Board of Health Quarterly Meeting

December 15, 2023

Richmond, Virginia

WELCOME AND INTRODUCTIONS

AGENDA

Agenda

Approval of September 15, 2023 Minutes	Gary Critzer, Chair
Commissioner's Report	Karen Shelton, MD State Health Commissioner
Regulatory Action Update	Michael Capps, MPH Sr. Policy Analyst for Governmental and Regulatory Affairs
Public Comment Period	
Break	
Lunch Presentation: Workforce Incentive Programs	Sandra Serna Director Office of Health Equity
Regulations Governing the Dental Scholarship and Loan Repayment Program 12VAC5-520 (Final Amendments)	Ms. Serna

Agenda

Food Regulations 12VAC5-421 (Fast Track Amendments)	Julie Henderson Director Office of Environmental Health Services
Regulations for the Certificate of Public Need 12VAC5-220 (Fast Track Amendments)	Rebekah Allen, JD Senior Policy Analyst Office of Licensure and Certification
2024 Travel Meeting Recommendations	Joe Hilbert Deputy Commissioner for Governmental and Regulatory Affairs
Policy Committee Discussion	Patricia Kinser, PhD, WHNP-BC, RN Chair, Policy Committee
Other Business	
Adjourn	

MINUTES FROM SEPTEMBER 14, 2023

State Board of Health – Policy Committee
September 14, 2023 - 8:15am
Perimeter Center, Boardroom 2

Members Present: Lee Jones, DMD; Maribel Ramos; Patricia Kinser, PhD, Chair; Michael Desjadon.

Dr. Jones participated virtually from his home in Botetourt County due to caring for a family member with a temporary medical condition.

Other Board Members present: Gary Critzer

VDH Staff Present: Joseph Hilbert, Deputy Commissioner for Governmental and Regulatory Affairs.

Dr. Kinser gaveled the meeting to order at 8:33am.

Mr. Hilbert provided the committee with a reminder of the general Public Health Policy Agenda ("Agenda") development process and invited the Committee to discuss its role within the Board of Health and for the Agenda. There was discussion on options for the Committee's role, including requests to VDH to develop Problem Statements on the Board's behalf.

Mr. Hilbert reminded the committee the Board will receive a report on Problem Statements initiated by VDH once approved by the Commissioner. There was discussion ways in which the Committee may receive and process idea recommendations for Problem Statements. The Committee requested that VDH staff develop a brief overview of the mechanism to be shared with Committee and Board members. Members who wish to recommend ideas should email them to Dr. Kinser, Michael Capps, Alex Jansson, and Joe Hilbert with brief justification on why the topic is important to investigate. VDH staff will synthesize information on the topic to bring back to the Committee, who will then review the information, consider whether to recommend further development, and prioritize the recommended topics. The Policy Committee will then make those recommendations to the full Board, who will vote on the requests to VDH to develop the Problem Statement template. Mr. Hilbert noted that the Problem Statements will still go through the internal VDH process via the Policy Analysis Roundtable, so it may be a long time before a Problem Statement returns to the Board.

There was discussion around a number of ideas that the Committee could recommend for more information, including: telehealth's impact on workforce and access issues in rural areas; potential structural barriers to accessing mental health care; suicide prevention, especially among youth; electromagnetic radiation and if it is a topic under VDH's statutory authority; maternal mental health; youth mental health, such as the impacts of adverse childhood experiences and exposure to violence and firearms; and community paramedicine; equitable access to safe drinking water.

The meeting adjourned at 9:33am.

State Board of Health
September 14, 2023 - 10:00am
Perimeter Center, Boardroom 2

Members Present: Gary Critzer, Chair; Douglas Daniels, DVM; Michael Desjadon; Melissa Green; Anna Jeng, ScD; Lee Jones, DMD; Patricia Kinser, PhD, Vice Chair; Melissa Nelson, MD; Patricia O'Bannon; Holly Puritz, MD; Maribel Ramos; Stacey Swartz, PharmD; Ann B.R. Vaughters, MD; and Mary Margaret Whipple.

NOTE: Mr. Critzer participated virtually from his home in Waynesboro due to a temporary medical condition. Dr. Jones participated virtually from his home in Botetourt County due to caring for a family member with a temporary medical condition. Dr. Vaughters participated virtually from Upper Marlboro, Maryland for personal reasons involving pre-existing travel.

Members Absent: Elizabeth Ruffin Harrison.

VDH Staff Present: Mary Kate Bowser, Senior Public Health Nurse Manager; Michael Capps, Senior Policy Analyst; Tiffany Ford, Deputy Commissioner for Administration; Laurie Forlano, State Epidemiologist; Robert Hicks, Deputy Commissioner of Public Health & Preparedness; Joe Hilbert, Deputy Commissioner for Governmental and Regulatory Affairs; Alexandra Jansson, Senior Policy Analyst; Seth Levine, Deputy Director for the Division of Surveillance and Investigation; Christopher Lindsay, Chief Operating Officer; Maria Reppas, Director, Office of Communications; and Karen Shelton, State Health Commissioner.

Other Staff Present: Robin Kurz, JD, Senior Assistant Attorney General and Allyson Tysinger, Senior Assistant Attorney General/Section Chief.

Call to Order
Dr. Kinser called the meeting to order at 10:09 am.

Introductions
Dr. Kinser welcomed those in attendance to the meeting. Dr. Kinser then started the introductions of the Board members and VDH staff present.

Review of Agenda
Ms. Jansson reviewed the agenda and the items contained in the Board's binder. Dr. Kinser made a motion to amend the agenda to remove the Fast Track Regulations Governing Durable Do Not Resuscitate Orders 12VAC5-66. Dr. Nelson seconded the motion. It passed unanimously by voice vote.

Approval of June 15, 2023 Minutes
The minutes from the June 15 meeting were approved. Dr. Nelson made a motion to approve the minutes, seconded by Dr. Vaughters. Dr. Jones noted that the time listed for the nominating committee needed to be corrected. With that correction, the motion was approved unanimously by voice vote.

Commissioner's Report

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

- Agency Stars
- Suicide Prevention – Zero Suicide Website Launch
- Substance Misuse
- Virginia Operations Plan Exercise (VOPEX)
- Health Director Meeting
- Workforce Initiatives
- Language Access
- Workgroup on Local Health Department Structure and Financing
- Financial and HR Transformations

There was discussion regarding suicide prevention and how the Board can support the agency; the overlap of UniteUS, the suicide hotline and managed care organizations as payers to connect with services; naloxone distribution; the recently passed budget and the impact on behavioral health services and funding; the internship academy and outreach to Historically Black Colleges and Universities; ICD-10 codes for social determinants of health and the purpose or impact for reimbursement.

Regulatory Action Update

Mr. Capps reviewed the summary of all pending VDH regulatory actions.

Since the June 2023 meeting, the Commissioner approved one regulatory action on behalf of the Board while the Board was not in session. Approved Result of Periodic Review of Regulations – Rules and Regulations Governing the Virginia Nurse Practitioner/Nurse Midwife Scholarship Program (12VAC5-542). The decision resulting from the periodic review of Chapter 542 is to amend the Regulations to conform the language to the *Virginia Registrar of Regulations' Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Since the June 2023 meeting the Commissioner has not taken any non-regulatory action on behalf of the Board while the Board was not in session.

Mr. Capps advised the Board that there are 20 periodic reviews in progress:

- 12 VAC 5-67 Advance Health Care Directive Registry
- 12 VAC 5-125 Regulations for Bedding and Upholstered Furniture Inspection Program
- 12 VAC 5-215 Rules and Regulations Governing Health Data Reporting
- 12 VAC 5-216 Methodology to Measure Efficiency and Productivity of Health Care Institutions
- 12 VAC 5-217 Regulations of the Patient Level Data System
- 12 VAC 5-220 Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations
- 12 VAC 5-221 Virginia's Rules and Regulations Governing Cooperative Agreements
- 12 VAC 5-381 Home Care Organization Regulations

- 12 VAC 5-405 Rules Governing Private Review Agents
- 12 VAC 5-407 Regulations for the Submission of Health Maintenance Organization Quality of Care Performance Information
- 12 VAC 5-507 Guidelines for General Assembly Nursing Scholarships and Loan Repayment Program Requiring Service in a Long-Term-Care Facility
- 12 VAC 5-520 Regulations Governing the State Dental Scholarship Program
- 12 VAC 5-530 Regulations Governing the Virginia Medical Scholarship Program
- 12 VAC 5-545Guidelines for the Nurse Educator Scholarship
- 12 VAC 5-550 Board of Health Regulations Governing Vital Records
- 12 VAC 5-590 Waterworks Regulations
- 12 VAC 5-613 Regulations for Alternative Onsite Sewage Systems
- 12 VAC 5-620 Regulations Governing Application Fees for Construction Permits for Onsite Sewage Disposal Systems and Private Wells
- 12 VAC 5-640 Alternative Discharging Sewage Treatment Regulations for Individual Single Family Dwellings
- 12 VAC 5-650 Schedule of Civil Penalties

There was discussion about the scheduling of periodic reviews and if VDH was catching up with the back log.

Public Comment Period

There were four persons signed up for the public comment period. Susan Franz spoke regarding concerns about the COVID-19 vaccine and pregnant women and children. Sharon Landrum spoke about concerns for pregnant women and the RSV vaccine. Lori Leonard spoke about clarity on required vaccinations or optional vaccinations. Brent Rawlings spoke in support of the Certificate of Public Need Fast Track Amendments on the agenda, noting that there were some suggested amendments discussed with staff.

Additional written comments can be found at the end of the minutes document.

Fast Track Amendments to the Regulations for the Licensure of Hospice in Virginia 12 VAC 5-391

Ms. Allen presented the Fast Track Amendments to the Regulations for the Licensure of Hospice in Virginia. The purpose of the amendments is to be consistent with the current edition of the Guidelines for Design and Construction of Hospital and Health Care Facilities issued by the Facility Guidelines Institute (FGI). The regulatory change was prompted by the release of the 2022 edition of the FGI Guidelines for Design and Construction of Residential Health, Care, and Support Facilities. The amendments to the Regulation are to update the references of the 2018 FGI guidelines to the current edition, published in May of 2022.

Dr. Nelson made a motion to approve the fast-track regulations with Dr. Puritz seconding. The motion passed by unanimous voice vote.

Fast Track Amendments to the Regulations for the Certificate of Public Need 12VAC5-220

Ms. Allen presented the Fast Track Amendments to the Regulations for the Certificate of Public Need. The purpose of the amendments is to reflect changes from Chapter 1271 (2020 Acts of

Assembly), including changes to what constitutes a completed application, what is exempt from registration and COPN review, when public hearings are required, what are required conditions for COPNs, the timeline for application submission, and numerous updates to the definitions. The regulatory chapter has also been updated to reorganize and revise multiple sections for improved readability.

Dr. Swartz made a motion to adopt the amendments. Dr. Nelson seconded the motion. There were several line amendments:

- Dr. Kinser moved to amend the Fast Track Amendments to 12 VAC 5-220 at page 8, beginning of Line 363, insert "into or by an existing medical care facility" seconded by Dr. Nelson.
- Dr. Kinser moved to amend the Fast Track Amendments to 12 VAC 5-220 at page 9, Line 372, after "replacement of" insert "existing" seconded by Ms. Green.
- Dr. Kinser moved to amend the Fast Track Amendments to 12 VAC 5-220 at page 22, Line 948: strike the colon and insert "date, time, and location of the public hearing." and then strike Lines 949 through 951, seconded by Ms. Ramos.
- Dr. Kinser moved to amend the Fast Track Amendments to 12 VAC 5-220 at page 23, Line 968: strike "30" and insert "40"; strike "may" and insert "shall" seconded by Dr. Puritz.
- Dr. Kinser moved to amend the Fast Track Amendments to 12 VAC 5-220 at page 35, Line 1502: strike "30" and insert "40"; strike "may" and insert "shall" seconded by Dr. Puritz.

There was discussion about the amendments in a bloc around the legality of using will versus shall, why these amendments were brought forward, and procedural questions. The line amendments were adopted as a bloc by unanimous voice vote.

There was a further line amendment from Mr. Desjadon to replace the term mental retardation with consistent language as it appeared throughout. The motion was seconded by Dr. Nelson. The motion was approved by unanimous voice vote.

There was discussion around the role of telehealth and Certificate of Public Need, the time lag between the legislative changes and the updates to the regulations and how the changes are communicated in the interim to regulants, and if the lag is expected to decrease moving forward.

The fast track amendments were approved by unanimous voice vote.

Final Amendments to Regulations for Disease Reporting and Control 12VAC5-90

Dr. Forlano presented the Final Amendments to the Regulations for Disease Reporting and Control. The purpose of the amendments is to bring the regulatory chapter into compliance with recent changes in the field of communicable disease detection and control and to allow greater flexibility with respect to reporting requirements in light of rapidly changing laboratory technologies and the emergence of new pathogens that are of public health concern.

This action was originally published in the Virginia Register of Regulations as a Fast Track in 2019. More than 10 comments were received objecting to the use of the Fast Track action. The

majority of commenters objected to the Virginia Department of Health receiving reports, which include personal information, of their influenza data. This action does not add any influenza reporting requirements. Instead, this amendment will strike "influenza should be reported by number of cases only (and type of influenza, if available)" to clarify that only confirmed influenza cases are required to be reported. The final stage has incorporated changes in influenza reporting requirements, to clarify the intent to simplify and reduce the burden of reporting for healthcare providers. The final stage also adds Monkeypox virus to a grouping of Orthopoxviruses to be reported, requires the inclusion of a patient's ethnicity and telephone number for certain reports, and requires persons in charge of certain programs to report additional information to facilitate public health investigation of reported outbreaks.

Dr. Puritz made a motion to approve the fast-track regulations with Dr. Nelson seconding. There were several line amendments:

- Dr. Kinser moved to amend the Final Amendments to 12 VAC 5-90 at Line 550, after the words "(Neisseria meningitidis)" insert "Pertussis (Bordetella pertussis)" seconded by Dr. Puritz.
- Dr. Kinser moved to amend the Final Amendments to 12 VAC 5-90 at Line 601, strike "(SARS-CoV-2)" and at Line 602, after the words "a person who is infected with" insert "SARS-CoV-2" seconded by Dr. Nelson.
- Dr. Kinser moved to amend the Final Amendments to 12 VAC 5-90 at Line 1253, strike "update" and insert "report" seconded by Ms. Whipple.

There was discussion seeking clarity on why amendments were brought forward. The motion was approved by unanimous voice vote.

There was discussion regarding flu reporting concerns and why persons suspected of a COVID-19 infection were included in reporting requirements.

The motion was approved by unanimous voice vote.

Proposed Regulations for Certification of Community Health Workers 12VAC5-402

Dr. Walker Harris presented the Proposed Regulations for the Certification of Community Health Workers. The purpose of the regulations is to establish the minimum requirements to be considered a "certified community health worker" in Virginia based on the core competences for community health worker used by community-based organizations in Virginia. This regulation will also outline the minimum standards required of the entity, approved by the Board, responsible for confirming certified community health workers, approving the training and education to meet community health worker certification requirements and maintaining a registry of certified community health workers available to the general public.

Ms. Whipple made a motion to approve the fast-track regulations with Mrs. O'Bannon seconding.

There was discussion regarding changes in how community health workers would be able to identify themselves; if there was an inadvertent barrier being created through these regulations; what the benefits to becoming certified are; the application fee; sourcing for curriculum and

continuing education requirements; if there was opportunity to have minors in some way qualify through a waiver.

The motion passed by unanimous voice vote.

Report of the Policy Committee

Dr. Kinser described the role of the policy committee as a source for helping to generate and review Board members' ideas for exploration through the Public Health Policy Agenda process developed by VDH. A graphic was shared to help demonstrate the process, and there was discussion about how this was different than what is currently happening. VDH staff were asked to further develop of a one-pager describing the process and a graphic to illustrate for the Board by the December meeting.

There was also a discussion about ideas could be generated. Examples included unsolicited information received by the Board, and the need to vet this information to make sure that the underlying issue falls within the purview of the Board. This prompted a discussion about public comment at the Board meetings and how it is captured in the minutes. The Board asked VDH staff to prepare information about how other Boards do or do not include this information in their minutes and what is legally required to be included in the minutes for public comments.

2024 Travel Meeting Recommendations

Mr. Hilbert presented recommendations to the Board regarding a potential travel meeting in June 2024. Three options were provided for a location, one in Northern Virginia, one in Tidewater, and one in Southwest Virginia.

The Board requested more information on what types of site visits would be planned in each area.

2024 Proposed Meeting Dates

Ms. Jansson presented the dates for the 2024 meetings of the Board of Health as follows:
Wednesday, April 10
Thursday June 13 – NOTE: This would be the travel meeting with the business meeting held on the 13th
Thursday, September 19
Thursday, December 5

There was no objection to these dates for the 2024 meeting dates, and they were adopted by consensus.

Other Business

There was no other business to come before the Board.

Adjourn

The meeting adjourned at 2:04pm.

VAMFA Speech 140923 for State Board of Health Meeting; shortened version
Lori D. Leonard

Poisoning and Death, or Virginia's Altered Truth Continues

Dr. Shelton[1,2] and the Virginia Dept. of Health continue with their version of truth. Three of the four choices on VDH's vaccination[3] "Events" web page (Covid, Flu, and HPV) are not absolutely required for attendance in school. They can be declined by parents. This is not transparency, but coercion and manipulation plus fear-mongering. No studies have proven that the HPV vaccine prevents HPV, or other types of cancer. All citizens are owed the right to informed medical consent and freedom of choice.

Dr. Thorp, a practicing Ob/Gyn, has documented by FOIA that 13 billion dollars from the CDC and HHS were paid to over 300 'influencers' including contracts with the American College of Ob/Gyn[4]. These monies were paid so doctors could not discuss risks of vaccines in pregnancy, or offer informed consent. To do so, according to the contract, would require that the billions of dollars would need to be returned. This applies to over 60,000 Ob/Gyns and it means that if a woman were to ask her Ob/Gyn if it was safe to have an mRNA vaccine in pregnancy, the Ob/Gyn was bound to repeat the HHS/CDC script about "safe and effective", and not the truth. The CDC knew babies were being killed in utero, and dying from their Mom's poisoned breast milk.

There has been no improvement in Virginia infant mortality or in percent of live births born preterm[5]. Millions of dollars of grant money and dozens of people in Virginia have held conferences, work sessions, and so forth for years and yet Virginia continues to have dismal statistics related to infant and maternal mortality. Virginia must do better. Immediately.

References:

1.

LIST_ Minimum vaccine requirements

2. August 2, 2023
Dear WRIC News and abc8 news:

I just read an article by Kassidy Hammond, and watched an abc8 News video regarding back to school shots. This is to inform you that the HPV (human papillomavirus) shot is NOT required for attendance at any school in Virginia. The parent or guardian may elect for a child to not receive this shot, by writing a note to that effect and submitting it to the child's school. They can also opt out of shots by using a religious or medical exemption, which was mentioned in your video. Parents should also know that the HPV shot has been linked to serious effects in girls and boys. These effects include infertility (inability to conceive children), heart damage, cervical lesions or cancer, autoimmune disease and many more. In fact, there is currently a class-action law suit against the manufacturer, Merck, regarding these dangers. There were 40 deaths in the clinical trials of Gardasil, yet the trials were not stopped. Preadolescents and teens, for whom these HPV shots are

targeted, have a near-zero chance of developing cervical cancer. Suffice it to say, the HPV shot is a risk to a young boy's or girl's health, and offers no real benefits. It should be avoided. No studies have proven that the HPV shot prevents cancer.

A retraction or correction should be offered. Thank you.

Lori D. Leonard

3. https://www.vdh.virginia.gov/backtoschool/

4. https://naomiwolf.substack.com/p/the-covenant-of-death

5. https://www.marchofdimes.org/peristats/reports/virginia/report-card

FIRST, DO NO HARM.

A GUIDE FOR PRACTITIONERS AND HEALTHCARE WORKERS REGARDING **INFORMED CONSENT** FOR **COVID SHOTS IN INFANTS AND CHILDREN.**

As a **physician or healthcare worker**, you have a duty to patients to uphold medical ethics. **Patients have the right to "informed consent" before receiving a medical procedure** for themselves or their dependents—especially when the procedure is experimental under emergency use authorization.

The law requires you to inform patients of the treatment's known or potentially severe adverse effects. Are you sharing this information? If you recommend these shots to infants and young children, given all you know–or should know–are you **upholding your oath?** If not, could your actions later be grounds for removing your medical license?

Please read the following information carefully and **acknowledge that you've shared this data with your patients**:

- ☐ I understand there are **no long-term safety data for COVID vaccination of young children**, and children are receiving this vaccine under Emergency Use Authorization (EUA). **Vaccinating small children for COVID-19 is experimental**, not a standard medical procedure.
- ☐ I understand that **children have a 99.997% recovery rate**, and medical literature indicates that almost zero healthy children under five years old have died from COVID.
- ☐ I understand that **the COVID vaccines do not prevent transmission, nor do they prevent infection.** There is no statistically valid evidence that they prevent severe disease or death in children.
- ☐ I understand that **most children are already immune. Natural immunity is superior to vaccine-induced immunity,** and vaccinating the already immune is excessive and potentially harmful. CNBC reported in April 2022, "An estimated 95% of the U.S. population ages 16 and older had developed antibodies against the virus either through vaccination or infection as of December, according to a CDC survey of blood donor samples." In February 2022, the CDC said over **75% of children already have partial or full immunity to COVID.**
- ☐ I understand that unnecessary vaccination will put children at **elevated risk of harm.** It is apparent that **most are already immune and will not benefit from vaccination.**

- ☐ I am aware that studies suggest that **vaccinating after infection increases the risk of vaccine-induced side effects such as myocarditis.**

- ☐ I understand the **risks demonstrably outweigh the benefits of COVID vaccination in children.** For example, a Hong Kong study showed that 1/2,700 12-17-year-old boys receive a myocarditis diagnosis following their 2nd dose of Comirnaty (37 per 100,000 vaccinated). Another study from Kaiser found the same rate of myocarditis in 12-17-year-old American boys, 1/2700.

- ☐ I understand that **myocarditis is not a mild disease.** The CDC's preliminary data revealed that nearly half of the young people diagnosed with myocarditis still had symptoms 3 months later, and 39% had their activity restricted by their physician. We know this serious adverse event frequently occurs in teenagers, but no one knows how often it occurs in younger children. This is of significant concern for babies and younger children.

- ☐ I understand **over one million adverse reactions to mRNA shots have been reported to the Vaccine Adverse Events Reporting System (VAERS),** including anaphylactic shock, allergic reactions, blood clotting and bleeding disorders, myocarditis, pericarditis, stroke, heart attacks, tinnitus, death, and more.

- ☐ I understand **some children will likely die and others will suffer permanently injury from these vaccines** based on reporting to the current VAERS database. The latest data shows 1,527,370 reports of adverse events from all age groups following COVID vaccines, including 34,576 deaths between Dec. 14, 2020, and Feb. 24, 2023

- ☐ I am aware **that the Pfizer clinical trials for children 2 - 4 years old failed to meet FDA-specified requirements for COVID vaccine EUAs.** The vaccines did not show 50% efficacy nor meet the required 30% lower bound with a 95% confidence interval. Therefore, I'm aware this product **failed FDA's established criteria in its clinical trials.**

- ☐ I am aware that **the pediatric clinical trials for the COVID vaccines were too small** (the booster trial for 5-to-11-year olds had 140 participants) **to detect safety signals for serious adverse events**–especially for a recipient population in the tens of millions.

- ☐ **I am aware that on August 23, 2021, FDA's letter to BioNTech explained that neither the VAERS nor the VSD surveillance systems were adequate for FDA to determine the risk of myocarditis resulting from the Pfizer vaccine.** Therefore, Pfizer and BioNTech were instructed by FDA to carry out a series of studies on myocarditis to ascertain the risk in different groups, including children. These studies were scheduled to produce final reports to FDA over the next five years.

- ☐ **I understand safer drugs could be used prophylactically and therapeutically for COVID in children.** There is extensive and compelling medical evidence for this assertion, and the choice to eschew use of these drugs in favor of a demonstrably dangerous vaccine is arbitrary and capricious.

- ☐ **I understand the current liability-free status for these injections may not carry through in perpetuity.** Under the PREP Act of 2005, all actors advancing an EUA agenda for medical countermeasures enjoy liability protection, absent "willful misconduct." Therefore, liability could later apply if these shots are deemed non-therapeutic gene products that practitioners knowingly and recklessly recommended, and administered to children.

NO COVID VACCINE MANDATES FOR SCHOOL
TEXT **STOPTHESHOTS** TO 55444

Scan for references and Robert F. Kennedy, Jr.'s letter to Dr. Califf, Dr. Walensky, Sec. Becerra, Dr. Marks & VRBPAC Members

Children's Health Defense

COVID SHOTS & KIDS

A GUIDE FOR PARENTS + CAREGIVERS REGARDING **INFORMED CONSENT** FOR COVID VACCINE USE IN BABIES & CHILDREN.

Did you know you have the right to "informed consent" before receiving a medical procedure for yourself or your dependents—especially when the procedure is experimental and under emergency use authorization?

Did you know by law, your practitioner or healthcare provider must inform you of the treatment's known or potentially serious adverse effects? Is your practitioner or healthcare provider sharing this information with you?

Please read the following information carefully so that you can make an **informed decision.**

- ☐ **Did you know there are no long-term safety data for COVID-19 vaccination of young children,** and children are receiving this vaccine under an Emergency Use Authorization (EUA)? These facts establish that vaccinating small children for COVID is experimental, not a standard medical procedure.
- ☐ **Did you know that children have a 99.997% recovery rate?** Medical literature indicates that **almost zero healthy children under five years old** have died from COVID.
- ☐ **Did you know that COVID vaccines do not prevent transmission, nor do they prevent infection?** There is no statistically valid evidence that they prevent severe disease or deaths in children.
- ☐ **Did you know that most children are already immune? Natural immunity is superior to vaccine-induced immunity,** and vaccinating the already immune is excessive and potentially harmful. CNBC reported in April 2022, "An estimated 95% of the U.S. population ages 16 and older had developed antibodies against the virus either through vaccination or infection as of December, according to a CDC survey of blood donor samples." In February 2022, the CDC said **over 75% of children already have partial or full immunity to COVID.**
- ☐ **Did you know that unnecessary vaccination will put children at elevated risk of harm? It appears that most are already immune and will obtain NO benefit from vaccination.**
- ☐ **Did you know** that studies have suggested that vaccinating after infection increases the risk of vaccine-induced side effects such as myocarditis?

