcement of any regulations or statute through an injunction, mandamus or criminal prosecution.

H. Proceedings before the commissioner or his designee shall include any of the following forms depending on the nature of the controversy and the interests of the parties involved.

1. Informal fact-finding conferences. An informal fact-finding conference is a meeting with a district or local health department with the district or local health director presiding and held in conformance with § 2.2-4019 of the Code of Virginia.
2. Adjudicatory hearing. The adjudicatory hearing is a formal, public adjudicatory proceeding before a hearing officer as defined by § 2.2-4001 of the Code of Virginia, and held in conformance with § 2.2-4020 of the Code of Virginia.

\[12\text{VAC5-421-4010. }\text{Penalties, injunctions, civil penalties and charges for violations.}\]

(Repealed.)

1. Any person willfully violating, or refusing, failing, or neglecting to comply with any regulations or order of the board or commissioner, or any provision of this title, shall be guilty of a Class 3 misdemeanor unless a different penalty is specified. Each day of violation shall constitute a separate offense.
2. Any person violating, or failing, neglecting, or refusing to obey any order of the board or commissioner, or any provision of this part may be compelled, in a proceeding instituted in an appropriate court by the board or commissioner, to obey and comply with such regulations, order, or any applicable provision of Title 35.1 of the Code of Virginia. The proceeding may be by injunction, mandamus, or other appropriate remedy.

3. Without limiting the remedies which may be obtained pursuant to the above subsection, any person violating or failing, neglecting, or refusing to obey any injunction, mandamus, or other remedy obtained pursuant to the above subsection shall be subject, in the discretion of the court, to a civil penalty not to exceed ten thousand dollars for each violation. Each day of violation shall constitute a separate offense.

4. With the consent of any person who has violated or failed, neglected or refused to obey any regulation or order of the board or commissioner or any applicable provision of Title 35.1, the board may provide, in an order issued by the board against such person, for the payment of civil charges for past violations in specific sums not to exceed the limit set forth in the above subsection. Such civil charges shall be in place of any appropriate civil penalty which could be imposed under the above subsection.

12VAC5-421-4020. Compliance with the Uniform Statewide Building Code.

All buildings or structures utilized as restaurants or food establishments constructed prior to the effective date of the Virginia Uniform Statewide Building Code shall be maintained in conformance with the Virginia Fire Safety Law or other code in effect at the time of construction.

12VAC5-421-4035. Exempt facilities that choose to be regulated. (Repealed.)

Exempt facilities, as defined in subdivision 6 of 12VAC5-421-10 of the definition of a “food establishment” and subdivision A 7 of 12VAC5-421-3560, that choose to be regulated by this chapter, shall be exempt from the following requirements:

1. In lieu of 12VAC5-421-1200, home model dishwashers may be used in lieu of manual cleaning and drying of utensils;
2. 12VAC5-421-1340, the requirement for internal baffles in warewashing machines does not apply to home model dishwashers;
3. 12VAC5-421-1350, the requirement for temperature measuring devices does not apply to home model dishwashers;
4. 12VAC5-421-1360, manual warewashing equipment, heaters and baskets are not required but manual warewashing shall include, as a minimum, thorough washing with adequate soap or detergent, thorough rinsing, and drying before storage or use. Drying may be by clean towels used for no other purpose;
5. 12VAC5-421-1370, the requirement for a sanitizer level indicator does not apply to home model dishwashers;
6. 12VAC5-421-1380, the requirement for flow pressures device does not apply to home model dishwashers;
7. 12VAC5-421-1460, the requirement for sink compartments does not apply to exempt facilities. It shall include thorough washing with adequate soap or detergent, thorough rinsing, and drying before storage or use. Drying may be by clean towels used for no other purpose;
8. 12VAC5-421-1520, temperature measuring devices for manual warewashing are not required;
9. 12VAC5-421-1530, sanitizing solutions testing devices are not required;
10. 12VAC5-421-1620, warewashing sinks in exempt facilities may be used for handwashing, however, approved dispensers, soap, and single-use paper towels are provided;

11. 12VAC5-421-1640, clean solutions in warewashing equipment is not required for exempt facilities. It shall include, as a minimum, thorough washing with adequate soap or detergent, thorough rinsing, and drying before storage or use. Drying may be by clean towels used for no other purpose;

12. 12VAC5-421-1660, minimum wash solution temperature for mechanical warewashing equipment shall not be required for home model dishwashers;

13. 12VAC5-421-1670, minimum hot water sanitization temperatures for manual warewashing equipment shall not be required;

14. 12VAC5-421-1680, minimum hot water sanitization temperatures for mechanical warewashing equipment shall not be required for home model dishwashers;

15. 12VAC5-421-1690, sanitization pressure for mechanical warewashing equipment shall not be required;