- [ ] **Did you know the risks demonstrably outweigh the benefits of COVID vaccination in children?** A Hong Kong study showed 1/2,700 12-17-year-old-boys receive a myocarditis diagnosis following their 2nd dose of Comirnaty vaccine (37 per 100,000 vaccinated). A study from Kaiser found the same rate of myocarditis in 12-17-year-old American boys, 1/2700.

- [ ] **Did you know that myocarditis is not a mild disease?** The CDC's preliminary data, revealed that nearly half of the young people diagnosed with myocarditis still had symptoms 3 months later, and 39% had their activity restricted by their physician. We know this serious adverse event frequently occurs in teenagers, but we do not know how often it occurs in younger children; this is a significant concern for babies and younger children.

- [ ] **Did you know over one million adverse reactions have been reported after mRNA shots in Vaccine Adverse Events Reporting System (VAERS),** including anaphylactic shock, allergic reactions, blood clotting and bleeding disorders, myocarditis, pericarditis, stroke, heart attacks, tinnitus, death, and more.

- [ ] **Did you know some children will likely die, and others will be permanently injured from these vaccines based on reporting to the current VAERS database?** The latest data shows 1,527,370 reports of adverse events from all age groups following COVID vaccines, including 34,576 deaths between Dec. 14, 2020, and Feb. 24, 2023

- [ ] **Did you know that the Pfizer clinical trials for children 2-4 years old failed to meet FDA-specified requirements for COVID vaccine EUAs?** The vaccines did not show 50% efficacy nor meet the required 30% lower bound with a 95% confidence interval. Therefore, this product failed FDA's established criteria in its clinical trials.

- [ ] **Did you know the pediatric clinical trials for COVID vaccines were too small** (the booster trial for 5-to-11-year olds had 140 participants) to detect safety signals for serious adverse events–especially for a recipient population in the tens of millions?

- [ ] **Did you know that on August 23, 2021, FDA's letter to BioNTech explained that neither the VAERS nor the VSD surveillance systems were adequate for FDA to determine the risk of myocarditis resulting from the Pfizer vaccine?** Therefore, the FDA instructed Pfizer and BioNTech to carry out a series of studies on myocarditis to ascertain the risk in various groups, including children. These studies were scheduled to produce final reports to FDA over the next five years.

- [ ] **Did you know there are safer drugs that could be used prophylactically and therapeutically for COVID in children?** There is extensive and compelling medical evidence for this assertion; and the choice for practitioners and healthcare workers to eschew use of these drugs in favor of a demonstrably dangerous vaccine is arbitrary and capricious.

- [ ] **Did you know the COVID shots are currently liability-free under the PREP Act of 2005?** In addition, the federal government's Countermeasures Injury Compensation Program has not compensated a single person injured by COVID vaccines.

- [ ] **Did you know there is no available care for children injured by COVID shots?** There is no way to remove the spike protein (and other toxic byproducts of vaccination), which the body may produce for a considerable period following injection of messenger RNA. Science and medicine have not yet developed, and most families are unable to cover the costs of potential catastrophic injuries.

NO COVID VACCINE MANDATES FOR SCHOOL

TEXT **STOPTHESHOTS** TO 55444

Scan for references and Robert F. Kennedy, Jr.'s letter to Dr. Califf, Dr. Walensky, Sec. Becerra, Dr. Marks & VRBPAC Members

Children's Health Defense

Important Facts

Number of studies linking vaccines to neurological and autoimmune issues common to autism: 130

Number of studies quoted by vaccine promoter Paul Offit showing no vaccine-autism link: 14

Rate of autism in the 1980s: 1 in 10,000

Rate of autism today: 1 in 59

Projected rate of autism in 2025: 1 in 2

Number of doses recommended by age six per the CDC vaccine schedule 1972: 2

Number of doses recommended by age six per the current CDC vaccination schedule: 50

Amount of aluminum in the four doses at the two month baby checkup: 1,225 mcg

Maximum allowable aluminum per day for intravenous parenteral feeding: 25 mcg

Amount of aluminum received by fully vaccinated eighteen-month old baby: 4,925 mcg

Number of studies proving safety of injecting aluminum into human infants: 0

Amount of mercury in liquid the EPA classifies as hazardous waste: 200 ppb

Amount of mercury in "trace," "thimerosal-free" vaccines: 2,000 ppb

Amount of mercury in some single-dose vaccines and some infant flu shots: 50,000 ppb

Amount of mercury in multi-dose flu vaccines, given to pregnant women: 50,000 ppb

Number of current vaccines proven effective: 0

Number of current vaccines proven safe: 0

Cost of caring for a child diagnosed with autism over his lifespan: $3,000,000-$5,000,000

Liability of vaccine manufacturers for vaccine injury: 0

Rate of asthma in vaccinated children: 6-15%

Rate of asthma in unvaccinated children: 0.2-3%

Rate of ADHD in unvaccinated children: 1-2%

Rate of ADHD in vaccinated children: 8-11%

Projected income to pharmaceutical industry from vaccines 2025: $48 billion

References at www.westonaprice.org/wp-content/uploads/WAPFVaccinationIndex.pdf.

A Diet for Natural Immunity

A good diet can help children develop strong natural immunity to infectious and chronic disease without the risk of vaccinations:

- Minimize sugar, additives and processed food.
- Raw whole milk is highly nourishing and contains many components that help build natural immunity.
- Vitamins A and D in cod liver oil provide powerful protection against disease.
- Cholesterol-rich foods like egg yolks, livewurst, butter and cream help build a strong nervous system and support good gut integrity.
- Fermented foods like sauerkraut provide protective bacteria in the digestive tract.
- Gelatin-rich bone broth contributes to good gut intregity and helps detoxify.
- Vitamin C from fresh fruits and vegetables and from fermented foods like sauerkraut helps fight infectious illness.
- Red meat, seafood and kefir are good sources of zinc, which is an important nutrient for the immune system.

If Forced to Vaccinate. . .

- Wait until the child is at least three years old.
- Do not give more than one vaccination at a time.
- Never vaccinate when the child is sick.
- Be sure that the vaccines are thimerosal-free.
- Supplement the child with extra cod liver oil, vitamin C and B12 before and after each shot.
- Put your child to bed and keep him quiet for at least twenty-four hours after a shot.
- Do NOT give aspirin, tylenol or other NSAIDs either before or after a shot.
- Obtain a medical exemption if the child has had a bad reaction to a vaccination or has a family history of vaccine reactions, convulsions or neurological disorders, severe allergies and/ or immune system disorders.

Vaccination

The Most Important Decision Parents Will Ever Make

THE WESTON A. PRICE FOUNDATION®

for

WiseTraditions

IN FOOD, FARMING AND THE HEALING ARTS

Education • Research • Activism

WESTONAPRICE.ORG (703) 820-3333

Myths and Truths About Vaccination

MYTH: Vaccination is the main contributor to the twentieth century decline in infectious disease.
TRUTH: Infectious diseases (measles, diphtheria, whooping cough and tetanus) were in steep decline before the advent of vaccinations, thanks to better sanitation, cleaner water and improved living conditions. Scarlet fever also declined, even though there has never been a vaccination for it.

MYTH: Vaccinated individuals do not put others at risk.
TRUTH: Public health officials are aware of the fact that vaccinated individuals can spread the disease for which they have been vaccinated for up to several weeks after getting the vaccine. Adults have contracted polio from their recently vaccinated infants.

MYTH: Vaccinations give life-long immunity.
TRUTH: Immunity from vaccinations is temporary at best; health officials now recommend booster shots at regular intervals because the immunity from vaccinations wears off. Outbreaks of measles and whooping cough have occurred in fully vaccinated populations.

MYTH: It was vaccinations that stopped the deadly plague of polio.
TRUTH: Polio can be triggered by nervous system poisoning from teething powders containing mercury (now banned) and pesticides like lead arsenate and DDT. Polio declined in the U.S. when DDT was outlawed. Polio is making a comeback in the U.S., but it is called by a different name—acute flaccid myelitis—which occurs most frequently in August and September when children are getting their vaccinations for school.

MYTH: Measles, mumps, whooping cough and chicken pox are life-threatening childhood diseases.
TRUTH: Death from these diseases in the U.S. is extremely rare, and basically non-existant in well nourished children. When contracted in childhood, these diseases are mild and give immunity for life; having these illnesses in childhood also protects us against more serious disease like cancer later in life. Whooping cough (pertussis) has actually become more virulent since the introduction of the pertussis vaccine.

MYTH: Vaccinations are completely safe.
TRUTH: The National Vaccine Injury Compensation Program has paid out over four billion dollars for vaccination injuries and death since 1989. These payments come from a tax on vaccines; the pharmaceutical companies that make the vaccines are free from all liability for damages caused by their products. Only a very small percentage of vaccination injuries are reported or receive compensation

MYTH: Vaccinations have been well tested for safety.
TRUTH: Most vaccines are rushed through the FDA approval process with very inadequate safety testing. There has been no safety testing at all for multiple vaccines given at one time.

MYTH: The anti-vaccination movement is something new and was started by a "fradulent" researcher named Andrew Wakefield, MD.
TRUTH: Dr. Wakefield's findings have been scientifically corroborated. Since the first vaccinations, which were for small pox, citizens have mounted vigorous opposition after seeing adverse effects, including death, in their children from the vaccines. (The small pox vaccination was eventually discontinued because of frequent life-threatening reactions.)

For references and further information, visit westonaprice.org/vaccinations.

Harmful Ingredients in Vaccines

ALUMINUM: Toxic to brain and kidneys. Children with autism have very high concentrations of aluminum in their brains.

AMINO ACIDS AND FOREIGN PROTEINS INCLUDING EGG ALBUMIN: Associated with autoimmune disorders including type I diabetes.

FORMALDEHYDE OR FORMALIN: Embalming fluid; classified as a human carcinogen; toxic to nerves, liver and kidneys.

BENZETHONIUM CHLORIDE: Can cause seizures, coma, respiratory depression, central nervous system depression, convulsions and urinary system reaction.

GLUTARALDEHYDE: A disinfectant that can cause asthma, allergic reactions, respiratory problems and diarrhea.

PROTEINS FROM FETAL TISSUE: Taken from aborted babies; associated with an increased risk of autism.

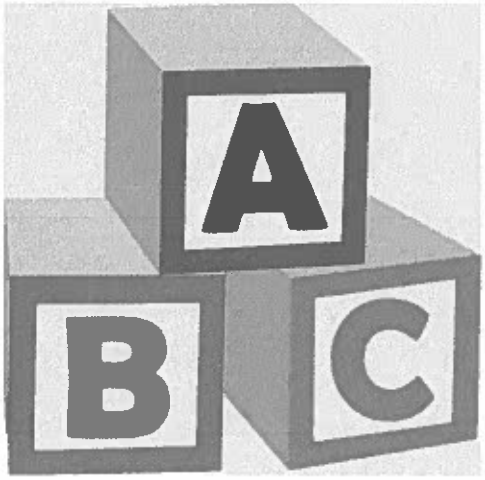
THIMEROSAL: Contains 50 percent mercury, the second most poisonous element known to man. Even "thimerosal-free" vaccines contain traces of mercury.

MSG: MSG may cause migraine headaches, sleeping disorders, irritable bowel syndrome, asthma, diabetes, Alzheimer's disease, Lou Gehrig's disease, attention deficit disorder, seizures, stroke and anaphylactic reaction.

CTAB (CETYLTRIMETHYLAMMONIUM BROMIDE): The Material Safety Data Sheet lists many serious health effects from CTAB.

2-PHENOXYETHANOL: Can cause headache, shock, convulsions, weakness, kidney damage, cardiac failure, kidney failure and death.

POLYSORBATE 80: Facilitates mercury and aluminum crossing the blood-brain barrier. May cause blood clots, stroke, heart attack and death.



ALWAYS BE CAUTIOUS

DID YOU KNOW?

- THE **COVID-19, HPV,** AND **FLU** VACCINES ARE **NOT REQUIRED** FOR SCHOOL ATTENDANCE.

- YOU HAVE THE RIGHT TO KNOW THE **RISKS** AND **ALTERNATIVES** TO EACH VACCINE. **BY LAW**, YOUR DOCTOR MUST GIVE THIS INFORMATION.

- YOU HAVE THE RIGHT TO SAY **"NO"** IF UNSURE.

- **BY LAW,** PUBLIC SCHOOLS MUST ACCEPT **RELIGIOUS** AND **MEDICAL EXEMPTIONS**.

VIRGINIA MEDICAL FREEDOM ALLIANCE
VAMFA.org

Follow QR Code For More Info

Good morning I'm susan franz, ~~I'm~~ an R.N. ~~And I'm~~ from Williamsburg, Virginia. Maternal and child health has been often a focus of the VDH ~~at every~~ meeting I've attended. There are 2 obstetricians and one pediatrician on this board. TheVDH website statistics for maternal and child health have not been updated since 2017. Why haven't they been updated? Are you aware of the decline in birth rates post COVID shot? Why is this happening? If you don't have data you don't know there is a problem. Based on his study of the data, renowned Dr. Peter McCullough, ~~a board-certified, internist~~ reports a 27 fold higher risk of miscarriage, and a more than twofold increased risk of adverse fetal outcomes across six different categories. Additionally Maternal Mortality has ↑ >50% after the vaccine rollout. Why is the VDH still promoting COVID-19 ~~vaccines~~ shots for pregnant women? Your website does not allow the public access to any maternal fetal health outcomes for the past 6 years. I ask that you post this information on your website immediately. I implore you to stop promoting Covid vaccines, as safe and effective for pregnant women and children. They are dangerous and deadly and this board is complicit in perpetuating the use of this toxic product. I'm leaving you with information to support my comments ~~for~~ including the stories of 50 ~~women~~ pregnant women who died post Covid vaccine.

mRNA & Pregnancy - CDC: Maternal Mortality is up over 50% after COVID-19 Vaccines rolled out in Dec.2020 - skyrocketing deaths of vaccinated pregnant women - 50 deaths of new mothers reviewed!

DR. WILLIAM MAKIS MD

AUG 23, 2023

· PAID

==========

HERE ARE 50 DEATHS OF COVID-19 VACCINATED PREGNANT WOMEN AND NEW MOTHERS:

Aug.15, 2023 - Scottsburg, IN - 34 year old Devonnia Tscheulin, a Paramedic and Deputy Chief for Scott County EMS, died from complications during delivery of her third child (photos above)

July 24, 2023 - TN - 39 yo Megan McCullah Burrows, a Physician Assistant at Siskin Children's Institute, specializing in Autism and ADHD evaluation, died on July 24, 2023 "after a sudden illness" She died < 3 months after giving birth (May 1, 2023)

July 22, 2023 - Perth, Australia - 24 year old Krystal Pitt collapsed while lining up at a local post office just 10 days after giving birth to her 2nd child, and died in hospital a few days later.

July 21, 2023 - Brazil - 26 year old Renata Pereira was 3 months pregnant when she had a cardiac arrest and died

July 14, 2023 - Lubbock, TX - 19 year old Ariana Nicole Sanchez gave birth to a baby girl who weighed 10 pounds 6 ounces and died unexpectedly during delivery.

June 10, 2023 - South Carolina - Justine Kostenbauder (wife of Connor Cave) delivered a baby girl but

died unexpectedly from complications during delivery

June 2, 2023 - Lafayette, IN - 26 year old Sha'Asia Johnson had a heart attack 2 hours after delivery and died unexpectedly.

May 15, 2023 - Perth, Australia - 36 year old Monika Mann died 7 days after giving birth to twins. She arrived at ER "unresponsive" and was declared dead.

May 11, 2023 - New Zealand - 32 year old Sue Maroroa Jones, International NZ Chess Champion, died suddenly after giving birth to her 2nd child, on May 11, 2023, due to "post natal complications".

May 2, 2023 - 32 yo Olympic sprinter Tori Bowie was found dead alone in bed after wellness check, was 8 months pregnant and was "undergoing labor" when she was found deceased.

April 27, 2023 - Narrows, VA - 35 year old Crystal Candler, who worked as a Child Care Director, had a medical emergency at 35 weeks pregnancy, and died unexpectedly while her baby Maddox survived.

April 26, 2023 - Boerne, Texas - 34 year old Dr.Sheena Nageli, a pediatric chiropractor, delivered baby Juliette on April 20, 2023 (home birth). On April 24, 2023 she was battling a localized infection "unrelated to her pregnancy", which inexplicably spread quickly. Despite quick medical intervention she died on April 25, 2023.

April 21, 2023 - Saskatchewan nurse, 29 year old Meaghan Riley Elizabeth Seipp died during delivery on April 21, 2023 from "bleeding complications".

March 25, 2023 - New York, 28 year old Samantha Dannecker died unexpectedly while giving birth to her first child, a baby girl.

March 25, 2023 - Texas - 29 year old Camylle Bowen-Ables died 2 days after delivering a baby girl (Josephine) via C-section, of unspecified complications.

March 21, 2023 - Brentwood, TN - 32 year old 5th grade teacher Kelsey Holder, died suddenly on March 21, 2023 with her stillborn baby.

March 20, 2023 - Cincinnati, Ohio - 25 year old Jada Arianna Turner (medical assistant in General Surgery at Mercy Fairfield Hospital and 10 days from getting her Licensed Practical Nursing Degree) Jada Arianna Turner died unexpectedly in her sleep at 8 months pregnant on March 20, 2023, baby died also (source)

March 15, 2023 - Guatemala - Pennsylvania mother of two boys, 27 year old Rocio "Rose" Michelle Roberts died suddenly on March 15, 2023, 4 days after giving birth, from a pulmonary embolism.

March 13, 2023 - Detroit, MI - 25 year old Alona White died of brain bleed 5 days after giving birth to her 2nd child on March 13, 2023 (click here)

March 13, 2023 - Brazil, Umuarama - 23 year old Fabianne Vitoria Ramos dos Anjos presented to emergency on March 13, 2023 in cardiorespiratory arrest, she was 3 months pregnant.

March 2, 2023 - Los Angeles, CA - 32 year old Bridgette Cromer, a healthcare worker (CNA) died unexpectedly hours after giving birth to her 5th child.

Feb.20, 2023 - Warren, AR - Megan Patterson died unexpectedly 10 days after giving birth to her 5th child

Feb.7, 2023 - Kettering, UK - 26 year old Zoe Green, mom of 3, was 7 months pregnant when she

suddenly felt unwell and died unexpectedly of a sudden cardiac arrest at home on morning of Feb.7, 2023

Jan.10, 2023 - 31 year old April Valentine had an emergency C-section for her daughter on Jan.9, complained of pain the following day and collapsed and died suddenly, while her boyfriend performed CPR on her (click here)(click here)

Dec.23, 2022 - Detroit, MI - 35 year old Nikita Marie Washington died unexpectedly several hours after delivery due to "excessive bleeding"

Nov.8, 2022 - Newtown, PA - 30 year old teacher Jennifer Krasna died suddenly only days after giving birth to her second son.

Oct.30, 2022 - Puyallup, WA - 44 year old mother of 5 Laura MacDonald Seymour died suddenly and unexpectedly during birth of her 6th child and 1st daughter on Oct.30, 2022. Laura experienced Amniotic Fluid Embolism, collapsed into her husband's arms and lost consciousness. Her body then went into Disseminated Intravascular Coagulation, and the bleeding never stopped. Every drop of blood from the Pierce County Blood Bank was used, and some from Seattle too, in attempts to save her. Over 70 medical personnel worked seven hours to bring her back. (source)

Oct.8, 2022 - Clarksville, TN - 33 year old Sasha Lewis-Williamson, a healthy mother of one, died unexpectedly giving birth to her 2nd baby boy.

Aug.26, 2022 - VAERS 2422892 - 37 year old woman from Texas, double Pfizer vaccinated, died with baby at 37 weeks pregnancy. She had 2 Pfizer doses on March 3, 2021 and March 28, 2021. She presented on August 12, 2022 at 37 weeks gestation with pain, acute mental status changes and hypoxia. She had a failed caesarean section, deteriorated rapidly and died Aug.26, 2022.

Aug.23, 2022 - Victoria, BC - Amanda Welch died one day after delivering her baby Rachelle Daisy Green-Welch, who died on Aug.22, 2022 (source)(source)

Jul.30, 2022 - UK - Young UK mother Laura Barnes developed blood clots at 32 weeks pregnancy which led to an emergency caesarean section and the birth of her baby Dexter. She died from the blood clots during delivery in April, 2022. Her infant died at 2 months of age on July 30, 2022 of "unknown causes". (source)

July 2022 - Manhasset, NY - 23 year old Josephine Winters was a tennis coach. She developed turbo cancer (melanoma) while pregnant and died 3 weeks after delivery

Feb.18, 2022 - VAERS 2193607 - 19 year old woman (foreign) had a Pfizer dose in early pregnancy, died at 6 months pregnancy

Feb.8, 2022 - VAERS 2266970 - 36 year old woman from Michigan had 3rd Moderna dose at 33 weeks of pregnancy. One week later she woke up at 4am having very hard time breathing and her husband called the ambulance. She went into respiratory arrest, CPR was initiated, she was transported to ER, emergency bedside C-section was performed and she died.

Feb.1, 2022 - UK - 41 year old Amber Pendlebury delivered a baby boy, then cried out "I can't breathe", had two cardiac arrests and died shortly after.

Dec.14, 2021 - Richmond, TX - Paramedic Jalesa Thompson died unexpectedly 6 days after giving birth. (source)

Nov.30, 2021 - El Paso, TX - 22 year old Jaqueline Ayala died shortly after giving birth to baby girl (blamed on COVID-19). The media used her story but never said she was unvaccinated, therefore she was presumably vaccinated.

Nov.25, 2021 - VAERS 1930989 - 31 year old woman (foreign) had a Moderna dose at 34 weeks of pregnancy and died of cardiac arrest and septic shock.

Oct.19, 2021 - Mountainside, NJ - 36 year old Jennifer Margaret Handley Chiarello, died unexpectedly one week after giving birth to a baby girl (source)

Oct.17, 2021 - Stacey Martin fell ill while pregnant and had premature labor by 2 months, delivering baby Emery. She died weeks after delivery from unspecified "complications". She was COVID-19 vaccinated but COVID-19 was blamed for her death.

Sep.29, 2021 - Spartanburg, SC - 36 year old Melissa Anne Gray, ESL Teacher, died unexpectedly while giving birth to her daughter Grace.

Sep.17, 2021 - Saint Cloud, FL - 25 year old Cristina Viloria, teacher, became ill with pneumonia when 7 months pregnant. Baby was delivered by C-section but she died. Death was blamed on COVID-19 but she was presumably COVID-19 vaccinated.

Sep.2, 2021 - VAERS 1669875 - 36 year old woman from Minnesota had Pfizer vaccine at 33.5 weeks pregnancy. She presented 9 days later with preterm labor. Twins were delivered by C-section. She was found to have AML leukemia, started chemo 2 days after giving birth, 2 weeks later suffered intracranial hemorrhage and died.

Aug.26, 2021 - Broken Arrow, OK - 33 year old Lacy Hutchison, care assistant was 8 months pregnant when she fell ill. Baby was delivered by C-section but she died. Her death was blamed on COVID-19 but she was COVID-19 vaccinated.

Aug.26, 2021 - VAERS 1730068 - 37 year old woman (foreign) had 2nd Moderna dose at 36 weeks of pregnancy, 13 days later she developed myalgia, night sweats and uterine contractions. She had a stillbirth and died.

Aug.19, 2021 - VAERS 1710421 - 27 year old woman (foreign) had 1st Pfizer dose at 33 weeks of pregnancy. On the same day after vaccination she experienced dyspnea, respiratory distress, myalgia, arthralgia, afebrile seizure, was hospitalized and died.

Aug.12, 2021 - VAERS 1547035 - 25 year old woman (foreign) had 1st Pfizer dose in early pregnancy. She developed Cerebral venous sinus thrombosis and died.

Aug.7, 2021 - VAERS 2011009 - 23 year old woman from South Dakota received Moderna vaccines at 4 and 5th month of pregnancy. About 3 weeks after giving birth she was hospitalized with cardio-

respiratory arrest and died 5 days later.

July 23, 2021 - Ackworth, GA - 41 year old Doreen Plunkett, a registered nurse who worked on front lines with COVID-19 patients, died while giving birth to her 3rd child, from an amniotic fluid embolism.

June 3, 2021 - VAERS 1371338 - 32 year old woman from Massachusetts received 2 Pfizer doses while pregnant, died 4 days after delivery

==========

My Take...

In 2021 and 2022, mainstream media reported the vaccine status of every unvaccinated pregnant woman who died with a positive PCR test for COVID-19.

This was used in an aggressive and malicious propaganda push to get pregnant women to accept taking toxic experimental COVID-19 vaccines. The media didn't hesitate going international to find these rare deaths.

It is probable some of these pregnant women were killed by hospital protocols for COVID-19.

It is also probable that some had false positive COVID-19 tests.

These pregnant women were reported as unvaccinated. Many are of a more advanced age and may have suffered pregnancy complications unrelated to COVID-19 and were then fraudulently re-labeled as "COVID-19 deaths" to push a false propaganda narrative.

Antonietta Delli Santi (age 26) Italy

Amanda Perry (age 36)

Crystal Hernandez

Davy Macias (age 37)

Jennifer Rosebluff-Thomas (age 35) Canada

Haley Mulkey Richardson (age 32)

Keighlie Rennee Reaux (age 24)

Kimmie Pavone (age 35)

Kristen McMullen (age 30)

Kristen Roy (age 38)

Natalie Forshaw (age 30) UK

Paige Ruiz (age 32)

WASHINGTON POST CONFIRMS SKYROCKETING MATERNAL MORTALITY in Aug.18, 2023 article (CDC Data)

Since COVID-19 vaccines rolled out in Dec.2020, maternal mortality has skyrocketed over 50% in 2021 compared to 2019 (all races 20.1 per 100,000 in 2019 vs 32.9 in 2021). How bad is the 2022 data?

Why are COVID-19 vaccinated pregnant women dying?

A quick look at the deaths I've covered in this article:

9/50 were healthcare workers and 4/50 were teachers (COVID-19 vaccine mandated professions are driving these maternal deaths to a significant extent)

18/50 (36%) died during the course of pregnancy:

these deaths are being driven by cardiac arrests, fetal demise that puts the mother at high risk of death, and medical emergencies that force an emergency delivery that puts the mother at high risk of death

9/50 (18%) COVID-19 vaccinated women who die during delivery usually die of unexpected complications related to abnormal clotting or bleeding

23/50 (46%) The post-partum deaths are shocking: women collapse and die without ANY warning. Autopsies are rarely done and almost never reported.

These collapses are commonly cardiac arrests or unexpected blood clots in the lungs (pulmonary emboli), but most often remain "unexplained" because proper autopsies are NOT being done.

I believe COVID-19 Vaccines are responsible for the 50% increase in Maternal Mortality in 2021, and this may be 100% or more by now in 2023 compared to 2019.

COVID-19 Vaccines are extremely toxic for pregnant women who should never take any COVID-19 or

mRNA vaccines, given the extremely poor safety record of this experimental technology.

Subscribed

62 Likes

3 Restacks

10 Comments

Write a comment...

Kamikaze ~ Spirit Wind

Aug 23

Liked by Dr. William Makis MD

Words do not suffice... 😟

LIKE (11)

REPLY

SHARE

founding

A T

Writes A's Substack

Aug 23

Liked by Dr. William Makis MD

What an unenviable vocation God has charged you with Dr. Makis, to bring to light this ongoing demonic and cruel slaughter of the innocents. And still you have not shirked from your calling, thank you, bless you

Humanity has come to a Crossroad here on Earth. There are those who are overwhelmed with compassion and sorrow witnessing and experiencing this deadly cold-blooded assault on humanity. And there are others who mock God, and mock you and those who like yourself, are only shouting warnings from whatever rooftops you can climb up on, risking yourselves for the few who will listen.

A crossroad similar to the cross of Jesus where some mourned, and others mocked...

"At the foot of the Cross were collected,

The haters and lovers

The cruel and the compassionate

The heart and the stone

The living and the dead

Of course, "No man comes to the Father except through the Son", at the Crossroad"

LIKE (7)

REPLY

SHARE

8 more comments...

Top

New

Community

Musicians Injured - Eric Clapton: "I can't sleep because of the pain...the vaccine took my immune system and just shook it around"

Watch now (7 mins) | Eric Clapton bravely discusses his neurological COVID-19 vaccine injuries

FEB 11

•

DR. WILLIAM MAKIS MD

456

310

Children Dying Suddenly - Canada's youngest athletes, ages 6-13 are dying suddenly: COVID-19 vaccine mandates for children playing sports...

COVID-19 vaccines are banned for kids under 18 in Scandinavian countries

FEB 22

•

DR. WILLIAM MAKIS MD

344

181

Pilot Incapacitated - Southwest Airlines WN6013 LAS-CMH departing Las Vegas diverted as pilot collapsed shortly after takeoff morning of...

Pilot Josh Yoder reports: "I'm being notified by passengers on a Southwest flight departing Las Vegas that the captain became incapacitated soon after...

MAR 22

•

DR. WILLIAM MAKIS MD

283

146

Cardiac Injury - Cardiac testing at Washington public event found 53% myocarditis rate, including 2 active duty US military pilots - what...

An interesting story was reported on Feb.26, 2023 by News 8 WTNH, New Haven, CT. They took the story down about 24 hours later but it is still available...

FEB 28

•

DR. WILLIAM MAKIS MD

297

126

Canadian doctor sudden deaths have reached 150 since COVID-19 vaccines rolled out - our Canadian Medical Association celebrates the occasion...

These days, there are far stronger morals, ethics and honorable behavior in the Mexican drug cartels, than in Canada's entire healthcare leadership...

APR 22

•

DR. WILLIAM MAKIS MD

267

151

2023 Alberta Election results - Rural Alberta pauses Canada's slide into communism - and former Premier Jason Kenney's COVID Cabinet members...

Unless orange suitcases full of pre-filled out ballots show up at 3am, Alberta's election has been comfortably won by Danielle Smith and the UCP party...

MAY 30

•

DR. WILLIAM MAKIS MD

260

79

High School "died suddenly" - Epidemic of 15-19 year olds dropping dead in schools and dorms across USA and Canada in April 2023

There truly seems to be an epidemic of sudden deaths in schools across USA and Canada recently. Here are the most recent tragic cases: Jena, LA - 15...

APR 23

•

DR. WILLIAM MAKIS MD

242

184

Died Suddenly - Young chefs are dying suddenly and unexpectedly - 28 sudden deaths - COVID-19 vaccine mandates?

(Left) France, Champagne - Chef Laurent Fresnet, age 56, died suddenly April 3, 2023 (click here) (Right) UK Chef Matt Halford, age 38, died suddenly...

APR 20

•

DR. WILLIAM MAKIS MD

239

171

Neurological Injury - Spike protein accumulates in the brain and causes infarcts, bleeds, inflammation - Pfizer & Moderna COVID-19 mRNA...

A new paper from Germany posted on April 5, 2023 proves that the spike protein accumulates in the brain and causes death of brain cells (which would...

APR 7

•

DR. WILLIAM MAKIS MD

213

167

Turbo Cancer Leukemia - children from ages 11 to 21 are dying within hours or days of cancer diagnosis (new case: 16 year old Kyle Limper)

Philadelphia, PA - 16 year old Kyle Limper died within 24 hours of leukemia diagnosis on April 13, 2023 (click here) His father, Ken Limper, initially...

MAY 2

•

DR. WILLIAM MAKIS MD

204

114

See all

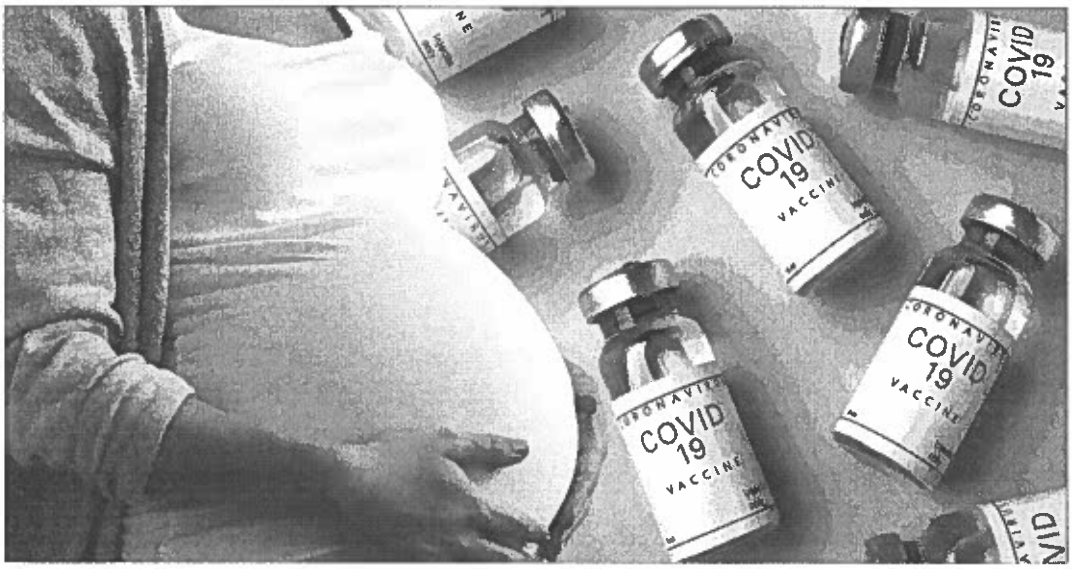
05/15/23 • COVID › VIEWS

Many Pregnant Women Were Forced to Get COVID Shots. Here's What Happened to Them.

COVID-19 shot contents are biodistributed into the bloodstream within hours and cross "all physiologic barriers including the maternal-placental-fetal barrier and the blood brain barriers in both the mother and the fetus," according to maternal-fetal medicine expert Dr. James Thorp.

By Dr. Joseph Mercola

43



Miss a day, miss a lot. *Subscribe to The Defender's Top News of the Day.* ***It's free.***

Story at a glance:

- Compared to the flu vaccine, COVID-19 shots are associated with a significant increase in adverse events among women of reproductive age.
- Data revealed a 27-fold higher risk of miscarriage and a more than two-fold increased risk of adverse fetal outcomes across six different categories following COVID-19 shots.

Latest News


An Eye Te for Autism Good, But Perfect


'Legalized Poisoning 5,500 Peo Oregon County Fi Plan to Sp 473 Acres With Glyphosat


California Threatens Defund 60 Schools O Low Vacci Rates

MORE NEWS

Latest Views


RSV: Fact Fiction Wi Dr. Meryl Nass and Brian Hoo Ph.D.


A Journali

- COVID-19 shot contents are biodistributed into the bloodstream within hours and cross "all physiologic barriers including the maternal-placental-fetal barrier and the blood brain barriers in both the mother and the fetus."
- Birth rates in multiple European countries fell significantly at the end of 2021, months after COVID-19 shots became widely utilized.
- Researchers have called for the immediate suspension of COVID-19 vaccination for all persons of childbearing and reproductive age.

While a typical vaccine must undergo 10 to 12 years of trials before it's released, during the pandemic, COVID-19 shots were made available to the public just 10 months after development, courtesy of an Emergency Use Authorization.

Even pregnant women were subjected to the shots, and in many cases were mandated to receive them.

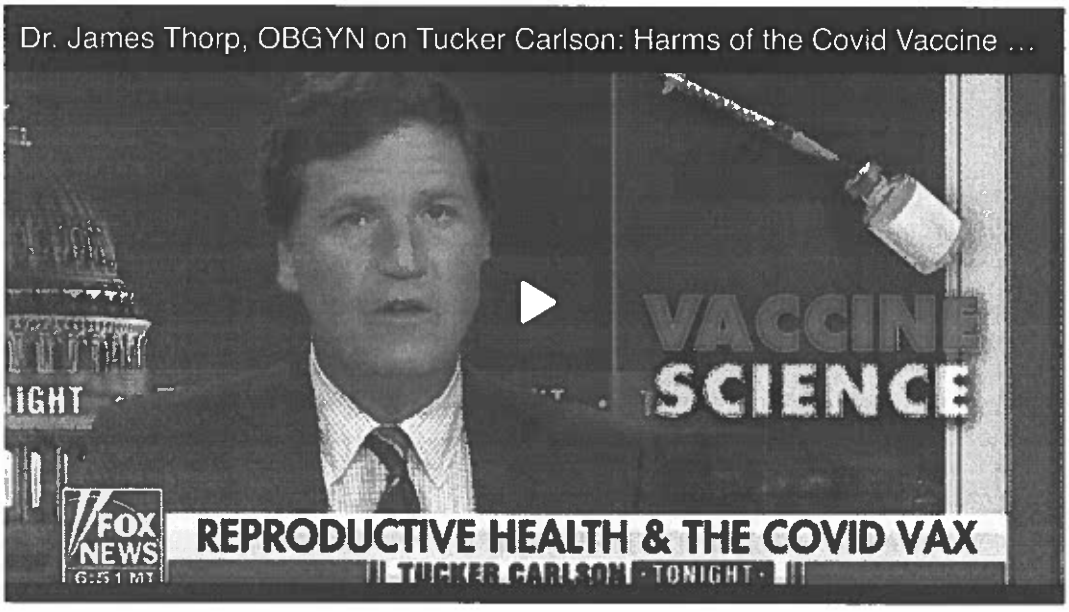
"The pushing of these experimental COVID-19 vaccines globally is the greatest violation of medical ethics in the history of medicine, maybe humanity," Dr. James Thorp, a maternal-fetal medicine expert, told Tucker Carlson (see video below).

Thorp and colleagues published a preprint study that found striking risks to pregnant women who received the shots, along with their unborn babies.

The outcomes were so dire that the researchers concluded pregnant women should not receive COVID-19 shots until further research is completed.

The researchers explained:

> "A worldwide moratorium on the use of COVID-19 vaccines in pregnancy is advised until randomized prospective trials document safety in pregnancy and long-term follow-up in offspring."



COVID shots linked to 27-fold higher risk of miscarriage

Thorp and colleagues used data from the Centers for Disease Control and Prevention's Vaccine Adverse Events Reporting System (VAERS) to assess adverse events experienced by women of reproductive age following receipt of a COVID-19 shot, compared to receipt of a flu shot.

The researchers compared to the flu vaccine, COVID-19 shots were associated with a significant increase in adverse events (AE), including:

- Menstrual abnormality
- Miscarriage
- Fetal chromosomal abnormalities
- Fetal malformation
- Fetal cystic hygroma
- Fetal cardiac disorders
- Fetal arrhythmia
- Fetal cardiac arrest
- Fetal vascular malperfusion
- Fetal growth abnormalities
- Fetal abnormal surveillance
- Fetal placental thrombosis
- Low amniotic fluid
- Fetal death/stillbirth

The researchers noted:

> "When normalized by time-available, doses-given, or persons-received, all COVID-19 vaccine AE far exceed the safety signal on all recognized thresholds ... Pregnancy and menstrual abnormalities are significantly more frequent following COVID-19 vaccinations than that of Influenza vaccinations."

Specifically, the data revealed a 27-fold higher risk of miscarriage and a more than two-fold increased risk of adverse fetal outcomes across six different categories, according to board-certified internist and cardiologist Dr. Peter McCullough.

Were nurses issued gag order against speaking out?

Problems began to appear shortly after COVID-19 shots were rolled out, such that a leaked email from a large California hospital was sent out in warning to 200 nurses.

The email, from September 2022, contained the subject line, "Demise Handling," referring to an increase in stillbirths and fetal deaths.

A TCW report by journalist Sally Beck shared the email's content, which read:

> "It seems as though the increase of demise patients [babies] that we are seeing is going to continue. There were 22 demises [stillbirths and fetal deaths] in August [2022], which ties [equals] the record number of demises in July 2021, and so far in September [2022] there have been 7 and it's only the 8th day of the month."

Beck reports that one nurse, Michelle Gershman, who works in the neonatal ward had her bonus withheld because she spoke out about the rise in fetal deaths.

"We used to have one fetal demise per month. That rose to one or two per week," Gershman said.

Beck reported:

> "Her experience, and the experience of doctors working with pregnant women, is contrary to official 'safe and effective' observation and advice, but no one was free to speak out because of a gagging order imposed in September 2021 by the American Board of Obstetrics and Gynecology (ACOG). ..."

> "At the beginning of the rollout, in December 2020, pregnant women who were healthcare workers or deemed to be at risk from COVID began receiving the shots. By May 2021, the vaccine was being recommended to all pregnant American women, despite the fact that none of the vaccine manufacturers had completed reproductive toxicology reports in animals, and none had started clinical trials in pregnant women.
>
> "Two months later, hospitals noticed a huge increase in miscarriage, stillbirth, preterm births, pregnancy complications and menstrual abnormalities."

COVID shots should be Category X

The mRNA from COVID-19 shots circulates in the body for 28 days or more, and the spike protein may trigger clotting, bleeding and tissue damage, according to McCullough.

Because of this and other concerns, he states that, conservatively, COVID-19 shots should be given the "Category X" designation during pregnancy, which means, "The risk of use of the drug in pregnant women clearly outweighs any possible benefit. The drug is contraindicated in women who are or may become pregnant."

Unfortunately, health officials in the U.S. continue to affirm its safety, even for vulnerable populations such as this, as they have from the very beginning.

"Shockingly, in the very first week of mass vaccination in December of 2020," McCullough wrote, "news reels depicted well-intentioned pregnant mothers getting injected with synthetic lipid nanoparticles laced with long-lasting mRNA coding for the Wuhan Institute of Virology Spike protein."

Thorp's study also reported that Pfizer's data showed COVID-19 shot contents are biodistributed into the bloodstream within hours and cross "all physiologic barriers including the maternal-placental-fetal barrier and the blood brain barriers in both the mother and the fetus."

A separate study is, in fact, looking at using ionizable lipid nanoparticles (LPNs) like those used as mRNA delivery platforms in COVID-19 shots, as tools to deliver drugs to the placenta, because they're so effective at reaching it.

"LNPs enhance mRNA stability, circulation time, cellular uptake and preferential delivery to specific tissues compared to mRNA with no carrier platform," the researchers wrote.

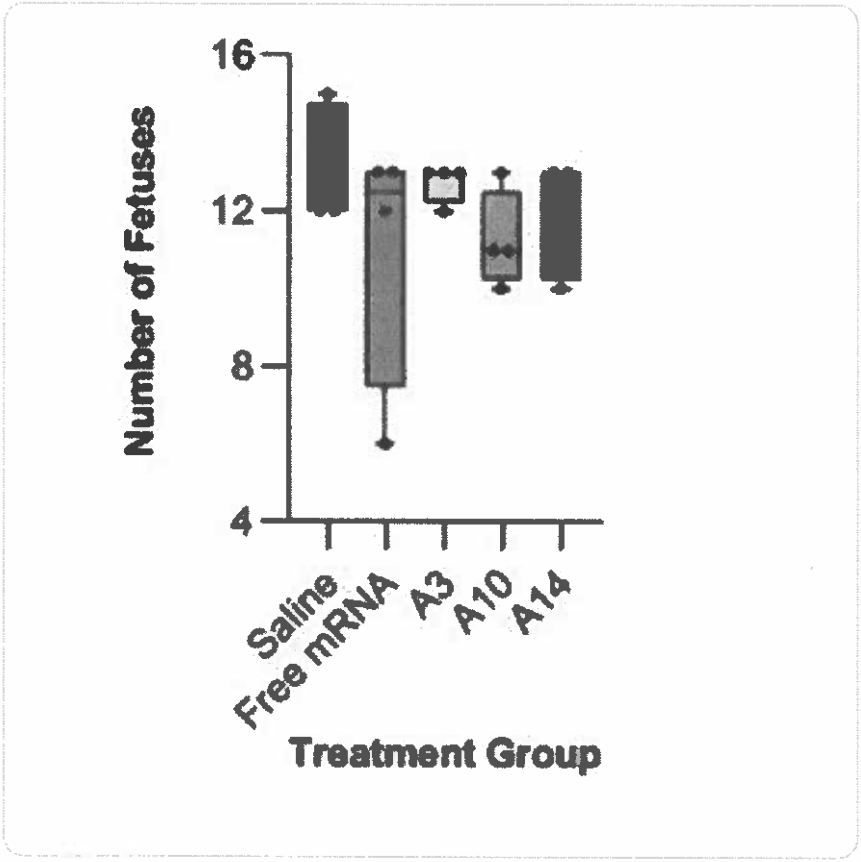
But the study contains some concerning data, which was shared on Twitter:

Jikkyleaks
@Jikkyleaks · **Follow**

More #Placentagate

This could be one of the biggest scandals in medicine.

Check this out.
What do you see?
biorxiv.org/content/10.110...



10:03 PM · Mar 18, 2023

3.7K Reply Share

Read 217 replies

Health officials made the recommendation that COVID-19 shots are safe and effective for pregnant women based on a 42-day study from Pfizer involving 44 rats.

What's more, the Pfizer-BioNTech rat study revealed the shot more than doubled the incidence of preimplantation loss and also led to a low incidence of mouth/jaw malformations, gastroschisis (a birth defect of the abdominal wall) and abnormalities in the right-sided aortic arch and cervical vertebrae in the fetuses.

Pfizer BNT162b2 animal study # 20256434

Control arm				Treatment arm			
Animal Number	Corpora Lutea	Pre-implant loss	Live fetus	*Animal Number*	Corpora Lutea	Pre-implant loss	Live fetus
1	14	0	11	*1*	16	2	13
2	15	0	15	*2*	18	1	17
3	17	1	16	*3*	16	4	12
4	16	0	14	*4*	12	2	10
5	15	1	13	*5*	20	3	13
6	12	2	10	*6*	14	4	9
7	14	0	14	*7*	16	1	15
8	17	0	12	*8*	16	1	13
9	17	4	13	*9*	20	4	16
10	13	1	11	*10*	15	1	13
11	12	0	12	*11*	15	1	13
12	14	0	13	*12*	15	0	15
13	15	0	14	*13*	16	0	14
14	14	0	13	*14*	17	1	13
15	16	2	13	*15*	14	2	12
16	14	1	13	*16*	14	1	13
17	16	0	15	*17*	15	1	14
18	14	0	14	*18*	12	0	12
19	13	0	12	*19*	15	1	12
20	17	1	16	*20*	17	0	17
21	14	0	13	*21*	13	2	10
Mean	*14.714*	*0.619*	*13.190*	*Mean*	*15.524*	*1.524*	*13.143*
	Overall mean %		**4.2%**		**Overall mean %**		**9.8%**
					T.test.p	**0.01588**	

"In that study the fetal loss rate DOUBLED (4.2% to 9.8%) but had little impact on the overall number of fetuses," Jikkyleaks tweeted, sharing the chart above.

The tweet continued:

> "This is how this information is hidden. That single slide should have been enough to prompt much more investigation, because it showed fewer fetuses in EVERY GROUP."

Shocking decline in birth rates post-COVID shots

Birth rates in multiple European countries fell significantly in the end of 2021, months after COVID-19 shots became widely utilized.

The data, compiled by a team of European researchers, found declines in birth rates in all the countries they studied, including:

- Germany
- Austria
- Switzerland
- France
- Belgium

- Netherlands
- Denmark
- Estonia
- Finland
- Latvia
- Lithuania
- Sweden
- Portugal
- Spain
- Czech Republic
- Hungary
- Poland
- Romania
- Slovenia
- Iceland
- Northern Ireland
- Montenegro
- Serbia

The team explained:

> "In advance it should be noted that every single examined European country shows a monthly decline in birth rates of up to more than 10% compared to the last three years. It can be shown that this very alarming signal cannot be explained by infections with COVID-19.
>
> "However, one can establish a clear temporal correlation to COVID vaccinations incidence in the age group of men and women between 18 and 49 years. Therefore, in-depth statistical and medical analyses have to be demanded."

The declines in birth rates ranged from a low of 1.3% in France to a high of 19% in Romania.

Seven countries had a decline in birth rate of more than 10%, while 15 countries had declines of greater than 4%. Switzerland's drop was said to have exceeded the drop that occurred from World War I, World War II, the Great Depression and the release of oral contraceptives.

No connection was found between the declines in birth rates and COVID-19 infections or hospitalizations, with the team noting:

> "Adverse reactions related to the female reproductive organs and study findings related to male fertility point to a causal interpretation of the association of birth declines and the Covid-19 vaccinations."

COVID shots affect menstrual cycles

It remains unknown how COVID-19 shots affect reproductive health in men and women.

For instance, The Vaccine Reaction reported:

> "To date, the manufacturer's insert for FDA-approved COVID shots explicitly states that it has not been tested for the potential to impair male fertility."

However, data on U.S. infertility after the rollout of COVID shots aren't available.

Meanwhile, women around the globe have reported changes in their menstrual cycles following COVID-19 shots, and health officials largely brushed off the reports or labeled them anecdotal.

But a study published in Obstetrics & Gynecology — and funded by the National Institute of Child Health and Human Development and the National Institutes of Health Office of Research on Women's Health — confirms an association between menstrual cycle length and COVID-19 shots.

Clinical trials for COVID-19 shots did not collect data about menstrual cycles following injection, and VAERS does not actively collect menstrual cycle information either, making it difficult to initially determine whether the shots were having an effect.

Anecdotal reports on social media, however, are numerous and, according to the study, "suggest menstrual disturbances are much more common."

The Obstetrics & Gynecology study involved 3,959 individuals between the ages of 18 and 45 years. Those who had not received a COVID-19 shot noted no significant changes in cycle 4 during the study compared to their first three cycles.

However, those who received COVID-19 shots had longer menstrual cycles, typically by less than one day, when they received the shots.

The longer cycles were noted for both doses of the injection, with a 0.71-day increase after the first dose and a 0.91-day increase after the second dose.

Cycle changes of eight days or more noted

The overall declines were described as not clinically significant.

However, some women, particularly those who received two shots in the same menstrual cycle, experienced significant changes, including a two-day increase in cycle length and, in some cases, changes in cycle length of eight days or more.

Considering a regular menstrual cycle is "an overt sign of health and fertility," any changes could have major ramifications.

Further, the team noted:

> "Questions remain about other possible changes in menstrual cycles, such as menstrual symptoms, unscheduled bleeding, and changes in the quality and quantity of menstrual bleeding."

Taken together, the links to miscarriage, reproductive changes and declining birth rates raise major red flags about the safety of COVID-19 shots for people of reproductive age.