16. 12VAC5-421-1700, minimum and maximum pressure, pH, sanitizer concentration, and hardness levels shall not be required for home model dishwashers;

17. 12VAC5-421-1710, chemical sanitization for manual warewashing using detergent sanitizers shall not be required;

18. 12VAC5-421-1720, determination of chemical sanitizer concentration shall not be required;

19. 12VAC5-421-1885, food-contact surfaces and utensils shall not be required to be sanitized;

20. 12VAC5-421-1890, before use after cleaning, utensils and food-contact surfaces shall not be required to be sanitized;

21. 12VAC5-421-1900, hot water and chemical sanitizing shall not be required;

22. 12VAC5-421-2790, floors, walls, and ceilings shall be in good repair and kept clean;

23. 12VAC5-421-2810, floors, walls, and ceilings in exempt facilities shall not be required to meet the cleanability requirements but shall be in good repair and kept clean;

24. 12VAC5-421-2820, the prohibition of exposed utility service lines and pipes shall not apply;

25. 12VAC5-421-2840, floor carpeting in exempt facilities may be installed in food preparation areas, walk-in refrigerators, warewashing areas, toilet rooms, refuse storage rooms or other areas, however they shall be kept in good repair and kept clean;

26. 12VAC5-421-2850, floor covering, mats and duckboards may be used in exempt facilities, however, they shall be kept clean and in good repair;

27. 12VAC5-421-2870, attachments to walls and ceilings in exempt facilities shall be kept in good repair and kept clean;

28. 12VAC5-421-3130, approved dispensers, soap and single-use paper towels shall be made available to accommodate hand washing;

29. 12VAC5-421-3310, live animals may be allowed in the facility but shall not be fed using the same equipment or utensils that are used to feed humans.

12VAC5-421-4040. Investigation and control, obtaining information: personal history of illness, medical examination, and specimen analysis.

The regulatory authority department shall act when it has reasonable cause to believe that a food employee or conditional employee has possibly transmitted disease; may be infected with a
disease in a communicable form that is transmissible through food; may be a carrier of infectious agents that cause a disease that is transmissible through food; or is affected with a boil, an infected wound, or acute respiratory infection, by:

1. Securing a confidential medical history of the employee suspected of transmitting disease or making other investigations as deemed appropriate; and
2. Requiring appropriate medical examinations, including collection of specimens for laboratory analysis, of a suspected employee and other employees: food employee or conditional employee.

12VAC5-421-4050. Restriction or exclusion of food employee, or summary suspension of permit.

Based on the findings of an investigation related to a food employee or conditional employee who is suspected of being infected or diseased, the regulatory authority department may issue an order to the suspected food employee, conditional employee, or permit holder instituting one or more of the following control measures:

1. Restricting the food employee or conditional employee;
2. Excluding the food employee or conditional employee; or
3. Closing the food establishment by summarily suspending a permit to operate in accordance with law.

12VAC5-421-4060. Restriction or exclusion order: warning or hearing not required, information required in order.

Based on the findings of the investigation as specified in 12VAC5-421-4040 and to control disease transmission, the regulatory authority department may issue an order of restriction or exclusion to a suspected food employee or the permit holder without prior warning, notice of a hearing, or a hearing if the order:

1. States the reasons for the restriction or exclusion that is ordered;
2. States the evidence that the food employee or permit holder shall provide in order to demonstrate that the reasons for the restriction or exclusion are eliminated;
3. States that the suspected food employee or the permit holder may request an appeal hearing by submitting a timely request as provided in law; and
4. Provides the name and address of the regulatory authority department representative to whom a request for an appeal hearing may be made.
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 have a regular health care provider
- 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.

“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

<table>
<thead>
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<th>Income Level</th>
<th>Less than 20 percent</th>
<th>20 to 29 percent</th>
<th>30 percent or more</th>
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</table>