As such, the European research team echoed Thorp in calling for a moratorium on COVID-19 shots for pregnant women, and took it a step further suggesting a suspension for everyone of reproductive age:

US Maternal Death Rates Up Sharply

CDC Oblivious to COVID-19 Illness and Vaccination as Determinants

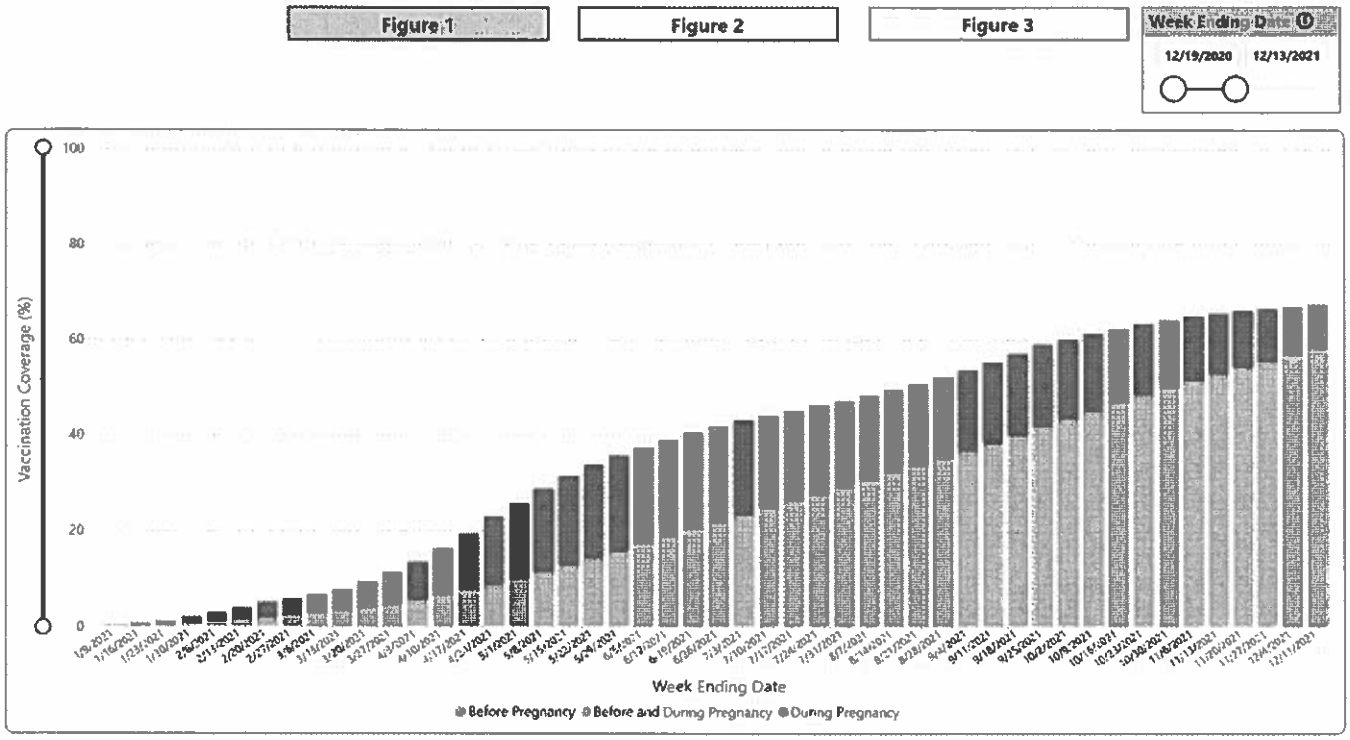
PETER MCCULLOUGH, MD
APR 12, 2023

By Peter A. McCullough, MD, MPH

Modern obstetrical care in the US has had a major impact in reducing maternal death rates over several decades. Now there is reversal of these trends. From the start of the pandemic there have been reports with mixed results for mortality among pregnant women with COVID-19 infection and after COVID-19 vaccination. Sadly, many women have had both exposures in 2021 and beyond.

The CDC reports that ~65% of women have taken a vaccine—most before conception and the remainder through the term of gestation. This occurred because the CDC advised that pregnant women take this risk with no assurances on the health of the mother or baby through pregnancy.

Figure 1: Percent of Pregnant People Ages 18–49 Years Who Completed the Primary Series of COVID-19 Vaccine Before and During Pregnancy, by Timing of Vaccination and Week Ending Date — Vaccine Safety Datalink,* United States December 14, 2020 – December 11, 2021



COVID-19 vaccination among pregnant people aged 18-49 years overall, by race and ethnicity, and date reported to CDC - Vaccine Safety Datalink,* United States, Accessed April 10, 2023

Now the CDC is reporting record maternal death rates in 2021 compared to prior decades and in the report by Hoyert et al, has shown a stepwise increase for death during or shortly after pregnancy. All groups are up but the worst is for African American women.

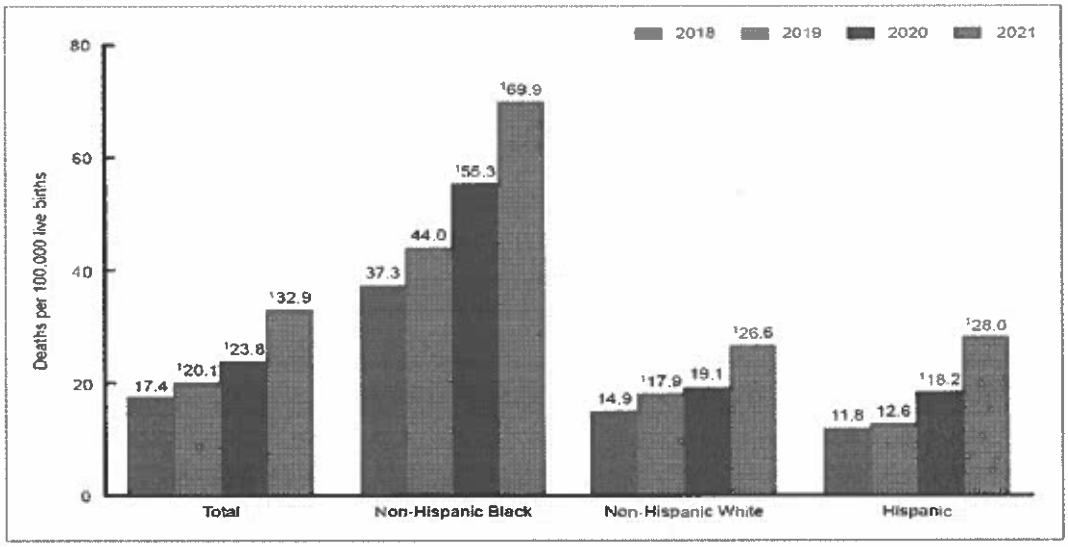
NATIONAL CENTER FOR HEALTH STATISTICS
Health E-Stats
MARCH 2023

Maternal Mortality Rates in the United States, 2021

by Donna L. Hoyert, Ph.D., Division of Vital Statistics

This report presents maternal mortality rates for 2021 based on data from the National Vital Statistics System. A maternal death is defined by the World Health Organization as "the death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and the site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes (1)." Maternal mortality rates, which are the number of maternal deaths per 100,000 live births, are shown in this report by age group and race and Hispanic origin.

Figure 1. Maternal mortality rates, by race and Hispanic origin: United States, 2018–2021



¹Statistically significant increase from previous year ($p < 0.05$).
NOTE: Race groups are single race.
SOURCE: National Center for Health Statistics, National Vital Statistics System, Mortality.

Hoyert, CDC, Maternal Mortality Rates in the United States, 2021

While lockdowns, reduced access to prenatal care, and a variety of factors could be related to maternal outcomes, the CDC report is willfully blind to major exposures 1) acute COVID-19 which could have played a role in 2020 and 2) COVID-19 vaccination which was prevalent in 65% of mothers in 2021. The CDC must open up all data on COVID-19 cases and vaccination to researchers for urgent epidemiologic evaluation of these disturbing trends. Death among pregnant women should be a top priority for public health researchers.

Women of childbearing age and pregnant women should refrain from COVID-19 vaccination given its pregnancy category X status and the absence of any assurances on short or long-term safety.

If you find "Courageous Discourse" enjoyable and useful to your endeavors, please subscribe as a paying or founder member to support our efforts in helping you engage in these discussions with family, friends, and your extended circles.

COMMISSIONER'S REPORT

Commissioner’s Report

December 15, 2023

Richmond, VA

Presentation Outline

- Agency Stars
- Communicable Disease Update
- Holiday Satellite Media Tour
- American Rescue Plan Act Projects
- JCHC Local Health Department Workgroup Outcomes
- Workforce: Non-Physician Directors/Medical Officers
- EMS Update
- Monthly Operating Reviews
- Language Access
- Strategic Planning Update

Agency Stars

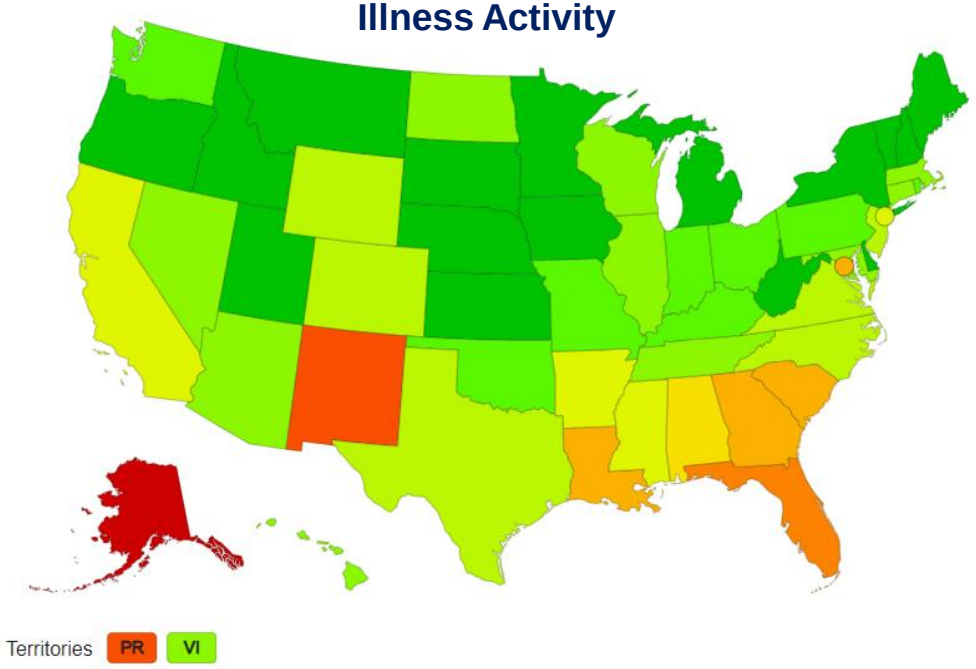
Amy Tharp, MD

Brenden Rivenbark, MHCDS

Respiratory Virus Activity

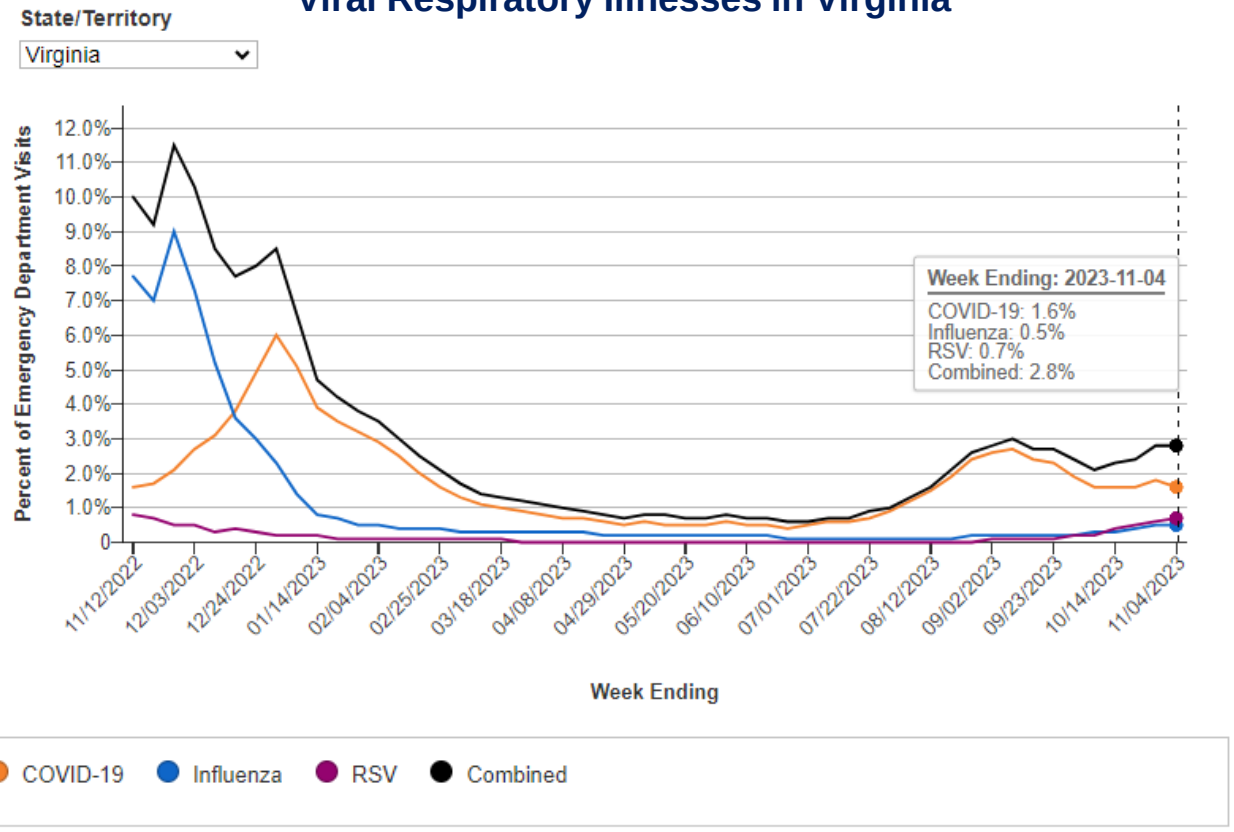
Week 44 - ending November 4, 2023

National Levels of Respiratory Illness Activity



Respiratory Illness Activity Level

Emergency Department Visits for Viral Respiratory Illnesses in Virginia



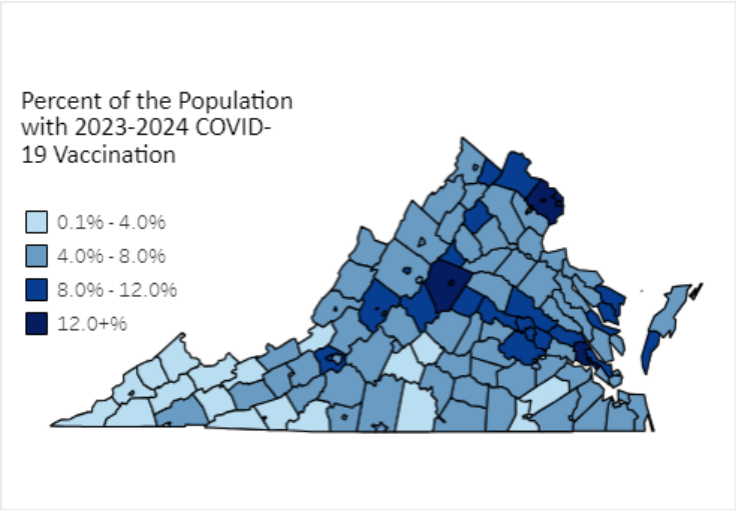
Source: CDC Respiratory Illnesses; Accessed 11/14/23

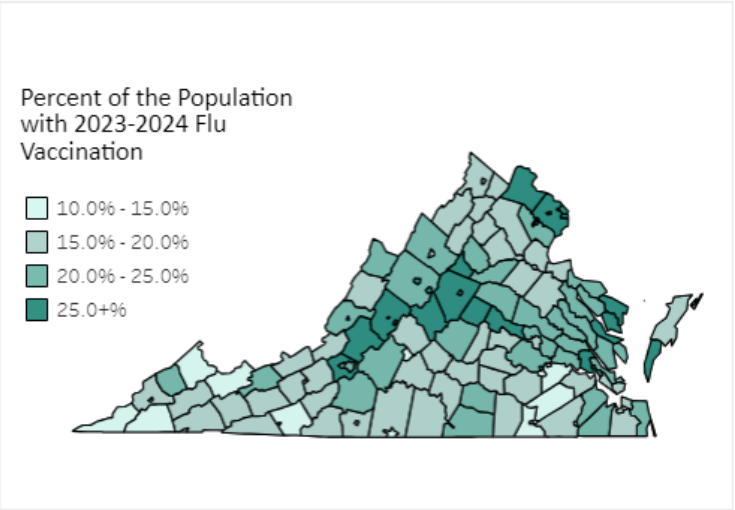
VDH VIRGINIA DEPARTMENT OF HEALTH

Respiratory Virus Vaccination Trends

As of November 14, 2023

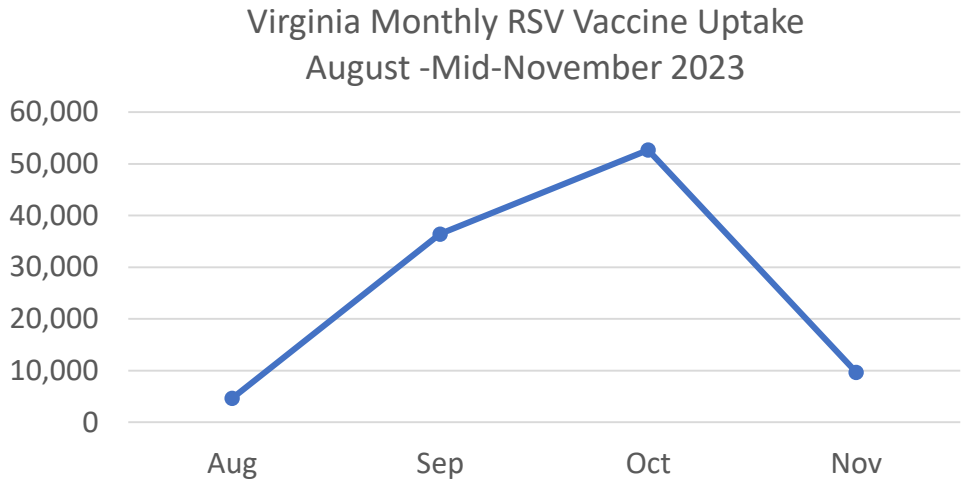
Vaccine :	2023-2024 COVID-19 Vaccine	2023-2024 Flu Vaccine
Total Doses Administered :	795,404	1,999,349
Doses Administered per 100k :	9,312	23,407

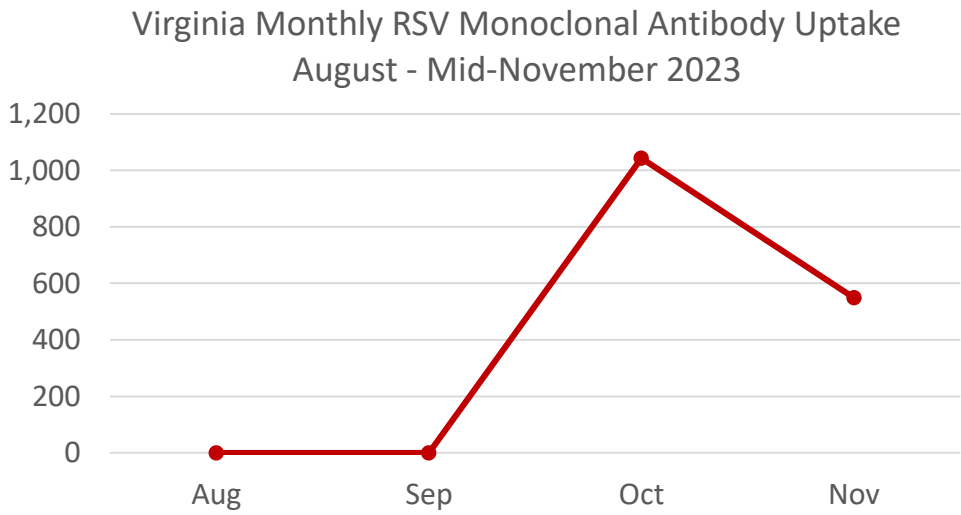




Coverage Rates for 2023-2024 COVID-19 & Flu Vaccination

Ages :	6 months +	Ages : 5-17	Ages : 5+	Ages : 18+	Ages : 50+
COVID-19 % Vaccinated :	8.5%	3.3%	8.9%	10.0%	16.7%
Flu % Vaccinated :	21.5%	16.1%	21.5%	22.6%	34.5%

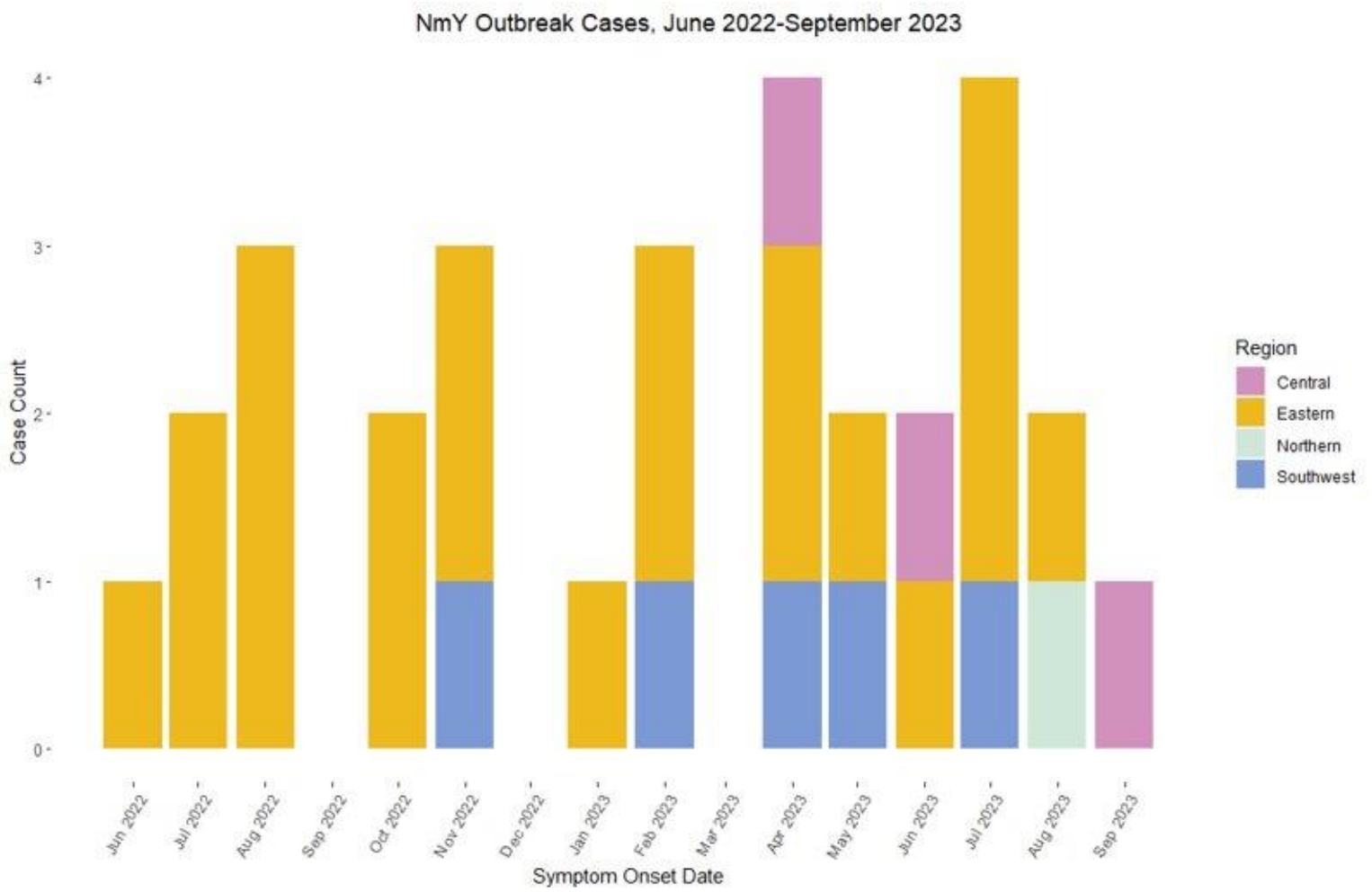




Source: VDH COVID-19 and Flu Vaccine Dashboard; Accessed 11/14/23
RSV Source: Virginia Immunization Information System; Accessed 11/09/23

VDH VIRGINIA DEPARTMENT OF HEALTH

Statewide Outbreak of Meningococcal Disease Serogroup Y



- Since June 2022, **30 outbreak-associated cases** have been reported across Virginia, including **6 deaths**.

§ The first case in a resident of **Northern Virginia** was reported in August 2023.

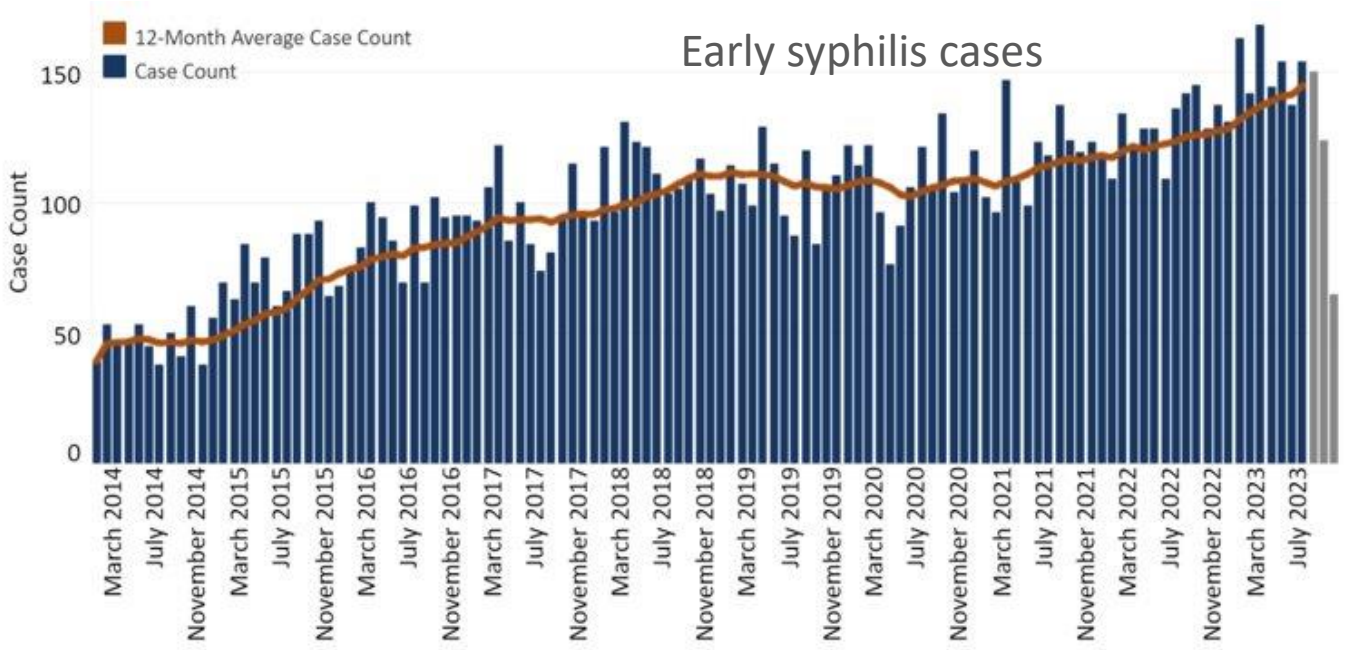
§ VDH has not identified any direct connections or a common risk factor between case-patients.

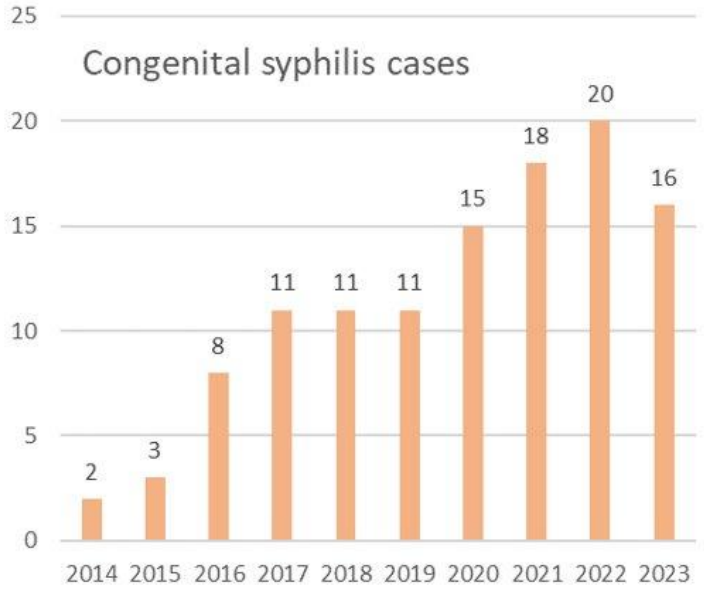
§ All isolates available for sequencing (28 out of 30) were found to be the **same strain**, sequence type 1466 within clonal complex 174, and **highly genetically related**.

§ The majority of case-patients are African American adults between 30-60 years of age.

Syphilis

- 1,429 early syphilis cases diagnosed so far in 2023- 21% higher compared to 2022
- Significant increases in congenital syphilis and syphilis diagnoses among women
- Increase in cases reporting substance use (opioids, methamphetamine, cocaine)
- VDH launched a syphilis task force and a new syphilis web page to address increases
- New CDC report on congenital syphilis strengthened syphilis testing recommendations





Satellite Media Tour:
Preventing Severe Respiratory Illness During the Holidays

On Tuesday, November 21, State Epidemiologist Dr. Laurie Forlano joined Virginia morning TV and radio programs to talk about ways Virginians can keep severe respiratory illnesses at bay this holiday season.

Interviews were conducted one-on-one via satellite and Zoom. As of November 20, 16 stations across the state scheduled for the tour, more were expected to join.

A self-contained interview will be distributed to any station unable to join the tour, including smaller stations in rural areas of the Commonwealth.

Dr. Forlano has participated in several satellite media tours on public health topics. Her interviews from **last year's tour** on preventing respiratory illness over the holidays was aired **1,535 times and earned more than 105 million media impressions.**

WHSV interview, November 2022

ARPA Project Well & Septic Improvements

Key Accomplishments:

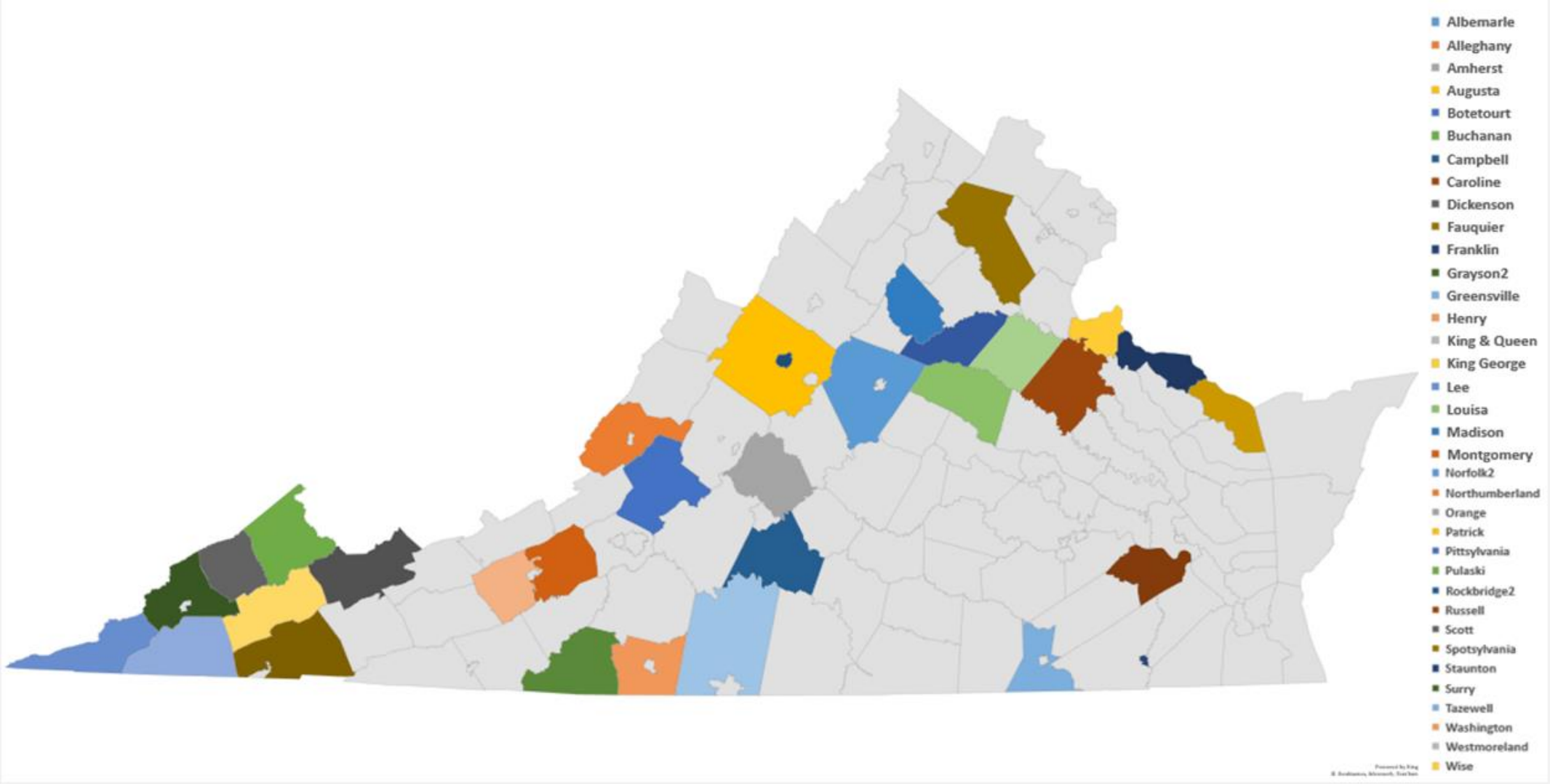
- Continued to track direct homeowner projects against the regional distribution
    - 419 projects from 270 applications received as of 11/17/23; 67 projects canceled/denied; estimated 351 projects to complete (485 including 134 additional pumpouts).
    - Requesting an estimated $6.969 million of the $7.2M available
    - On track to complete most Direct projects by 6/30/2024, 2.5 years ahead of schedule

- 458 Direct projects (94.4%) in the construction/procurement/award phase
    - 420 (91.6%) will be through VDH eVa process: 182 (43.9%) projects completed, 28 under construction, 6 Bids under review or awaiting award, 20 in the eVA process, 5 projects were installed but not paid by SWAP, 21 were cancelled before award but will be rebid in a different form, 6 were cancelled and will not be installed. An additional 18 projects had their vendor contracts canceled due to DPOR issue and were rebid. There are 134 contracts for additional emergency pumping of failing systems of which 115 have been completed to date.
    - 38 (8.4%) were awarded via 3 Direct to Partner Initiative (D2PI) contracts totaling $984,838 SWAP and $275k Most Effective Basin Grant.

- Local Partner Project Update:
    - First subawards for local partners awarded to 5 entities: $1,499,980.
        - - Estimated that these projects have received and are reviewing upwards of 80 applications
        - (and continuing to accept applications)
    - One additional local partner applications will be awarded $299,158.

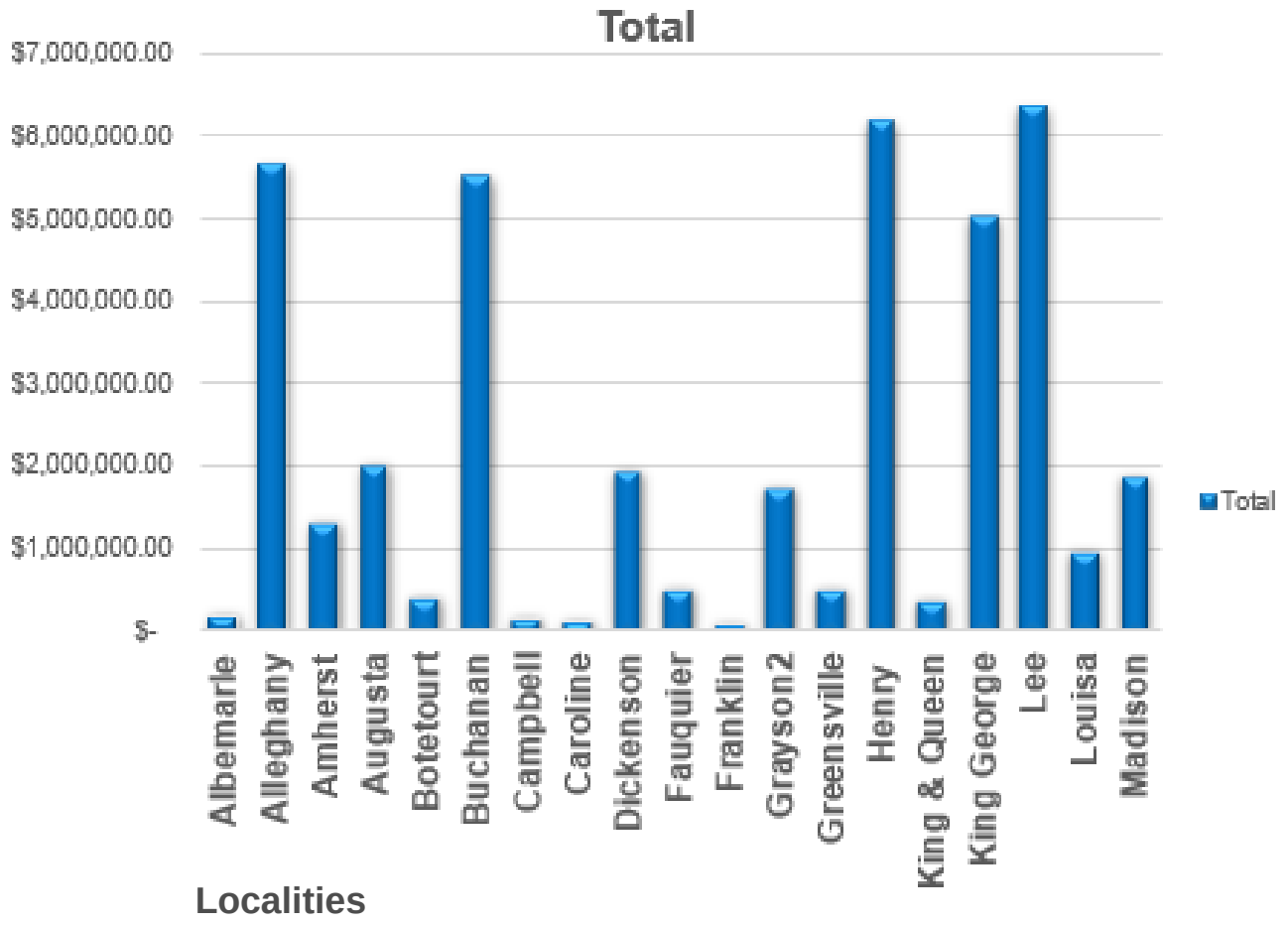
- **Total commitment: To date $9.161m of the $9.6m (95%) of project funds.**

ARPA Drinking Water Projects

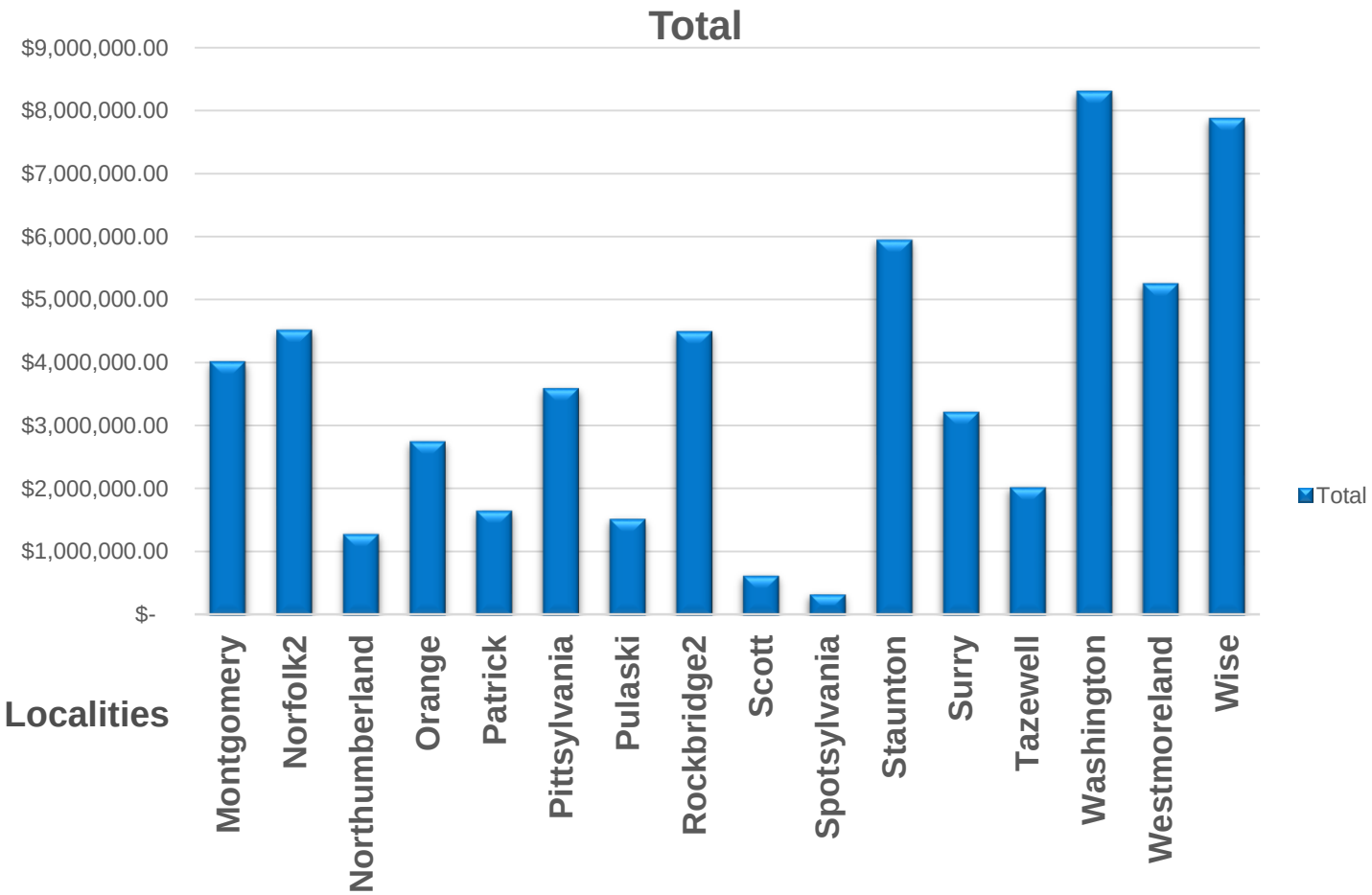


Drinking Water ARPA Projects – Nov 2023

Locality	Sum of Total Execution
Albemarle	$ 195,638.50
Alleghany	$ 5,629,590.00
Amherst	$ 1,304,576.00
Augusta	$ 2,000,000.00
Botetourt	$ 400,000.00
Buchanan	$ 5,500,000.00
Campbell	$ 150,000.00
Caroline	$ 100,000.00
Dickenson	$ 1,919,925.00
Fauquier	$ 500,000.00
Franklin	$ 77,700.00
Grayson2	$ 1,725,400.00
Greensville	$ 500,000.00
Henry	$ 6,165,600.00
King & Queen	$ 350,000.00
King George	$ 5,000,000.00
Lee	$ 6,314,250.00
Louisa	$ 965,000.00
Madison	$ 1,876,875.00



Drinking Water ARPA Projects – Nov 2023



Locality	Sum of Total Execution
Montgomery	$ 4,000,000.00
Norfolk2	$ 4,500,000.00
Northumberland	$ 1,260,000.00
Orange	$ 2,734,200.00
Patrick	$ 1,634,200.00
Pittsylvania	$ 3,575,000.00
Pulaski	$ 1,500,000.00
Rockbridge2	$ 4,476,075.00
Russell	$ 1,490,000.00
Scott	$ 600,000.00
Spotsylvania	$ 300,000.00
Staunton	$ 5,930,000.00
Surry	$ 3,200,000.00
Tazewell	$ 2,000,000.00
Washington	$ 8,284,688.50
Westmoreland	$ 5,235,678.00
Wise	$ 7,856,000.00
Grand Total	$ 99,250,396.00

ARPA Broadband Project Update

- 150 VDH sites were targeted for Broadband internet access.
- 94 of those 150 sites have been completed and have access to the higher speed internet service now.
- The remaining sites are targeted to be completed by June of 2024.
- The average increase in download bandwidth is 16 times greater than before the upgrade, for each site.

ARPA Electronic Health Records Update

- $30 million budget to procure & implement the system
- Currently in final Contract Negotiations
- Estimated start to implementation: March 14, 2024
- 30 months projected for full implementation (34 Districts)
- Phased go live with initial Districts start using new system: 09/15/25

Other ARPA Project Updates

- Substance Misuse and Suicide Prevention
  - Supported the implementation of the 988 Suicide Prevention Lifeline
  - Commenced Comprehensive Suicide Prevention trainings for mental health providers
  - Executed contracts to expand Comprehensive Harm Reduction programs

- Oral Health Taskforce
  - Launched two key tele-dentistry pilot programs to provide oral heal services to HIV+ and OBGYN patients.
  - Supported Virginia Western Community College and regional community clinics to launch a dental assisting pathway program.

Other ARPA Project Updates

- Records Management
  - A total of 1,150,882 records have been purged by offices and districts since March 2023
  - Over 17,000 records scanned for digital storage

- Local Health District Maintenance
  - 31 freezers and 30 refrigerators were installed across 11 health districts, resulting in an increased capacity of approximately 1 million vials of vaccines
  - More than 77 teleconferencing systems have been upgraded or installed

Joint Commission on Health Care Workgroup

- In 2022 the General Assembly's Joint Commission on Health Care completed a study on "VDH Local Health Department Structure and Financing."

- The Joint Commission sent a letter to VDH early in 2023 requesting that VDH put together a workgroup to prioritize the recommendations contained in the 2022 study report. The letter also specified who should be included in the workgroup (Office of the Secretary of Health and Human Resources, Virginia Association of Counties, and Virginia Municipal League.)

- VDH assembled the Workgroup and had two meetings in 2023.

Joint Commission on Health Care Workgroup

Joint Commission on Healthcare meeting on Monday November 13th

VDH presented the three priorities the Workgroup chose to focus on

- Option 7 - Directing VDH to require all health districts to participate in the CHA/CHIP process, in coordination with the state health assessment process and local health system Community Health Needs Assessments. The legislation should include an enactment clause directing VDH to update the Local Government Agreements to reflect these changes.

- Option 2 - Directing VDH to design a state performance management process for each LHD, with the goals of assessing the ability of each LHD to meet minimum capacity requirements, assisting in continuous quality improvement, and providing a transparent accountability mechanism to ensure public health functions are being met.

- Option 9 - Directing that VDH track cooperative budget funding per capita, compare that funding to the identified needs of each LHD, and make appropriate adjustments as additional funding is made available.

Non-Physician Local Health Directors

Authorized by General Assembly in 2022 (Chap. 804) in response to director vacancies in certain districts

Non-Physician Directors have been hired in five districts:

Western Tidewater

Eastern Shore

Mount Rogers

Lenowisco/Cumberland Plateau

Lord Fairfax

Under consideration as part of director recruitment in other districts

Office of EMS Update

Financial Report

November 17, 2023 – Emergency Medical Services Advisory Committee Meeting

Virginia Office of Emergency Medical Services
FY2024 Projected Special Revenue

FY2024	Fund Classification	Projected FY2024 Revenue	Description of Spend
$4 For Life	30% (Operating)	$ 9,181,769	Includes OEMS staff, MOUs with the EMS Councils, Business admin costs, ESO related costs, other vendors through Council contracts
	10% (OEMS Administration)	$ 3,060,590	OEMS staff costs, Cardinal transfer fees, travel, food, clerical, building lease, management fees, VITA costs, etc.
	26 % Return to Locality	$ 7,957,533	Mandated by Code transfer to localities across Virginia based on vehicles registered in those areas
	2% Virginia Volunteer Rescue Squads	$ 612,118	Mandated transfer to VAVRS
	32% Rescue Squad Assistance Fund	$ 9,793,887	Mandated to fund Rescue Squad Assistance Fund grants program, will be used to fund past years obligations
$2 Pass Through	Pass through to VSP and general funds	$ 15,302,948	Mandated $12.5M transfer back to the General Fund and mandated $2M transfer to Virginia State Police to support MEdflight
$0.25 RSAF	$0.25 for Rescue Squad Assistance Fund (NREMT)	$ 1,912,869	Mandated funds to the National Registry
Trauma Funds	Trauma Funds	$ 8,252,717	Captured from license reinstatement with mandated use to fund Trauma Centers in Virginia

Monthly Operating Reviews (MORs)

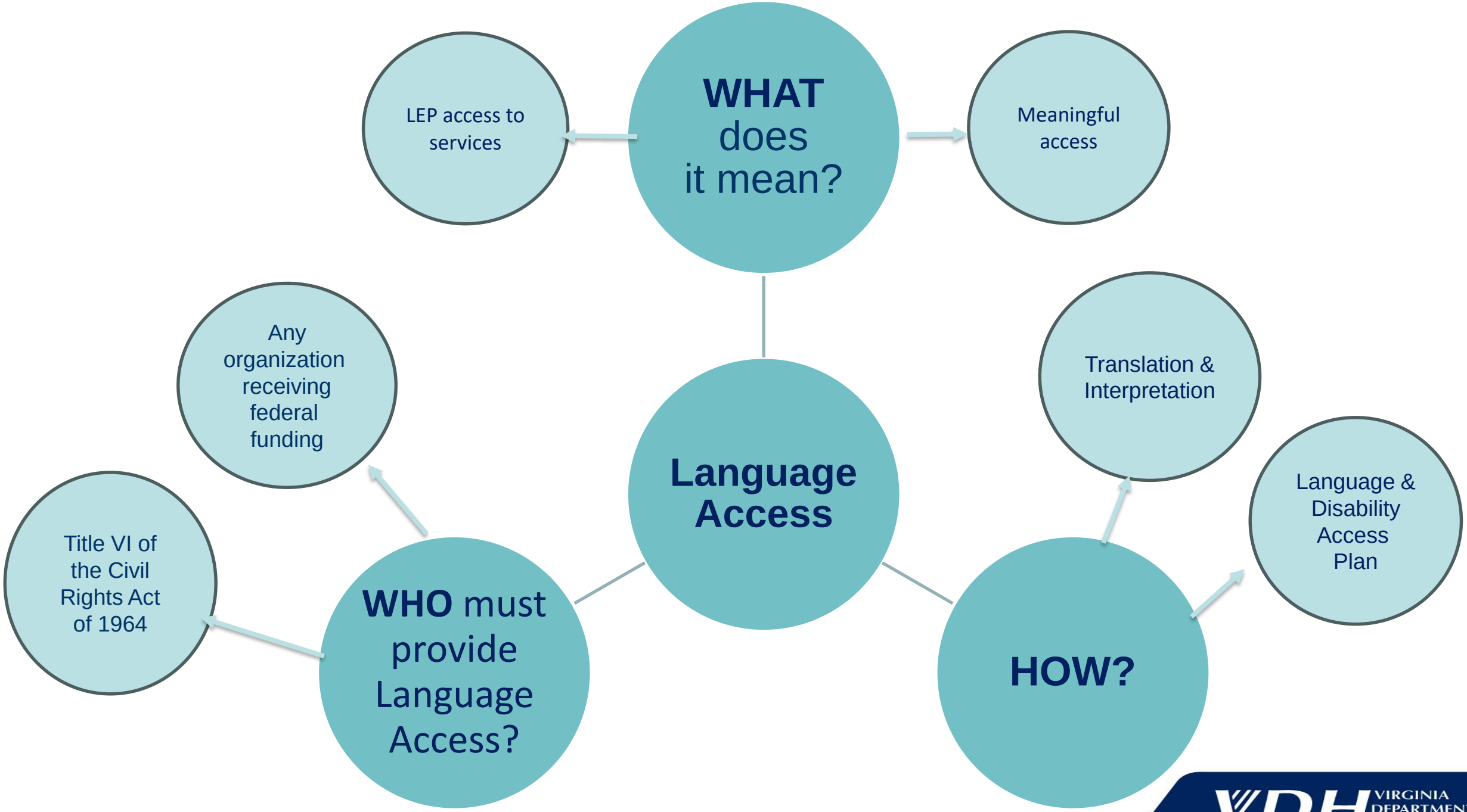
Goal: promote accountability across VDH through leadership involvement in the details of the organization and cross-communication with key Administration offices

Monthly meetings driven by the COO and senior leaders with Directors of every Office across the Agency

- Includes representatives from Finance, Human Resources, and Procurement

MOR Agenda:

- Budget/Finance
- Human Resources
- Objectives and Key Results (OKRs)
- Employee Engagement


WHAT does it mean?
LEP access to services
Meaningful access
Language Access
WHO must provide Language Access?
Any organization receiving federal funding
Title VI of the Civil Rights Act of 1964
HOW?
Translation & Interpretation
Language & Disability Access Plan

How does VDH provide Language Access?