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

<table>
<thead>
<tr>
<th>School Year</th>
<th>Subject</th>
<th>Race</th>
<th>Test Level</th>
<th>Test Source</th>
<th>Pass Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018-2019</td>
<td>Reading</td>
<td>Asian</td>
<td>Grade 3</td>
<td>SOL</td>
<td>92.9</td>
</tr>
<tr>
<td>2018-2019</td>
<td>Reading</td>
<td>Hispanic</td>
<td>Grade 3</td>
<td>SOL</td>
<td>76.0</td>
</tr>
<tr>
<td>2018-2019</td>
<td>Reading</td>
<td>White, not of Hispanic origin</td>
<td>Grade 3</td>
<td>SOL</td>
<td>74.4</td>
</tr>
<tr>
<td>2018-2019</td>
<td>Reading</td>
<td>Native Hawaiian or Pacific Islander</td>
<td>Grade 3</td>
<td>SOL</td>
<td>65.2</td>
</tr>
<tr>
<td>2018-2019</td>
<td>Reading</td>
<td>American Indian or Alaska Native</td>
<td>Grade 3</td>
<td>SOL</td>
<td>59.7</td>
</tr>
<tr>
<td>2018-2019</td>
<td>Reading</td>
<td>Black, not of Hispanic origin</td>
<td>Grade 3</td>
<td>SOL</td>
<td>56.5</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th></th>
<th>Sample Size</th>
<th>Weighted Counts</th>
<th>Weighted Percent (%)</th>
<th>LowerCL</th>
<th>UpperCL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Virginia</td>
<td>2,514</td>
<td>1,463,864</td>
<td>22.0</td>
<td>20.9</td>
<td>23.0</td>
</tr>
<tr>
<td>&lt; H.S.</td>
<td>357</td>
<td>299,450</td>
<td>40.4</td>
<td>35.9</td>
<td>44.9</td>
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<tr>
<td>H.S. or G.E.D.</td>
<td>878</td>
<td>494,801</td>
<td>29.4</td>
<td>27.1</td>
<td>31.8</td>
</tr>
<tr>
<td>Some College</td>
<td>646</td>
<td>411,340</td>
<td>21.0</td>
<td>19.0</td>
<td>23.0</td>
</tr>
<tr>
<td>College Graduate</td>
<td>622</td>
<td>253,522</td>
<td>11.2</td>
<td>10.0</td>
<td>12.4</td>
</tr>
</tbody>
</table>

Table 4: Adults Who are Overweight or Obese, by Race Virginia, 2017.
Source: Behavioral Risk Factor Surveillance System, VDH

<table>
<thead>
<tr>
<th></th>
<th>Sample Size</th>
<th>Weighted Counts</th>
<th>Weighted Percent (%)</th>
<th>LowerCL</th>
<th>UpperCL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Virginia</td>
<td>6,481</td>
<td>4,024,306</td>
<td>66.3</td>
<td>64.9</td>
<td>67.7</td>
</tr>
<tr>
<td>Black/Non-Hispanic</td>
<td>1,147</td>
<td>852,871</td>
<td>75.1</td>
<td>71.9</td>
<td>78.3</td>
</tr>
<tr>
<td>White/Non-Hispanic</td>
<td>4,570</td>
<td>2,571,561</td>
<td>65.2</td>
<td>63.6</td>
<td>66.8</td>
</tr>
<tr>
<td>Hispanic</td>
<td>299</td>
<td>253,059</td>
<td>63.0</td>
<td>56.8</td>
<td>69.2</td>
</tr>
<tr>
<td>Other/Non-Hispanic</td>
<td>346</td>
<td>282,958</td>
<td>58.4</td>
<td>51.2</td>
<td>65.5</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th></th>
<th>Sample Size</th>
<th>Weighted Counts</th>
<th>Weighted Percent (%)</th>
<th>LowerCL</th>
<th>UpperCL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Virginia</td>
<td>1,673</td>
<td>1,119,728</td>
<td>17.3</td>
<td>16.3</td>
<td>18.4</td>
</tr>
<tr>
<td>&lt; H.S.</td>
<td>211</td>
<td>191,613</td>
<td>26.8</td>
<td>22.8</td>
<td>30.7</td>
</tr>
<tr>
<td>H.S. or G.E.D.</td>
<td>598</td>
<td>387,693</td>
<td>23.9</td>
<td>21.6</td>
<td>26.1</td>
</tr>
<tr>
<td>Some College</td>
<td>523</td>
<td>384,163</td>
<td>20.2</td>
<td>18.1</td>
<td>22.3</td>
</tr>
<tr>
<td>College Graduate</td>
<td>341</td>
<td>156,259</td>
<td>7.1</td>
<td>6.0</td>
<td>8.2</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Income Level</th>
<th>Sample Size</th>
<th>Weighted Counts</th>
<th>Weighted Percent (%)</th>
<th>Lower CL</th>
<th>Upper CL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Virginia</td>
<td>5,267</td>
<td>3,432,680</td>
<td>60.7</td>
<td>59.3</td>
<td>62.2</td>
</tr>
<tr>
<td>$15,000 or less</td>
<td>383</td>
<td>250,632</td>
<td>67.8</td>
<td>62.4</td>
<td>73.2</td>
</tr>
<tr>
<td>$15,000 to less than $25,000</td>
<td>694</td>
<td>433,612</td>
<td>66.3</td>
<td>62.7</td>
<td>70.0</td>
</tr>
<tr>
<td>$25,000 to less than $35,000</td>
<td>434</td>
<td>270,729</td>
<td>61.3</td>
<td>56.1</td>
<td>66.5</td>
</tr>
<tr>
<td>$35,000 to less than $50,000</td>
<td>545</td>
<td>357,857</td>
<td>62.1</td>
<td>57.6</td>
<td>66.6</td>
</tr>
<tr>
<td>$50,000 or more</td>
<td>2,565</td>
<td>1,682,797</td>
<td>60.7</td>
<td>58.6</td>
<td>62.8</td>
</tr>
</tbody>
</table>

**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
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 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.