Language Access Hub

On the VDH Intranet containing information and resources for language access needs.

- Language Services: clear instructions to request language services, including American Sign Language; glossary, language services resources, translation library, and FAQs
- Language and Disability Access Plan

CDC Public Health Infrastructure Grant

Currently recruiting for a Language Access Coordinator

- Translation Library
- Interpreter Training
- 'I Speak" posters
- Translation software. One year membership
- Translation of Non-Discrimination complaint form, policy, and procedures into 10 languages

Language & Disability Access Plan

A comprehensive document designed to ensure that LEP individuals and people with disabilities receive high-quality language services.

- Comply with federal regulations
- Comprehensive guide for language services
- Include sections as assessments and evaluation

Strategic Plan Updates

In 2022 VDH finalized its agency strategic plan. This included five goals:

Goal 1: Maintain a competent and valued workforce

Goal 2: Foster healthy, connected, and resilient communities

Goal 3: Be a trusted source of public health information and services

Goal 4: Assure the conditions that improve health opportunity

Goal 5: Provide internal systems that deliver consistent and responsive support

Strategic Plan Updates

- VDH has made progress on implementing projects and objectives under these goals:

- VDH has created a Talent Acquisition team within the Office of Human Resources to improve the recruiting and hiring process and to prioritize key positions.

- VDH is developing new career paths to help retain talented employees.

- VDH has developed occupational health infrastructure – this was a gap in the agency before COVID began.

- VDH is working to improve our policies, processes, and systems that are part of the administrative operations of the agency (finance, human resources, and procurement.)

Questions?

REGULATORY ACTION UPDATE

State Board of Health
Regulatory Action Update
December 15, 2023

Overview of Pending Regulatory Actions:

There are 49 pending actions under development:

- 10 NOIRAs
- 10 proposed actions
- 8 final actions
- 21 fast track actions

A spreadsheet containing additional detail concerning each of these actions is attached.

A NOIRA is the first stage in the standard rulemaking process in Virginia. It describes the nature and scope of the regulatory changes being considered. Should a NOIRA be approved, the next stage in the rulemaking process (the proposed stage) would involve the drafting of actual amending regulatory language for consideration. The proposed stage—if approved—is in turn followed by the final stage. Each of these three stages includes a public comment period.

The Virginia Administrative Process Act (§ 2.2-4000 et. seq. of the Code of Virginia) provides that certain types of regulatory actions are exempt from certain requirements of the state regulatory process. This includes regulatory actions that are:

i. Necessary to conform to changes in Virginia statutory law or the appropriation act where no agency discretion is involved, or
ii. Necessary to meet the requirements of federal law or regulations, provided such regulations do not differ materially from those required by federal law or regulation, and the Registrar has so determined in writing.

The Administrative Process Act also describes a "Fast Track" rulemaking process, which is utilized for regulations that are expected to be noncontroversial. The Fast Track process generally involves an action with a single stage.

Regulatory Actions Taken by the Commissioner on Behalf of the Board pursuant to § 32.-20 of the Code of Virginia since the September 14, 2023 Board Meeting while the Board was not in Session:

Approved Result of Periodic Review of Regulations – Board of Health Regulations Governing Vital Records (12VAC5-550)

- The decision resulting from the periodic review of Chapter 550 is to amend the Regulations to conform the language to the Virginia Registrar of Regulations' *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code ("Style Guide")*, clarify the processes for filing, registering, and obtaining copies of vital records, and reduce regulatory burden where possible.

Approved Final Exempt Action - Regulation for the Certificate of Quality Assurance of Managed Care Health Insurance Plan (MCHIP) Licensees (12VAC5-408).

- This non-discretionary action conforms the regulation to Chapters 376 and 377 of the 2023 Acts of Assembly, regarding the process to credential healthcare providers into insurance networks.

Approved NOIRA – Certified Nursing Facility Staffing Standards Regulation (12VAC5-375).

- This NOIRA initiates the promulgation of a new regulation to implement Chapters 482 and 483 of the 2023 Acts of Assembly.

Approved NOIRA – Managed Care Health Insurance Plan Quality Assurance Regulation (12VAC5-409).

- This NOIRA initiates an action to implement the results of the recent Periodic Review by repealing Chapter 408 and replacing it with Chapter 409. Changes to the requirements will address conforming to the *Style Guide,* changes that have taken place in the regulated industry, and regulatory reduction where possible.

Approved NOIRA – Regulation for the Licensure of Nursing Facilities (12VAC5-372).

- This NOIRA initiates a Periodic Review of the Regulations for the Licensure of Nursing Facilities (12VAC5-371), the results of which will be promulgated into a new Chapter 372, repealing Chapter 371. Changes to the requirements will address conforming to the *Style Guide,* changes that have taken place in the regulated industry, and regulatory reduction where possible.

Non-Regulatory Actions Taken by the Commissioner on Behalf of the Board since the September 14, 2023 Board Meeting while the Board was not in Session:

None

Periodic Review of Regulations

The process for conducting periodic reviews of regulations is governed by the Virginia Administrative Process Act and Executive Order.

All regulations are to be reviewed every four years to determine whether they should be continued without change or be amended or repealed, consistent with the stated objectives of applicable law, to minimize the economic impact on small businesses in a manner consistent with the stated objectives of applicable law.

VDH has 22 periodic reviews in progress:

12 VAC 5-67††	Advance Health Care Directive Registry
12 VAC 5-90†	Regulations for Disease Reporting and Control
12 VAC 5-105†	Rabies Regulations
12 VAC 5-115†	Virginia Immunization Information System Regulations
12 VAC 5-125*	Regulations for Bedding and Upholstered Furniture Inspection Program
12 VAC 5-215††	Rules and Regulations Governing Health Data Reporting
12 VAC 5-216††	Methodology to Measure Efficiency and Productivity of Health Care Institutions
12 VAC 5-217††	Regulations of the Patient Level Data System
12 VAC 5-220†	Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations
12 VAC 5-221†	Virginia's Rules and Regulations Governing Cooperative Agreements
12 VAC 5-371**	Regulations for the Licensure of Nursing Facilities
12 VAC 5-381**	Home Care Organization Regulations
12 VAC 5-405†	Rules Governing Private Review Agents

12 VAC 5-407[††]	Regulations for the Submission of Health Maintenance Organization Quality of Care Performance Information
12 VAC 5-507[†]	Guidelines for General Assembly Nursing Scholarships and Loan Repayment Program Requiring Service in a Long-Term-Care Facility
12 VAC 5-520[*]	Regulations Governing the State Dental Scholarship Program
12 VAC 5-545[†]	Guidelines for the Nurse Educator Scholarship
12 VAC 5-590[*]	Waterworks Regulations
12 VAC 5-613[††]	Regulations for Alternative Onsite Sewage Systems
12 VAC 5-620[†]	Regulations Governing Application Fees for Construction Permits for Onsite Sewage Disposal Systems and Private Wells
12 VAC 5-640[††]	Alternative Discharging Sewage Treatment Regulations for Individual Single Family Dwellings
12 VAC 5-650[††]	Schedule of Civil Penalties

[†]The Results of Periodic Review for 14 chapters are due to the Regulatory Coordinator before the December Board Meeting.
[††] The Results of Periodic Review for 8 chapters have been submitted and are under OCOM review.
[*]The Result of Periodic Review will be concluded after the current regulatory actions amending these chapters are effective.
[**]The Notice of Periodic Review for this chapter was issued with a Notice of Intended Regulatory Action. The result will be included in the Proposed stage.

Executive Branch Review Activity Completed since the September 14, 2023 Board Meeting:

The Office of the Attorney General certified:

- Proposed Regulations for the Certification of Community Health Workers (12VAC5-402)
- Final Exempt Action for the Regulation for the Certificate of Quality Assurance of Managed Care Health Insurance Plan (MCHIP) Licensees (12VAC5-408)

The Department of Planning and Budget completed the review of:

- NOIRA for the Certified Nursing Facility Staffing Standards Regulation (12VAC5-375)
- NOIRA for the Managed Care Health Insurance Plan Quality Assurance Regulation (12VAC5-409)

The Office of Regulatory Management and the Governor's Office completed the review of:

- Proposed Rainwater Harvesting Systems Regulations (12VAC5-635)
- Final Exempt Action for the Regulation for the Certificate of Quality Assurance of Managed Care Health Insurance Plan (MCHIP) Licensees (12VAC5-408)

PUBLIC COMMENT

Public Comment Period

- There is a two minute time limit for each person to speak.
- We will be calling from the list in the room.
- After the 2 minute public comment limit is reached we will let you complete the sentence and move on to the next attendee.
- We will call the name of the person on list and also the name of the person is next on the list.

We will return at…

BREAK

LUNCH PRESENTATION: WORKFORCE INCENTIVE PROGRAMS

Regulations Governing the Dental Scholarship and Loan Repayment Program
12VAC5-520
Final Amendments

Sandra Serna

Director

Office of Health Equity

COMMONWEALTH of VIRGINIA
Department of Health
Karen Shelton, MD
State Health Commissioner
P O BOX 2448
RICHMOND, VA 23218
TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: October 18, 2023

TO: Virginia State Board of Health

FROM: Sandra Serna, Director - Office of Health Equity

SUBJECT: Final Amendments – Amend Regulations Governing the Dental Scholarship and Loan Repayment Program (12VAC5-520) Following Periodic Review

---

Enclosed for your review and approval are Final Amendments to the Regulations Governing the Dental Scholarship and Loan Repayment Program (12VAC5-520). The Virginia Department of Health (VDH) conducted a periodic review of 12VAC5-520. As a result of the review, VDH determined it was necessary to use the regulatory process to amend these regulations, as the regulatory chapter has not been comprehensively revised in over a decade.

This regulatory action is necessary to amend the regulations so that 12VAC5-520 aligns with the regulations governing the other scholarship and loan repayment programs administered by VDH. The amendments include corrections to the definitions of terms utilized within the regulatory chapter; changes to make the regulatory chapter easier to read; formatting changes to make the regulatory chapter conform to other similar programs; and correcting or inserting language regarding 1) how to apply to the program and 2) the penalty to be paid in the event a recipient defaults after graduation.

If approved by the Board, it will be submitted for Executive Branch Review and publication in the *Register of Regulations*. Upon publication, a 30-day final adoption period will begin, after which the regulation will become effective.

townhall.virginia.gov

Final Regulation
Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-520
VAC Chapter title(s)	Regulations Governing the Dental Scholarship and Loan Repayment Programs
Action title	Amend Regulation Following Periodic Review
Date this document prepared	October 20, 2023

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Brief Summary

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

In June 2016, the Virginia Department of Health (VDH) conducted a periodic review of 12VAC5-520, Regulations Governing the Dental Scholarship and Loan Repayment Programs. As a result of the review, VDH determined it was necessary to use the regulatory process to amend these regulations as the regulatory chapter has not been comprehensively revised in over a decade.

This regulatory action is necessary to amend the regulations so that 12VAC5-520 aligns with the regulations governing the other scholarship and loan repayment programs administered by VDH. The amendments include corrections to the definitions of terms utilized within the regulatory chapter; changes to make the regulatory chapter easier to read; formatting changes to make the regulatory chapter conform to other similar programs; and correcting or inserting language regarding 1) how to apply to the program and 2) the penalty to be paid in the event a recipient defaults after graduation.

Acronyms and Definitions

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

CFR- Code of Federal Regulations
USC – United States Code
VDH- Virginia Department of Health

Statement of Final Agency Action

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

Mandate and Impetus

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.

There are no changes to previously reported information.

Legal Basis

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

The regulation is promulgated under the authority of §§ 32.1-12, 32.1-122.9 and 32.1-122.9:1 of the Code of Virginia (Code). Section 32.1-12 grants the Board of Health the legal authority "to make, adopt, promulgate, and enforce such regulations necessary to carry out the provisions of Title 32.1 of the Code."

Section 32.1-122.9 of the Code directs the Board of Health to establish an annual dental scholarship for students in good standing at Virginia Commonwealth University and to promulgate regulations to administer the scholarship program.

Section 32.1-122.9:1 of the Code directs the Board of Health to establish a dental loan repayment program for graduates of accredited dental schools who meet criteria determined by the Board.

Purpose

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

In June of 2016, VDH conducted a periodic review of 12VAC5-520, "Regulations Governing the Dental Scholarship and Loan Repayment Programs." As a result of the review, VDH determined it was necessary to use the regulatory process to amend these regulations, as the regulatory chapter has not been comprehensively revised in over a decade.

This regulatory action is necessary to amend the regulations so that 12VAC5-520 aligns with the regulations governing the other scholarship and loan repayment programs administered by VDH. The regulatory action is essential to protect the health, safety and welfare of citizens as 12VAC5-520 is currently out of date and is not consistent with the regulations governing other workforce incentive programs. This proposed regulatory action updates the regulatory chapter and encourages the use of the scholarship and loan repayment programs, potentially leading to more dentists practicing within underserved areas within the Commonwealth of Virginia.

Substance

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

Definitions:
Add the definitions of "Dental student", "Dentistry", "Department", and "Recipient";
Remove the definitions of "Practice of general or specialty dentistry" and "Scholarship recipient";
Update the definitions of "Dental practice", "Dental underserved area", "Dentistry", "Designated state facility", "Full-time dental practice", "Loan repayment award", "Restitution" and "Scholarship award"; and "Interest".

Administration of program: Repeal an unnecessary section.

Population and dentist data: Update the CFR reference to proper section.

Eligibility for scholarships and repayment awards: Rename the section. Update the format of the section so that it resembles other similar regulatory chapters.

Scholarship and loan repayment award: Repeal an unnecessary section.

Number of applications per student, amount of scholarships, and selection criteria: Rename the section. Minor technical amendments.

How to apply: Addition of a new section that is present in similar regulatory programs.

Conditions of scholarships and contractual practice obligation: Rename the section. Update the format of the section to resemble other similar regulatory chapters. Technical amendments. Specify that obligated service must begin within 180 days of graduation rather than 90 days so that the timeframe is identical to other similar regulatory chapters. Add the requirement that recipients may only take a total of four weeks of leave for personal reasons without written permission from the commissioner. This is a requirement that is present in other similar regulatory chapters. Movement of information regarding repayment to a new section.

Special requests for approval: Minor technical amendments.

Breach of contract: Rename the section and update the format of the section so that it resembles other similar regulatory chapters.

Deferment and waivers: Addition of new section, which consists of some language from the previous "Default" section (now "Breach of contract" section). Update the format of the section so that it resembles other similar regulatory chapters.

Repayment: Restructure to clarify repayment requirements pursuant to the Code. Addition of the requirement that a scholarship recipient shall pay a penalty in the event of default after graduation, which reflects subsection F of § 32.1-122.9 of the Code.

Fulfillment after default payments: Addition of a new section.

Reporting requirements: Minor technical amendments. Update the format of the section so that it resembles other similar regulatory chapters.

General style and format changes were also made throughout for consistency, clarity, and to conform to the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Issues

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

The primary advantage of the proposed regulatory action to the public is a potential increase in the availability of dentists in underserved areas, should this program be funded. Additionally, these underserved areas will be better positioned to retain qualified dentists due to the obligation created by accepting the scholarship or loan repayment funds. VDH does not foresee any disadvantages to the public, the agency or the Commonwealth associated with the proposed regulatory action.

Requirements More Restrictive than Federal

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 are no applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

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.

No other state agencies will be particularly affected by the proposed regulation.

No locality will be particularly affected by the proposed regulation.

No other entity will be particularly affected by the proposed regulation.

Public Comment

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

No public comments were received during the public comment period following the publication of the Proposed Stage.

Detail of Changes Made Since the Previous Stage

*List all changes made to the text since the previous stage was published in the Virginia Register of Regulations and the rationale for the changes. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Put an asterisk next to any substantive changes.*

Current chapter-section number	New chapter-section number, if applicable	New requirement from previous stage	Updated new requirement since previous stage	Change, intent, rationale, and likely impact of updated requirements
-10		"Dentistry" definition	"Restitution" definition	**Change:** Added the definition of Dentistry to conform with the definition in § 54.1-2700 of the Code of Virginia. This replaces the definition of "practice of general or specialty dentistry". The definition of "restitution" was updated to clarify that it is three times the award amount, not two times. Three times is the

				language in the currently effective regulation. **Intent:** To provide clarity and uniformity and to conform to the Code of Virginia. **Rationale:** By providing uniform definitions, ambiguity and confusion can be avoided. Having a definition for "dental practice" which is specific to this program and a definition for "practice of general or specialty dentistry" which is more general may have contributed to confusion of terminology. Subsection F of § 32.1-122.9 clarifies the restitution amount as three times the amount of funds received by the recipient, plus interest. The change to the restitution amount was on the advice of legal counsel. **Likely Impact:** Greater clarity of the regulations and compliance with the Code of Virginia.
-150		Remove duplicative language.		**Change:** Remove sentence on giving preference for loan awards to graduates of VCU School of Dentistry. **Intent:** Remove duplicative language. **Rationale:** The provision is already present in the new subsection F of Section 130. **Likely Impact:** Greater clarity of the regulations. Reduction of unnecessary duplication.
-160		Removed duplicative language. Reworded "dental course of [VCU]" to "[VCU] School of Dentistry".		**Change:** Remove sentence on engaging in full time dental practice from subsection B. Reworded "dental course of Virginia Commonwealth University" to "Virginia Commonwealth University School of Dentistry". **Intent:** Remove duplicative language and use more clearly identifiable language.

				Rationale: The provision is already present earlier in the same subsection, but had not been removed. “VCU School of Dentistry” is a more immediately understandable reference to the intended academic program than the term “dental course” **Likely Impact:** Greater clarity of the regulations. Reduction of unnecessary duplication.
-160 & -210			Relocated a requirement from Section 210 to Section 160.	**Change:** Moved language requiring approval to change one’s practice location from section 210 to section 160. **Intent:** Co-locate similar requirements. **Rationale:** The requirement is more consistent with those found in -160 than those in -210. **Likely Impact:** Better clarity of the regulations.
-190			Clarified requirement to maintain satisfactory scholastic standing.	**Change:** Added the provision that failure to maintain satisfactory scholastic standing also constitutes breach of contract. **Intent:** Clarify existing requirement. **Rationale:** The provision was present in subdivision A 2 of the current language but had been incidentally missed in the writing of the new language. **Likely Impact:** Better clarity of the requirements.
-195			Changed “board” to “commissioner”.	**Change:** Changed the party acting on deferment, variance, and waiver requests from the board to the commissioner. **Intent:** Clarify the process. **Rationale:** In the Code, and elsewhere in the regulation, it is the commissioner who is acting on these requests. This

				recommendation came from legal counsel. **Likely Impact:** Better clarity of the regulations.
-200			Re-structure to clarify repayment requirements.	**Change:** Restructured the section to align more closely with subsections C through G of § 32.1-122.9 of the Code of Virginia. **Intent:** Clarify the amount of repayment owed depending on the recipient's situation. **Rationale:** The language in the Proposed stage may have contributed to confusion on the repayment amounts owed pursuant to the Code. **Likely Impact:** Better clarity of the regulations.
Everywhere			Style & Form	**Change:** Numerous stylistic and formatting updates throughout the regulation. **Intent:** To provide clarity and uniformity in the regulation to enhance readability and ease the regulatory burden on members of the public. **Rationale:** The rationale is that proper style and format, grammatical correctness, and consistency of language are required to conform to the journalistic style of the Virginia Register of Regulations. Removing unnecessary language inapplicable to regulants contributes to a reduction in regulatory requirements in accordance with Executive Order 19 (2022). **Likely Impact:** The likely impact is a properly formatted and easily readable regulation.

Detail of All Changes Proposed in this Regulatory Action

*List all changes proposed in this action and the rationale for the changes. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Put an asterisk next to any substantive changes.*

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of updated requirements
10		This section provides definitions for technical terms utilized throughout the regulatory chapter.	**Change:** Updating the definition of "Dental practice", "Dental underserved area", "Designated state facility" "Full-time dental practice", "Loan repayment award", "Restitution" and "Scholarship award"; updating the definition of "Interest" to conform to the statutory interest rate pursuant to § 6.2-302 of the Code; adding a definition of the terms "Dental student", "Department" and "Recipient"; and removing the definition of and "Scholarship recipient". Added the definition of Dentistry to conform with the definition in § 54.1-2700 of the Code of Virginia. This replaces the definition of "practice of general or specialty dentistry". Additionally, the definition of "loan repayment award" has been updated to replace "current in-state tuition and mandatory fees at Virginia Commonwealth University School of Dentistry" to "one academic year of in-state tuiton and mandatory fees at the recipient's accredited dental school at the time the recipient was enrolled in the dental school". **Intent:** The intent is to provide greater clarity of the regulations. The reference to VCU's tuition and fees is removed from the "loan repayment award" definition because loan repayment award recipients may come from other accredited dental schools, so their award amount should reflect the actual amount of loans they owe on dental school tuition and fees.

			Rationale The rationale is that proper style and format, grammatical correctness, and consistency of language are required to conform to the journalistic style of the Virginia Register of Regulations. Updating the definition of "loan repayment award" clarifies that students who attended a dental school other than VCU may still qualify for loan repayment, and it provides that the loan shall be equal to the tuition and fees paid by the recipient, not tuition and fees at the current rate at VCU. **Likely Impact:** The likely impact is greater clarity of the regulation and more consistent, logical application of the requirements once the program is funded.
20		This section states that the State Health Commissioner shall administer the regulatory chapter.	**Change:** Repealing this unnecessary section. **Intent:** Less burdensome regulations. **Rationale:** Removing unnecessary language inapplicable to regulants contributes to a reduction in regulatory requirements in accordance with Executive Order 19 (2022). **Likely Impact:** The likely impact is a properly formatted and easily readable regulation.
80		This section explains how dental underserved areas are calculated.	**Change:** Technical correction to the CFR reference within the regulations. **Intent:** The previous citation referenced the incorrect section. **Rationale:** The rationale is that by clearly explaining how dental underserved areas are calculated, the regulation can be better interpreted. **Likely Impact:** The likely impact is greater clarity of the regulation.
130		This section lays out the requirements for an individual to be an eligible applicant of the dental scholarship program and the dental loan repayment program.	**Change:** Renaming the section to "Eligibility for scholarships and loan repayment awards." Clarifying the maximum number of scholarship and loan repayment awards. Updating the format of the section to resemble other similar regulatory chapters.

			Intent: Greater clarity of the regulations; Less burdensome regulations as similar regulatory chapters shall be governed the same. **Rationale:** By renaming the section with a more accurate title, the information is more accessible and clearly presented to the reader. **Likely Impact:** The likely impact is greater clarity of the regulation.
140		This section states that any individual awarded a scholarship or loan repayment shall enter into a contract with the commissioner.	**Change:** Repealing this unnecessary section. **Intent:** Less burdensome regulations. **Rationale:** The rationale is that proper style, format, and construction are required to conform to the journalistic style of the *Virginia Register of Regulations*. Removing unnecessary language inapplicable to regulants contributes to a reduction in regulatory requirements in accordance with Executive Order 19 (2022). **Likely Impact:** The likely impact is a properly formatted and easily readable regulation.
150		This section discusses the establishment of the appropriation for the program along with how the awards shall be distributed.	**Change:** Renaming the section to "Scholarships and loan repayment awards details and selection criteria." Minor technical amendments. **Intent:** Greater clarity of the regulations. **Rationale:** By renaming the section with a more accurate title, the information is more accessible and clearly presented to the reader. **Likely Impact:** The likely impact is greater clarity of the regulation.
	155	This section discusses how applicants to the scholarship and loan repayment programs may apply.	**Change:** Inserting a new section. This section occurs in other similar regulatory chapters. **Intent:** Greater clarity of the regulations. **Rationale:** The rationale is that proper style and format, grammatical correctness, and consistency of

			language are required to conform to the journalistic style of the Virginia Register of Regulations. Removing unnecessary language inapplicable to regulants contributes to a reduction in regulatory requirements in accordance with Executive Order 19 (2022). **Likely Impact:** The likely impact is greater clarity of the regulation.
160		This section provides the requirements of the contract that a scholarship or loan repayment recipient must enter into with the commissioner.	**Change:** Renaming the section to "Conditions of scholarships, loan repayment awards and contractual practice obligation." Updating the formatting of the section to resemble other similar regulatory chapters. Specifying that obligated service must begin within 180 days of graduation rather than 90 days so that the timeframe is identical to other similar regulatory chapters. Adding the requirement that recipients may only take a total of four weeks of leave for personal reasons without written permission from the commissioner. This is a requirement that is present in other similar regulatory chapters. Moving information regarding repayment to a new section. Technical amendments for style and those discussed in the table "Detail of Changes Made Since the Previous Stage." **Intent:** Provide consistency and clarity throughout sections in the VAC. **Rationale:** By renaming the section with a more accurate title, the information is more accessible and clearly presented to the reader. **Likely Impact:** Greater clarity of the regulations.
170		This section lays out the requirements for a recipient to practice in an area that does not qualify as a dental underserved area.	**Change:** Minor technical amendment. **Intent:** Greater clarity of the regulations. **Rationale:** The rationale is that greater clarity of the regulations can be achieved by correcting technical deficiencies in existing text.