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.

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.

FALL 2019

HEALTH EQUITY BRIEF

TARGETING RESOURCES

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.

COST-BENEFIT ANALYSIS

Bringing Visability to the most vulnerable populations

COMMUNITY INTEGRATION

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.
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**

**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.

**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

- Dental
- Mental Health
- Primary
- Specialist
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

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.

In the past 5 months, P3’s response efforts have reached **8,400 persons** through training and community engagement events.

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

<table>
<thead>
<tr>
<th>Measure</th>
<th>Percent of adults in Virginia who report positive well-being; Baseline: 68% (2016).</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019 Update</td>
<td>73.3% (2018)</td>
</tr>
<tr>
<td>2020 Goal</td>
<td>70%</td>
</tr>
<tr>
<td>Description</td>
<td>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. 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.</td>
</tr>
</tbody>
</table>

AIM 1 — Healthy, Connected Communities

Goal 1.1 Virginia’s Families Maintain Economic Stability

1.1 A High School Graduates Enrolled in Higher Education

<table>
<thead>
<tr>
<th>Measure</th>
<th>Percent of Virginia high school graduates enrolled in an institute of higher education within 16 months after graduation; Baseline: 70.9% (2013).</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019 Update</td>
<td>77.7% (2018)</td>
</tr>
<tr>
<td>2020 Goal</td>
<td>75%</td>
</tr>
</tbody>
</table>
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).

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

<table>
<thead>
<tr>
<th>Measure</th>
<th>Gini Income Inequality Index score in Virginia; Baseline: 38.9 (2009-2013).</th>
</tr>
</thead>
<tbody>
<tr>
<td>2020 Goal</td>
<td>38.9</td>
</tr>
<tr>
<td>Data Source</td>
<td>The Virginia Department of Health utilizes the U.S. Census American Community Survey Data on income dispersion</td>
</tr>
<tr>
<td>Description</td>
<td>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.</td>
</tr>
</tbody>
</table>

Goal 1.2 Virginia’s Communities Collaborate to Improve the Population’s Health

1.2 Districts with Collaborative Community Health Improvement Processes

<table>
<thead>
<tr>
<th>Measure</th>
<th>Percent of Virginia health planning districts that have established an on-going collaborative community health improvement process; Baseline: 43.0% (2015).</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019 Update</td>
<td>97% (2018)</td>
</tr>
<tr>
<td>2020 Goal</td>
<td>100%</td>
</tr>
<tr>
<td>Data Source</td>
<td>Virginia Department of Health.</td>
</tr>
<tr>
<td>Description</td>
<td>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).</td>
</tr>
</tbody>
</table>
### 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**  

**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**  

**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


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%


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%


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.
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%

2020 Goal  Girls and Boys: 80.0%


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%


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.

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### 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**


**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**


**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).

<table>
<thead>
<tr>
<th>2019 Update</th>
<th>71.0% (2018)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2020 Goal</td>
<td>85.0%</td>
</tr>
</tbody>
</table>

**Data Source**  

**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).

<table>
<thead>
<tr>
<th>2019 Update</th>
<th>1,330 (2017)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2020 Goal</td>
<td>1,100</td>
</tr>
</tbody>
</table>

**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).

<table>
<thead>
<tr>
<th>2019 Update</th>
<th>47.07 (2018)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2020 Goal</td>
<td>40.0</td>
</tr>
<tr>
<td><strong>Data Source</strong></td>
<td>Virginia Vital Records and Health Statistics Electronic Death Certificates. Virginia Department of Health.</td>
</tr>
<tr>
<td>----------------</td>
<td>------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Description</strong></td>
<td>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.</td>
</tr>
</tbody>
</table>

### 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**  

**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**

**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.

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#### 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).

<table>
<thead>
<tr>
<th>Year</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>2020 Goal</td>
<td>7,600</td>
</tr>
</tbody>
</table>

**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.

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#### 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).

<table>
<thead>
<tr>
<th>Year</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019 Update</td>
<td>0 (2018)</td>
</tr>
<tr>
<td>2020 Goal</td>
<td>35</td>
</tr>
</tbody>
</table>

**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.

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### 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 *Clostridium difficile* infections; Baseline: 64.9% (2015).

<table>
<thead>
<tr>
<th>Year</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019 Update</td>
<td>87.2% (2018)</td>
</tr>
<tr>
<td>2020 Goal</td>
<td>100.0%</td>
</tr>
</tbody>
</table>
**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

48.2%  46.0%  47.9%  50.6%