			Likely Impact: Greater clarity of the regulations.
190		This section describes circumstances under which a recipient will be in breach of contract and will be required to forfeit the monetary award and repay the money to the Commonwealth of Virginia.	**Change:** Renaming the section to "Breach of contract." Formatting the section to resemble other similar regulatory programs. Separating the section into what constitutes a breach for scholarship recipients and what constitutes a breach for loan repayment award recipients. Removing certain language that shall be moved to a new section. Technical amendments for style and those discussed in the table "Detail of Changes Made Since the Previous Stage." **Intent:** Greater clarity of the regulations. Ease of reading for members of the public. **Rationale:** By renaming the section with a more accurate title, the information is more accessible and clearly presented to the reader. **Likely Impact:** Greater clarity of the regulations.
	195		**Change:** Inserting a new section that relates to when a scholarship or loan repayment recipient may receive a deferment, waiver or variance of obligation. **Intent:** More comprehensive regulations; greater clarity of the regulations; ease of reading the regulations for members of the public. **Rationale:** The rationale is that by restructuring existing language in the regulations greater clarity and ease of reading can be achieved. **Likely Impact:** Greater clarity of the regulations.
200		This section lays out the terms of repayment once a recipient defaults.	**Change:** Reformatted the explanation circumstances in which repayment or restitution may be owed. Addition of the requirement that a scholarship recipient shall pay a penalty in the event of default after graduation, which reflects subsection F of § 32.1-122.9 of the Code.

			Intent: Provide consistency throughout sections in the regulation. **Rationale:** By conforming to the language and structure in similar regulations, more uniformity and clarity can be achieved. **Likely Impact:** Greater clarity of the regulations. Compliance with the Code of Virginia.
	205	This section presents what occurs if a participant or recipient fulfills their obligation after a breach of contract.	**Change:** Inserting a new section that describes fulfillment of service obligation following a breach of contract. **Intent:** More comprehensive regulations; greater clarity of the regulations; ease of reading the regulations for members of the public. **Rationale:** The rationale is that by restructuring existing language in the regulations greater clarity and ease of reading can be achieved. **Likely Impact:** Greater clarity of the regulations.
210		This section lays out the reporting requirements of the Virginia Commonwealth University School of Dentistry regarding those students who receive the scholarship. The section also lays out the reporting requirements of scholarship and loan repayment recipients.	**Change:** Formatting changes to make the section resemble similar sections in other similar regulatory chapters. Minor technical changes. **Intent:** Greater clarity of the regulations. Less burdensome regulations as similar regulatory chapters shall be governed the same. **Rationale:** The rationale is that proper style and format, grammatical correctness, and consistency of language are required to conform to the journalistic style of the Virginia Register of Regulations. Removing unnecessary language inapplicable to regulants contributes to a reduction in regulatory requirements in accordance with Executive Order 19 (2022). **Likely Impact:** Greater clarity of the regulations.
Throughout the chapter		Style & Form.	**Change:** Numerous stylistic and formatting updates throughout the regulation.

			Intent: To provide clarity and uniformity in the regulation to enhance readability and ease the regulatory burden on members of the public. **Rationale:** The rationale is that proper style and format, grammatical correctness, and consistency of language are required to conform to the journalistic style of the Virginia Register of Regulations. Removing unnecessary language inapplicable to regulants contributes to a reduction in regulatory requirements in accordance with Executive Order 19 (2022). **Likely Impact:** The likely impact is a properly formatted and easily readable regulation.

Office of Regulatory Management

Economic Review Form

Agency name	Virginia Department of Health, Office of Health Equity
Virginia Administrative Code (VAC) Chapter citation(s)	12-VAC5-520
VAC Chapter title(s)	Regulations Governing the Dental Scholarship Program and Loan Repayment Programs
Action title	2023 Final Review of the Regulations Governing Dental Scholarship Program and Loan Repayment Programs
Date this document prepared	10/17/2023
Regulatory Stage (including Issuance of Guidance Documents)	Final Regulation

Cost Benefit Analysis

Complete Tables 1a and 1b for all regulatory actions. You do not need to complete Table 1c if the regulatory action is required by state statute or federal statute or regulation and leaves no discretion in its implementation.

Table 1a should provide analysis for the regulatory approach you are taking. Table 1b should provide analysis for the approach of leaving the current regulations intact (i.e., no further change is implemented). Table 1c should provide analysis for at least one alternative approach. You should not limit yourself to one alternative, however, and can add additional charts as needed.

Report both direct and indirect costs and benefits that can be monetized in Boxes 1 and 2. Report direct and indirect costs and benefits that cannot be monetized in Box 4. See the ORM Regulatory Economic Analysis Manual for additional guidance.

Table 1a: Costs and Benefits of the Proposed Changes (Primary Option)

<table>
<tr><td>(1) Direct & Indirect Costs & Benefits (Monetized)</td><td colspan="2">Direct Costs:
VDH has not identified any monetized direct costs as a result of this action. This amendment seeks to update existing regulatory language to better conform with similar programs and provide greater clarity of the regulation.

Additionally, pursuant to §§ 32.1-122.9 and 32.1-122.9:1, the Dental Scholarship Program and Loan Repayment Programs are subject to specific appropriation of funds by the Virginia General Assembly. This program is not funded in the 2022-2024 Biennium.

Indirect Costs:
There are no monetized indirect costs identified by this final review.

Direct Benefits:
There are no monetized direct benefits identified by this final review.

Indirect Benefits: There are no monetized indirect benefits identified by this final review.</td></tr>
<tr><td>(2) Present Monetized Values</td><td>Direct & Indirect Costs</td><td>Direct & Indirect Benefits</td></tr>
<tr><td></td><td>(a) $0</td><td>(b) $0</td></tr>
<tr><td>(3) Net Monetized Benefit</td><td colspan="2">$0</td></tr>
<tr><td>(4) Other Costs & Benefits (Non-Monetized)</td><td colspan="2">There are no non-monetized costs for any of the proposed changes. VDH anticipates a future public health benefit to the Commonwealth at such time the program is funded by clarifying, updating, and streamlining existing regulatory language as listed below:

• (12VAC5-520-10) Updating the definition of “Dental practice”, “Dental underserved area”, “Designated state facility” “Full-time dental practice”, “Loan repayment award”, “Restitution” and “Scholarship award”; updating and simplifying the definition of “Interest” to conform to the Code; adding a definition of the terms “Dental student”, “Department” and “Recipient”; and removing the definition of and “Scholarship recipient”.
Benefit: Increases the clarity of terms frequently used in the regulation and aligns the use of the terms more closely with the Code of Virginia.

• (12VAC5-520-20) Repealing unnecessary section stating that the State Health Commissioner shall administer this regulation.</td></tr>
</table>

	Benefit: Removal of unnecessary language lessens regulatory burden. • **(12VAC5-520-80) Updating the CFR reference within the regulation, which was previously cited incorrectly** Benefit: Greater regulatory clarity. • **(12VAC5-520-130) Renaming the section to "Eligibility for scholarships and loan repayment awards." Clarifying the maximum number of scholarship and loan repayment awards. Updating the format of the section to resemble other similar regulatory chapters.** Benefit: Greater clarity of the regulations; Less burdensome regulations as similar regulatory chapters shall be governed the same. • **(12VAC5-520-140) Repealing unnecessary section providing duplicative information.** Benefit: Less burdensome regulations. • **(12VAC5-520-150) Renaming section to "Scholarships and loan repayment awards details and selection criteria." Minor technical amendments.** Benefit: Greater clarity of the regulations. • **(12VAC5-520-155) Inserting a section outlining application process.** Benefit: The application process is more clearly outlined and is in line with other similar regulatory programs. This gives greater clarity of the regulations. • **(12VAC5-520-160) Renaming section to "Conditions of scholarships, loan repayment awards and contractual practice obligation." Updating the formatting of the section to resemble other similar regulatory chapters. Specifying that obligated service must begin within 180 days of graduation rather than 90 days so that the timeframe is identical to other similar regulatory chapters. Remove requirement for a 30-day notice of the intent to comply with 90-day deadline. Adding the requirement that recipients may only take a total of four weeks of leave for personal reasons without written permission from the commissioner. This is a requirement that is present in other similar regulatory chapters. Moving information regarding repayment to a new section. Minor technical amendments.** Benefit: Regulants now have double the amount of time within which they must begin their service, making the program, once

	funded, easier to comply with and potentially more attractive to applicants, which in turn will increase the effectiveness of the program's goals of addressing communities in need of dental care. Greater clarity of the regulation and reduction in recipient burden. • **(12VAC5-520-170) Minor technical amendment.** Benefit: Greater clarity of the regulations • **(12VAC5-520-190) Renaming the section to "Breach of contract." Formatting the section to resemble other similar regulatory programs. Separating the section into what constitutes a breach for scholarship recipients and what constitutes a breach for loan repayment award recipients. Removing certain language that shall be moved to a new section.** Benefit: Greater clarity of the regulations. Ease of reading for members of the public • **(12VAC5-520-195) Inserting a new section that relates to when a scholarship or loan repayment recipient may receive a deferment, waiver or variance of obligation.** Benefit: More comprehensive regulations; greater clarity of the regulations; ease of reading the regulations for members of the public. • **(12VAC5-520-200) Updating regulatory language to better explain circumstances for repayment in the event that a scholarship award recipient or loan repayment recipient fail to meet necessary requirements.** Benefit: More comprehensive regulations that reduce opportunity for confusion and align more closely with the Code of Virginia. • **(12VAC5-520-205) Inserting a new section that describes fulfillment of service obligation following a breach of contract.** Benefit: More comprehensive regulations that clarify the ability to fulfill contractual obligations after having been in breach of the contract, in order to receive the award funds that had been reimbursed to the Commonwealth. This clarity may make the program more attractive to potential future applicants and to staff administering the program. • **(12VAC5-520-210) Formatting changes to make the section resemble similar sections in other similar regulatory chapters. Minor technical changes.**

	Benefit: Greater clarity of the regulations. Less burdensome regulations as similar regulatory chapters shall be governed the same.
(5) Information Sources	Virginia Department of Health Office of Health Equity

Table 1b: Costs and Benefits under the Status Quo (No change to the regulation)

(1) Direct & Indirect Costs & Benefits (Monetized)	There are no monetized direct or indirect costs with maintaining the status quo regarding this regulation. There are no monetized direct or indirect benefits with maintaining the status quo regarding this regulation.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $0
(3) Net Monetized Benefit	$0	
(4) Other Costs & Benefits (Non-Monetized)	**Costs:** Maintaining the current regulation as written may cause confusion to readers or potential applicants. Once funded, having clear regulations in the best posture possible will ensure the program is run effectively, efficiently, and in compliance with the Code. Not making the change to Section -160, (allowing 180 days to begin service obligation after graduation vs. 90 plus a 30-day notice) would make the program more burdensome, less consistent with other workforce incentive programs, and potentially less attractive to potential applicants. **Benefits:** There are no other non-monetized benefits identified by this final review.	
(5) Information Sources		

Table 1c: Costs and Benefits under Alternative Approach(es)

(1) Direct & Indirect Costs &	There are no monetized direct costs under Alternative Approaches identified by this final review.

Benefits (Monetized)	There are no monetized indirect costs under Alternative Approaches identified by this final review. There are no monetized direct benefits under Alternative Approaches identified by this final review. There are no monetized indirect benefits under Alternative Approaches identified by this final review.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $0
10-	$0	
(4) Other Costs & Benefits (Non-Monetized)	There are no non-monetized direct costs under Alternative Approaches identified by this final review. There are no non-monetized indirect costs under Alternative Approaches identified by this final review. There are no non-monetized direct benefits under Alternative Approaches identified by this final review. There are no non-monetized indirect benefits under Alternative Approaches identified by this final review.	
(5) Information Sources	Virginia Department of Health Office of Health Equity	

Impact on Local Partners

Use this chart to describe impacts on local partners. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

Table 2: Impact on Local Partners

(1) Direct & Indirect Costs & Benefits (Monetized)	There are no monetized direct or indirect costs or benefits to local partners identified by this final review.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $0

(3) Other Costs & Benefits (Non-Monetized)	**Other Costs**: There are no non-monetized costs to local partners identified by this final review. **Other Benefits**: Update to the regulations will help make the regulations clearer for the regulants.
(4) Assistance	None
(5) Information Sources	

Impacts on Families

Use this chart to describe impacts on families. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

Table 3: Impact on Families

(1) Direct & Indirect Costs & Benefits (Monetized)	There are no monetized, direct or indirect costs or benefits particular to families, other than those already identified in Tables 1a-1c.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $0
(3) Other Costs & Benefits (Non-Monetized)	**Other Costs**: There are no non-monetized costs to families identified by this final review. **Other Benefits**: Amending the regulations will help make the regulations clearer for the regulants and Virginia families.	
(4) Information Sources	None	

Impacts on Small Businesses

Use this chart to describe impacts on small businesses. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

Table 4: Impact on Small Businesses

(1) Direct & Indirect Costs & Benefits (Monetized)	There are no monetized, direct or indirect costs especially borne by small businesses identified by this final review. It's possible that once funded, the program may provide a distinct benefit for dental clinics that are small businesses in dental underserved areas, which may see an improvement in recruitment/retention.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $0
(3) Other Costs & Benefits (Non-Monetized)	**Other Costs:** There are no non-monetary costs to small businesses identified by this final review. **Other Benefits:** Amending the regulations will help make the regulations clearer for the regulants and small businesses.	
(4) Alternatives	The regulation does not pose a burden to small businesses and is worded clearly and structured to be as least burdensome as possible while accomplishing the goals of the program, so no regulatory alternative would otherwise benefit small businesses more.	
(5) Information Sources	None	

Changes to Number of Regulatory Requirements

Table 5: Regulatory Reduction

For each individual action, please fill out the appropriate chart to reflect any change in regulatory requirements, costs, regulatory stringency, or the overall length of any guidance documents.

Change in Regulatory Requirements

VAC Section(s) Involved*	Authority of Change	Initial Count	Additions	Subtractions	Net Change
12VAC5-520-10	**Statutory:**	**0**			0
	Discretionary:	**0**			0
12VAC5-520-20	**Statutory:**	**1 (G/S)**		1 (G/S)	-1
	Discretionary:	**1 (G/D)**		1 (G/D)	-1
12VAC5-520-80	**Statutory:**	**4 (G/S)**			0
	Discretionary:	**0**			0
12VAC5-520-130	**Statutory:**	**5 (9/S)**	1 (R/S)		+1
	Discretionary:	**1 (R/D)**	1 (R/D)		+1
	Statutory:	**1 (R/S)**		1 (R/S)	+1

12VAC5-520-140	**Discretionary:**	**0**			0
12VAC5-520-150	**Statutory:**	**2 (R/S)**			0
	Discretionary:	**0**			0
12VAC5-520-155	**Statutory:**	**0**			0
	Discretionary:	**0**	1 (G/D) 1 (R/D)		+2
12VAC5-520-160	**Statutory:**	**1 (G/S)** **8 (R/S)**			0
	Discretionary:	**2 (R/D)**	1 (R/D)	-1 (R/D)	0
12VAC5-520-170	**Statutory:**	**1 (R/S)**			0
	Discretionary:	**1 (G/D)** **1 (R/D)**			0
12VAC5-520-190	**Statutory:**	**8 (R/S)**	1 (R/S)	3 (R/S) moved to 200	-2
	Discretionary:	**0**			
12VAC5-520-195	**Statutory:**	**0**	4 (G/S) 1 (R/S)		+5
	Discretionary:	**0**			0
12VAC5-520-200	**Statutory:**	**1 (G/S)** **3 (R/S)**	3 (R/S) moved from 190		+3
	Discretionary:	**1 (G/D)**			0
12VAC5-520-205	**Statutory:**	**0**	1 (G/S) 2 (R/S)		+3
	Discretionary:	**0**			0
12VAC5-520-210	**Statutory:**	**5 (R/S)**	+2 (R/S)		+2
	Discretionary:	**0**			0
				Total Net Change of Statutory Requirements:	**+11**
				Total Net Change of Discretionary Requirements:	**+2**

Other Decreases or Increases in Regulatory Stringency (if applicable)

VAC Section(s) Involved*	**Description of Regulatory Change**	**Overview of How It Reduces or Increases Regulatory Burden**
12VAC5-520-130 and -155	Addition of language regarding the application process,	Clarification of the process improves enforcement for both regulants and VDH staff. The

	including a requirement to apply online.	requirement to apply online is consistent with other workforce incentive programs and having one application process will help with administration, at such time the program is funded.
12VAC5-520-160	Currently, a scholarship recipient must notify VDH in writing within 30 days of graduation from dental school or residency of the intent to begin the practice obligation within 90 days of that graduation. Now, the recipient must sent the notice of intent to begin practice within 180 days of graduation. Also adds the requirement to request written permission for absence from employment for over four weeks in one year and a penalty for an unapproved absence being reduction of the period of credit toward fulfilment of the practice obligation.	It gives scholarship recipients more time to submit the notice and to begin the practice. While regulants would be required to submit a request not directly required before, the ability to hold recipients accountable to their contractual obligations is a must, and extended absences that result in not fulfilling the practice obligation must be documented and handled according to a clear process.
12VAC5-520-190	Addition of language regarding breach of contract for termination of employment. The language clarifies requirements to transfer to another site within 180 days of termination.	Because the employment is mandatory for compliance with the contractual and regulatory obligations, a dentist who is terminated for cause would be unable to fulfill the obligation without transferring to another site, so a clear process in the regulation makes enforcement more efficient for regulants and VDH staff.
12VAC5-520-195	Addition of language and process related to deferment, waivers, and variances.	It makes the regulation clearer, and allows for a transparent process to ask for and receive reasonable exceptions to requirements in cases of inability to comply due to hardship.

Length of Guidance Documents (only applicable if guidance document is being revised)

Title of Guidance Document	**Original Length**	**New Length**	**Net Change in Length**

*If the agency is modifying a guidance document that has regulatory requirements, it should report any change in requirements in the appropriate chart(s).

Project 4924 - Final

Department of Health

Chp 520- Amend Regulation Following Periodic Review

12VAC5-520-10. Definitions.

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

"Accredited dental school" means any dental school in the United States receiving accreditation from the Commission on Dental Accreditation.

"Accredited residency" means an advanced dental education program in general or specialty dentistry accredited by the Commission on Dental Accreditation and approved by the American Dental Association.

"Board" or "Board of Health" means the State Board of Health.

"Commissioner" means the State Health Commissioner.

"Dental practice" means the practice of dentistry by a recipient in general or specialty dentistry in a ~~geographic area determined~~ location within Virginia that is designated as a dental underserved area to [~~be fulfillment of~~ fulfill] the recipient's scholarship or loan repayment obligation ~~or practice as a dentist within a designated state facility~~.

"Dental student" means an individual who is studying the practice of general or specialty dentistry.

"Dental underserved area" means (i) a geographic area in Virginia designated by the State Board of Health as a county or city in which the ratio of practitioners of dentistry to population is less than that for the Commonwealth as a whole ~~as determined by the commissioner or~~; (ii) a dental health ~~professions~~ professional shortage area using criteria described in Part II (12VAC5-520-80 et seq.) of this chapter; or (iii) a designated state facility.

"Dentist loan repayment program" means the program established by § 32.1-122.9:1 of the Code of Virginia that allocates funds appropriated in conjunction with the dental scholarship program to increase the number of dentists in underserved areas of Virginia.

["Dentistry" means the evaluation, diagnosis, prevention, and treatment through surgical, nonsurgical, or related procedures, of diseases, disorders, and conditions of the oral cavity and the maxillofacial, adjacent, and associated structures and their impact on the human body.]

"Department" means [the] Virginia Department of Health.

"Designated state facility" means [~~practice as a dentist in~~] a facility operated by the ~~Virginia Department of Health,~~ Virginia Department of Behavioral Health and Developmental Services, Virginia Department of Juvenile Justice, or the Virginia Department of Corrections.

"Full-time dental practice" means the practice of dentistry for an average of a minimum of 32 hours per week for 48 weeks per year excluding those exceptions enumerated in Part III (12VAC5-520-160 et seq.) of this chapter.

"Interest ~~at the prevailing bank rate for similar amounts of unsecured debt~~" means ~~the prime lending rate plus 2.0% as published in the Wall Street Journal on the first day of the month in which the decision to repay is communicated to the commissioner by the recipient or on the first day of the month that the commissioner determines the recipient to be in default~~ the legal rate of interest pursuant to § 6.2-302 of the Code of Virginia [unless otherwise specified in this chapter] .

"Loan repayment award" means an award paid to a dentist for dental school loans in an amount equivalent to [~~the current~~ one academic year of] in-state tuition and mandatory fees at [~~Virginia Commonwealth University School of Dentistry~~ the recipient's accredited dental school at the time the recipient was enrolled in the dental school] , and for which the dentist is under a contractual obligation to repay through practice in ~~an~~ a dental underserved area ~~or designated state facility~~. This amount may be capped at the discretion of the commissioner.

[~~"Practice of general or specialty dentistry" means the evaluation, diagnosis, prevention, and treatment (nonsurgical, surgical, or related procedures) of diseases, disorders, and conditions of the oral cavity, maxillofacial, and adjacent and associated structures and their impact on the human body.~~]

"Recipient" means an eligible applicant who enters into a contract with the commissioner and participates in the scholarship or loan repayment program.

"Restitution" means [three ~~two~~] times the award amount received plus interest ~~at the prevailing bank rate for similar amounts of unsecured debt as set forth in this regulation,~~ less any service obligation completed owed to the Commonwealth of Virginia by a scholarship or loan repayment award recipient who is in [~~default of his~~ breach of the] contractual obligation as provided for in this chapter.

"Scholarship award" means an amount equivalent to one year of in-state tuition and mandatory fees at Virginia Commonwealth University School of Dentistry for the academic year a student is enrolled and for which the dental student entered a contractual obligation to repay through practice in ~~an~~ a dental underserved area or designated state facility. This amount may be capped at the discretion of the commissioner.

~~"Scholarship recipient" means an eligible dental student who enters into a contract with the commissioner and receives one or more scholarship awards from the Virginia Dental Scholarship Program.~~

"Specialty dentistry" means the advanced practice of dentistry in any specialty approved by the American Dental Association and accredited by the Commission on Dental Accreditation.

Statutory Authority

§ 32.1-122.9 of the Code of Virginia.

Historical Notes

Derived from VR355-40-03 § 1.1, eff. December 1, 1979; amended, Virginia Register Volume 18, Issue 15, eff. May 8, 2002; Volume 29, Issue 3, eff. November 8, 2012.

12VAC5-520-20. ~~Administration of program.~~ (Repealed.)

~~The State Health Commissioner, as executive officer of the Board of Health, shall administer this program. Any requests for deviation from the prescribed definitions shall be considered on an individual basis by the board in regular session.~~

~~Statutory Authority~~

~~§§ 32.1-122.9 and 32.1-122.9:1 of the Code of Virginia.~~

Historical Notes

Derived from VR355-40-03 § 1.2, eff. December 1, 1979; amended, Virginia Register Volume 18, Issue 15, eff. May 8, 2002.

12VAC5-520-80. Population and dentist data.

[~~In order to determine~~ A. Every five years, the commissioner shall calculate] the population-to-dentist ratio [~~, the commissioner shall:~~ by:]

1. [~~Use~~ Using] the population data or projections from the United States Census for independent cities, counties, and counties with independent cities within their boundaries; [and]

2. [~~Determine~~ Determining] the number of practitioners of dentistry from data secured from the Virginia State Board of Dentistry and the American Dental Association, adjusting for those dentists licensed in Virginia but practicing in other states, the military, and retired dentists with active licenses [~~;~~ .]

[~~3. Calculate this ratio every five years; and~~

~~4. Include~~ B. The commissioner shall include] as dental underserved areas those cities and counties determined to be dental health professions shortage areas as defined by the Department of Health and Human Services or designated a federal shortage area for the practice of dentistry as outlined in ~~42 CFR 5.1~~ 42 CFR 5.2.

Statutory Authority

§§ 32.1-122.9 and 32.1-122.9:1 of the Code of Virginia.

Historical Notes

Derived from VR355-40-03 § 4.1, eff. December 1, 1979; amended, Virginia Register Volume 18, Issue 15, eff. May 8, 2002.

12VAC5-520-130. ~~Eligible applicants~~ Eligibility for scholarships and loan repayment awards.

~~A. Any currently enrolled dental student in good standing and full-time attendance at Virginia Commonwealth University School of Dentistry who has not entered the first year of an accredited residency shall be eligible for the Virginia Dental Scholarship Program. Preference for the scholarship award shall be given to residents of the Commonwealth, students who are residents of a dental underserved area, and students from economically disadvantaged backgrounds.~~

~~B. Any graduate of an accredited dental school in the United States who is establishing a practice in general or specialty dentistry in an underserved area or practicing dentistry in a designated state facility shall be eligible to apply for the Virginia Dentist Loan Repayment Program. General practice dentists will be within five years of graduation from an accredited undergraduate dental program and have existing loans accumulated as a result of their undergraduate dental program. Specialty practice dentists will be within five years of completion of their specialty training and have existing loans accumulated as a result of their undergraduate dental program. Dentists who received Virginia scholarship awards or other scholarships that paid their full tuition and fees are not eligible for the Dentist Loan Repayment Program for the years they received those awards.~~

A. An applicant for the Virginia Dental Scholarship Program [~~must~~ shall] submit a completed application form and required documentation before the established deadline dates.

B. To be considered for the Virginia Dental Scholarship Program, an applicant [~~must:~~ shall:]

1. Be a United States citizen, a United States national, or a qualified alien pursuant to 8 USC § 1621;

2. Be currently enrolled, [~~in good~~ maintain a satisfactory scholastic] standing with a cumulative GPA of at least 3.0, which is verified by an appropriate grade transcript, and attend the Virginia Commonwealth University School of Dentistry;

3. Not have entered the first year of an accredited residency; and

4. Demonstrate financial need, which is verified by the school's financial aid officer or authorized person as part of the application process.

C. Preference for scholarships shall be given to:

1. Bona fide residents of Virginia as evidenced by being domiciled in the Commonwealth for at least one year as defined by § 23.1-502 of the Code of Virginia;

2. Students who are residents of a dental underserved area; and

3. Students from economically disadvantaged backgrounds.

D. An applicant for the Virginia Dentist Loan Repayment Program [~~must~~ shall] submit a completed application form and required documentation before the established deadline dates.

E. To be considered for the Virginia Dentist Loan Repayment Program, an applicant [~~must:~~ shall:]

1. Be a United States citizen, a United States national, or a qualified alien pursuant to 8 USC §1621;

2. Be a graduate of an accredited dental school in the United States;

3. Secure employment at an approved practice site in general or specialty dentistry in a dental underserved area;

4. Be a general practice dentist within five years of graduation from an accredited dental program or a specialty practice dentist within five years of completion of specialty training;

5. Have existing loans accumulated as a result of the applicant's dental program;

6. Not have received Virginia scholarship awards or other scholarships that paid the applicant's full tuition and fees; and

7. Not have received a combined maximum of four scholarships or loan repayment awards.

F. Preference for loan repayment awards shall be given to Virginia Commonwealth University School of Dentistry graduates.

Statutory Authority

§ 32.1-122.9 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 18, Issue 15, eff. May 8, 2002; amended, Virginia Register Volume 29, Issue 3, eff. November 8, 2012.

12VAC5-520-140. ~~Scholarship and loan repayment award.~~ (Repealed.)

~~A Virginia dental scholarship or loan repayment shall be awarded to the recipient upon or following the recipient's execution of a contract with the commissioner for scholarship or loan repayment by practicing dentistry in an underserved area or designated state facility as defined in this chapter.~~

~~**Statutory Authority**~~

~~Statutory Authority§§ 32.1-122.9 and 32.1-122.9:1 of the Code of Virginia.~~

Historical Notes

Derived from Virginia Register Volume 18, Issue 15, eff. May 8, 2002.

12VAC5-520-150. ~~Distribution of scholarships and loan repayment awards~~ Scholarships and loan repayment awards details and selection criteria.

The Virginia General Assembly establishes the total combined appropriation for the dental scholarship and dentist loan repayment programs. Funds shall be awarded for these programs based on the following criteria:

1. Scholarship. The governing board of Virginia Commonwealth University School of Dentistry shall use the application procedure established by the commissioner and annually submit the names of qualified students to receive scholarships in accordance

with the criteria ~~for preference~~ enumerated in 12VAC5-520-130. The total number of scholarship awards ~~will~~ shall be based on availability of funds. Scholarship awards ~~will~~ shall be made annually by October 30 to third-year and fourth-year dental students. First-year and second-year students ~~will~~ shall be considered for an award only in the event of extreme financial need. Individual scholarship recipients may receive a maximum of ~~five~~ four scholarship awards.

2. Loan repayment. The application period for the Dentist Loan Repayment Program ~~will~~ shall begin in October with awards made by the end of each fiscal year. [~~Preference for loan repayment awards~~] ~~will~~ [~~shall be given to graduates of Virginia Commonwealth University School of Dentistry.~~] Individual loan repayment award recipients may receive a maximum of four awards upon graduation from dental school. All awards ~~will~~ shall be competitive and will be based on availability of funds.

3. Scholarship and loan repayment. A combination of scholarship and loan repayment awards shall not exceed a total of four awards for any individual recipient.

Statutory Authority

§ 32.1-122.9 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 18, Issue 15, eff. May 8, 2002; amended, Virginia Register Volume 29, Issue 3, eff. November 8, 2012.

12VAC5-520-155. How to apply.

[~~Eligible applicants~~ An eligible applicant] shall submit a complete application made available by the department on the department's website, www.vdh.virginia.gov. A complete application shall include documentation of all eligibility requirements. The [department shall announce the] deadline for submission of the application [~~shall be announced by the department~~] on the department's website.

Statutory Authority

§ 32.1-122.9 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume , Issue , eff. Month dd, yyyy.

12VAC5-520-160. ~~Contractual practice obligation~~ Conditions of scholarships, loan repayment awards, and contractual practice obligation.

A. Prior to ~~the payment of money to~~ becoming a scholarship or loan repayment award recipient, the applicant shall enter into a contract with the commissioner ~~shall prepare and enter into a contract with the recipient. The contract shall:~~, agreeing to terms and conditions upon which the scholarship or loan repayment award is granted.

~~1. Provide~~ B. The contract shall [~~provide~~ require] that the recipient of the scholarship award [~~shall~~] pursue the dental course of Virginia Commonwealth University until graduation ~~and upon graduation or upon graduation from an accredited residency program that does not exceed four years,~~ . For each scholarship received, the recipient [~~agrees to~~ shall] engage in the equivalent of one year full-time dental practice [~~in a dental underserved area of Virginia~~] . The recipient shall notify the ~~commissioner~~ department in writing ~~of his proposed practice location or intent to enter a residency not more than 30 days after graduation and begin his approved practice within 90 days after completing dental school or residency, and thereafter~~ within 180 days of graduation from the [~~dental course of~~] Virginia Commonwealth University [School of Dentistry] or upon graduation from an accredited residency program that does not exceed four years of the type of dental practice to be performed or [of the] intent to enter a residency. The notice shall include the name and address of the employer for approval. [

~~Thereafter the recipient shall continuously engage in full-time dental practice in a dental underserved area of Virginia~~] ~~or in a designated state facility~~ [~~for a period of years equal to the number of annual scholarships received.~~] Dental practice in federal agencies, military service, or the U.S. Public Health Service may not be substituted for scholarship obligation.

~~2. Provide~~ C. The contract shall [~~provide~~ require] that upon graduation from an accredited dental school ~~and receiving notification of the dentist loan repayment award~~ or residency program, the [~~dentist~~ recipient] shall begin [~~his~~ the] approved [dental] practice within ~~90~~ 180 days ~~and thereafter continuously engage in~~ . For each loan repayment award received, the recipient [~~agrees to~~ shall] engage in the equivalent of one year full-time dental practice [~~in~~ .] ~~an~~ [~~a dental underserved area of Virginia~~] ~~or in a designated state facility for a period of years equal to the number of loan repayment awards received~~ [~~as designated by the State Board of Health.~~]

~~3. Provide~~ D. The contract shall [~~provide~~ require] that at any time prior to entering practice, the scholarship or loan repayment award recipient shall be allowed to select a future practice location from the listing of dental underserved areas maintained by the board.

~~4. Provide~~ E. The contract shall [~~provide~~ require] that the recipient may request approval of a change of practice location. The commissioner [~~in his discretion~~] may [, in the commissioner's discretion,] approve [~~such a~~ the] request, but only if the change is to a practice location in a dental underserved area ~~or a state facility~~ [~~designated by the State Board of Health~~] . [The recipient shall submit the request to the commissioner in writing before the change of practice location.]

~~5. Provide~~ F. The contract shall [~~provide~~ require] that the recipient shall repay the scholarship or loan repayment obligation by practicing dentistry on a full-time basis in a dental underserved area, shall maintain office hours convenient for the population of the area to have access to the recipient's services , and shall participate in all government-sponsored insurance programs designed to ensure access to dental services of recipients of public assistance , including programs established pursuant to §§ 32.1-325 and 32.1-351 of the Code of Virginia . The recipient shall not ~~selectively~~ place limits on the numbers of such patients admitted to the practice.

~~6. Provide~~ G. The contract shall [~~provide~~ require] that the scholarship recipient shall not voluntarily obligate himself for more than the minimum period of military service required of dentists by the laws of the United States and that upon completion of the minimum period of military service, the recipient shall promptly begin and thereafter continuously engage in full-time dental practice [~~in a dental underserved area of Virginia~~] ~~or in a designated state facility~~ for the period of years equal to the number of scholarships received. ~~Dental practice in federal agencies, military service or the U.S. Public Health Service may not be substituted for scholarship obligation.~~

~~7. Provide that the recipient shall receive credit toward fulfillment of his contractual obligation at the rate of 12 months of dental practice for each scholarship or loan repayment award paid to the recipient. The recipient may be absent from the place of approved practice for a total of four weeks in each 12-month period for personal reasons. Absence for a period in excess of four weeks without the written permission of the commissioner shall result in proportional reduction of the period of credit toward fulfillment of the contractual obligation.~~

~~8. Provide that should the scholarship recipient pay restitution by not serving his scholarship obligation in an underserved area, and within five years of paying restitution fulfills the terms of his contract through dental practice as outlined in this section, that the recipient will be reimbursed for all or part of any scholarship award paid based on the fulfillment of the scholarship and availability of funds.~~

H. Absence for a period in excess of four weeks annually without the written permission of the commissioner shall result in proportional reduction of the period of credit toward fulfillment of the contractual obligation. The commissioner, in the commissioner's sole discretion, shall consider requests on an individual basis and determine the remaining fulfillment obligation.

Statutory Authority

§ 32.1-122.9 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 18, Issue 15, eff. May 8, 2002; amended, Virginia Register Volume 29, Issue 3, eff. November 8, 2012.

12VAC5-520-170. Special requests for approval.

[~~Special requests~~ A special request] for approval of the practice of dentistry in an area in which the ratio does not meet the definition of ~~an area of need~~ a dental underserved area shall be considered by the [~~State~~] Board of Health on an individual basis. To obtain the board's approval, the scholarship or loan repayment award recipient shall substantiate to the board's satisfaction that the ratio does not correctly depict the provision of dental services in the city or county and that additional practitioners are necessary. [~~Examples of situations~~ A situation] deserving special consideration may include topography, age , or physical health of dental practitioners in the area, and sub-areas of high density population that can be geographically identified and shown to have a ratio less than the state ratio.

Statutory Authority

§§ 32.1-122.9 and 32.1-122.9:1 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 18, Issue 15, eff. May 8, 2002.

Part VI

~~Default~~ Breach of contract

12VAC5-520-190. ~~Default~~ Breach of contract.

~~A. With respect to default, the contract shall provide that a scholarship or loan repayment recipient who fails to fulfill his obligation to practice dentistry as described in 12VAC5-520-160 shall be deemed in default under the following circumstances and shall forfeit all monetary scholarship or loan repayment awards made to him and shall repay the Commonwealth of Virginia as provided for in this chapter. The contract shall:~~

~~1. Provide that if the scholarship recipient defaults while still in dental school, by voluntarily notifying the commissioner in writing that he will not practice dentistry in a Virginia dental underserved area as required by his contract, by voluntarily not proceeding to the next year of dental education, or by withdrawing from dental school, the student shall pay the Commonwealth of Virginia all monetary scholarship awards plus interest at the prevailing bank rate for similar amounts of unsecured debt.~~

~~2. Provide that the scholarship recipient who defaults by failing to maintain grade levels that will allow the dental student to graduate, or by reason of his dismissal from dental school for any reason, shall repay the Commonwealth of Virginia all monetary scholarship awards plus interest at the prevailing bank rate for similar amounts of unsecured debt.~~

~~3. Provide that if the scholarship or loan repayment recipient is in default due to death or permanent disability so as not to be able to engage in dental practice, the recipient or his personal representative shall repay the Commonwealth all monetary awards plus 8.0% interest on the amount of the award. Partial fulfillment of the recipient's contractual~~

~~obligation by the practice of dentistry as provided for in this contract prior to death or permanent disability shall reduce the amount of repayment plus interest due by a proportionate amount of money, such proportion being determined as the ratio of the number of whole months that a recipient has practiced dentistry in an approved location to the total number of months of the contractual obligation the recipient has incurred. The commissioner may waive all or part of the scholarship or loan repayment obligation under application by the recipient or his estate under these conditions and consider whole or partial forgiveness of payment or service in consideration of individual cases of hardship or inability to pay.~~

~~4. Provide that any recipient of a scholarship or loan repayment who defaults by evasion or refusal to fulfill the obligation to practice dentistry in an underserved area or designated state facility for a period of years equal to the number of annual scholarships or loan repayment awards received shall make restitution to the Commonwealth of Virginia.~~

~~B. A scholarship or loan repayment recipient will be considered to be in such default on the date:~~

~~1. The commissioner is notified in writing by the recipient that he does not intend to fulfill his contractual obligation;~~

~~2. The recipient has not accepted a placement and commenced his period of obligated practice as provided for in subdivisions 1 and 2 of 12VAC5-520-160; or~~

~~3. The recipient absents himself without the consent of the commissioner from the place of dental practice that the commissioner has approved for fulfillment of his contractual obligation.~~

A. A scholarship recipient shall be in breach of contract if:

1. The recipient fails to complete [~~his~~ the required] dental studies [or maintain a satisfactory scholastic standing pursuant to subdivision B 2 of 12VAC5-520-130] ;

2. The recipient fails to begin or complete the terms of obligated service under the terms and conditions of the scholarship contract;

3. The recipient falsifies or misrepresents information on the program application, the verification of employment forms, or other required documents; or

4. The recipient's employment is terminated for good cause as determined by the employer and confirmed by the department. If employment is terminated for reasons beyond the recipient's control [~~(e.g.,~~ , including] closure of site [~~)~~] , the recipient shall transfer to another site in the Commonwealth approved by the board within 180 days of termination. Failure of recipient to transfer to another site shall be deemed to be a breach of the contract.

B. A loan repayment award recipient shall be in breach of contract if:

1. The recipient fails to begin or complete the term of obligated service under the terms and conditions of the loan repayment contract;

2. The recipient falsifies or misrepresents information on the program application, the verification of employment forms, or other required documents; or

3. The recipient's employment is terminated for good cause as determined by the employer and confirmed by the department. If employment is terminated for reasons beyond the recipient's control [~~(e.g.,~~ , including] closure of site [~~)~~] , the recipient shall transfer to another site approved by the board in the Commonwealth within 180 days of termination. Failure of the recipient to transfer to another site shall be deemed to be a breach of the contract.

C. In the event of a breach of contract and in accordance with the terms of the contract, the recipient shall make payments [~~as described in~~ pursuant to] 12VAC5-520-200. In the event of a breach of contract where the recipient has partially fulfilled the recipient's obligation, the total amount of reimbursement [or restitution owed] shall be [~~prorated~~ reduced] by the proportion of obligation completed.

Statutory Authority

§ [§] 32.1-122.9 [and 32.1-122.9:1] of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 18, Issue 15, eff. May 8, 2002; amended, Virginia Register Volume 29, Issue 3, eff. November 8, 2012.

12VAC5-520-195. Deferment, waivers and variances.

A. [~~Scholarship and~~ A scholarship or] loan repayment award [~~recipients have the obligation to~~ recipient shall] complete full-time continuous service for the period of [~~their~~ the recipient's] commitment. Under unusual circumstances as described in subsection C of this section, a recipient may request that the [~~board~~ commissioner] agree to a deferment of the service obligation. This deferment, if granted, shall not relieve the recipient of the responsibility to complete the remaining portion of the obligation. [~~Such~~ The] deferment shall not be permitted as a matter of course, but may be allowed in the most compelling cases.

B. For [~~recipients~~ a recipient] completing part of the scholarship or loan obligation prior to becoming permanently disabled or in the event of death, the total amount of the funds owed plus applicable interest shall be reduced by the proportion of obligated years served. The obligation to make repayment [~~and restitution~~] may be waived by the board upon application of the recipient or the recipient's personal representative to the [~~board~~ commissioner] .

C. [~~Individual cases~~ In an individual case] of undue hardship [~~may be considered for~~ the commissioner may consider] a variance [~~by the board of~~ to a] payment or service [obligation,] pursuant to § 32.1-12 of the Code of Virginia.

D. [~~All requests for deferments, waivers, or variances must be submitted~~ A recipient must submit a request for a deferment, waiver, or variance] in writing to the department for consideration and final disposition by the [~~board~~ commissioner] .

Statutory Authority

§ 32.1-122.9 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume , Issue , eff. Month dd, yyyy.

12VAC5-520-200. Repayment.

A. [If a scholarship award recipient fails to maintain a satisfactory scholastic standing, the recipient may, upon the commissioner's certification, be relieved of the contractual practice obligation upon repayment to the Commonwealth of the total amount of scholarship award funds received plus interest.

B. A scholarship award recipient who is still enrolled in dental school may terminate the contract with the commissioner upon sending to the commissioner written notice that the recipient will not fulfill the contractual practice obligation and immediate of the total amount of scholarship award funds received plus interest.

C. If a recipient dies or becomes permanently disabled so as not to be able to engage in the practice of dentistry, the recipient or recipient's estate may, upon the commissioner's certification, be relieved of the contractual practice obligation upon repayment to the Commonwealth of the total amount of scholarship or loan repayment award funds received plus interest computed at 8% annually from the date of receipt of the award funds.

D. Except pursuant to subsections A through C of this section, a scholarship or loan repayment award recipient who fails or refuses to fulfill the recipient's contractual practice obligation shall pay a restitution to the Commonwealth equivalent to three times the total amount of scholarship award funds received plus interest.

E.] Repayment requirements for scholarship and loan repayment award recipients are as follows:

1. Payment of restitution or repayment of award plus interest shall be due on the date that the recipient is deemed by the commissioner to be in ~~default~~ breach of contract.

2. The commissioner in his discretion shall permit extension of the period of repayment for up to ~~24 months~~ two years from the date that the recipient is deemed to be in ~~default~~ breach of contract.

3. Partial fulfillment of the recipient's contractual obligation by the practice of dentistry as provided for in ~~this~~ the recipient's contract shall reduce the amount of ~~restitution~~ repayment by a percentage based on the number of whole months that the recipient has practiced dentistry in an approved location and the total number of months of the contractual obligation the recipient has incurred.

4. Failure of a recipient to make any payment on his debt when it is due shall be cause for the commissioner to refer the debt to the Attorney General of the Commonwealth of Virginia for collection. The recipient shall be responsible for any costs of collection as may be provided in Virginia law.

[~~B. A scholarship recipient who commits a breach of contract while still in dental school by voluntarily notifying the commissioner in writing that the scholarship recipient will not practice dentistry in Virginia as required by the scholarship recipient's contract shall repay the total amount of scholarship funds received plus interest to the Commonwealth of Virginia. A scholarship recipient who commits a breach of contract after graduation shall pay a penalty of two times the amount of all monetary scholarship awards paid to the scholarship recipient plus interest, less any service obligation completed, to the Commonwealth of Virginia.~~]

Statutory Authority

§ 32.1-122.9 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 18, Issue 15, eff. May 8, 2002; amended, Virginia Register Volume 29, Issue 3, eff. November 8, 2012.

12VAC5-520-205. Fulfillment after breach of contract payments.

In the event that a recipient, in accordance with the terms of the contract, fully repays the Commonwealth for part or all of any scholarship or loan repayment award because of breach of contract and then later fulfills the terms of the contract after repayment, the Commonwealth shall reimburse the award amount repaid by the recipient minus applicable interest and fees. The award recipient shall request, in writing, the commissioner's approval to complete fulfillment as specified in the original terms of the contract.

Statutory Authority

§ 32.1-122.9 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume , Issue , eff. Month dd, yyyy.

12VAC5-520-210. Reporting requirements.

A. Reporting requirements of Virginia Commonwealth University School of Dentistry scholarship and loan repayment award recipients are as follows:

1. Virginia Commonwealth University School of Dentistry shall maintain accurate records of the enrollment and academic status of scholarship recipients until the recipient's graduation from dental school. The dental school shall provide a report listing the status of each recipient annually to the commissioner.

2. Each scholarship and loan repayment award recipient shall at any time provide information as requested by the commissioner to verify compliance with the contractual practice ~~requirements~~ obligation of the scholarship or loan repayment contract.

B. The recipient shall ~~report any changes of mailing address, change of academic standing, change of intent to fulfill his contractual obligation and any other information that may be relevant to the contract at such time as changes or information may occur. The recipient shall respond within 30 days with such information as may be requested by the commissioner.~~ notify the department in writing within 30 days if any of the following events occur:

1. Recipient changes name;

2. Recipient changes address;

3. Recipient changes practice [~~site (a recipient is required to request in writing and obtain prior approval of changes in practice site)~~ location] ;

4. Recipient no longer intends or is unable to fulfill service obligation as a dentist in the Commonwealth; or

5. Recipient ceases to practice [~~as a dentist~~ dentistry] .

C. In addition to the requirements listed in subsections A and B of this section, [a] scholarship award [~~recipients shall also~~ recipient shall] notify the department within 30 days if the following events occur:

1. Scholarship recipient changes dental program; or

2. Scholarship recipient ceases or no longer intends to complete [~~his~~ the required] dental program.

Statutory Authority

§ 32.1-122.9 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 18, Issue 15, eff. May 8, 2002; amended, Virginia Register Volume 29, Issue 3, eff. November 8, 2012.

FORMS (12VAC5-520)

Dental Scholarship and Loan Repayment Verification of Enrollment form (eff. 4/2022)

Dental Scholarship and Loan Repayment Verification of Financial Need form (eff. 4/2022)

Virginia Dental Scholarship and Loan Repayment Program Application (eff. 2022)

Food Regulations
12VAC5-421
Fast Track Action

Julie Henderson
Director
Office of Environmental Health Services

COMMONWEALTH of VIRGINIA

Department of Health

Karen Shelton, MD
State Health Commissioner

P O BOX 2448
RICHMOND, VA 23218

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

MEMORANDUM

DATE: December 15, 2023

TO: State Board of Health

FROM: Julie Henderson
Director, Office of Environmental Health Services

SUBJECT: Fast Track Action – Amend Food Regulations to Adopt 2022 FDA Food Code

---

Enclosed for your review are fast track amendments to the Food Regulations (12VAC5-421). The proposed regulatory action before you is to amend the Food Regulations to incorporate provisions of the 2022 FDA Food Code. Concurrently, the Virginia Department of Agriculture and Consumer Services (VDACS) is proposing these changes to their Retail Food Regulations.

Briefly, the substantive changes include:

- removal, addition, and revision of definitions; notably to include sesame as a major food allergen;
- revision of terminology related to intact meats, cubing and pounding, and mechanically tenderized meats to align with standards set by the United States Department of Agriculture;
- similar revisions to terminology used to describe shellfish and shellfish products to align with standards set by the National Shellfish Safety Model Ordinance;
- corrections to conditions under which ill employees should be restricted or excluded from duties;
- reduction of requirements for hot water at a hand sink from 100 degrees Fahrenheit to 85 degrees Fahrenheit;
- clarification of when time as a public health control may be used for food requiring refrigeration;
- the addition of monitoring thawing to the duties of a person in charge; and
- the correction of several minor errors from the 2017 version of the FDA Food Code.

Upon approval by the Board, the proposed Fast Track action will be submitted to the Virginia Register of Regulations via Town Hall. Typically, the administration will ensure the equivalent changes to the VDACS Retail Food Regulations go to publication concurrently with the VDH amendments to the Food Regulations. Following publication of the Fast Track action, there will be a 30-day public comment period. The regulatory action will become effective 15 days after close of the public comment period.

townhall.virginia.gov

Fast-Track Regulation
Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC5-421
VAC Chapter title(s)	Food Regulations
Action title	Amend Chapter 421 to Adopt 2022 FDA Food Code
Date this document prepared	October 24, 2023

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code.*

Brief Summary

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

The Food Regulations (12VAC5-421 et seq.) establish minimum sanitary standards for the operation of the Commonwealth's food establishments, which include traditional restaurants, mobile food units, temporary food vendors, hospital and nursing facility food service, and school food service. 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, 2022 amendments to the Food and Drug Administration (FDA) Food Code. Proposed edits include the addition and revision of definitions, updates to cross references, and changes to standards related to temperatures, food donation, and risk categorization. The FDA Food Code 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. Additional amendments are intended to ensure clarity and uniform application.

Acronyms and Definitions

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

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

Statement of Final Agency Action

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

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, "mandate" has the same meaning as defined in the ORM procedures, "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."

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

The Virginia Department of Health (VDH) is initiating this regulatory action to amend its regulations to: (1) align the Food Regulations with the 2022 FDA Food Code, and (2) to ensure clarity and ensure uniform application of the regulations. The FDA Food Code, revised by the FDA 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 used the FDA Food Code as a foundation of its regulations governing food safety in food establishments since before the year 2000.

This regulatory action is best suited for the fast-track process as it is non-controversial and follows the requirements outlined in § 35.1-14 C & E of the Code of Virginia. The proposed changes will ensure the Food Regulations reflect changes made to the 2022 FDA Food Code,

compliment current Virginia law, and provide minimal burdens on regulants while protecting public health.

Legal Basis

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

The promulgating agency is the State Board of Health.

Section 35.1-11 of the Code of Virginia states,

> "The Board shall make, adopt, promulgate, and enforce regulations necessary to carry out the provisions of this title and to protect the public health and safety. In promulgating regulations, the Board shall consider the accepted standards of health including the use of precautions to prevent the transmission of communicable diseases, hygiene, sanitation, safety, and physical plant management."

Section 35.1-14 of the Code of Virginia states in part,

> "A. Regulations of the Board governing restaurants shall include but not be limited to the following subjects: (i) a procedure for obtaining a license; (ii) the safe and sanitary maintenance, storage, operation, and use of equipment; (iii) the sanitary maintenance and use of a restaurant's physical plant; (iv) the safe preparation, handling, protection, and preservation of food, including necessary refrigeration or heating methods; (v) procedures for vector and pest control; (vi) requirements for toilet and cleansing facilities for employees and customers; (vii) requirements for appropriate lighting and ventilation not otherwise provided for in the Uniform Statewide Building Code; (viii) requirements for an approved water supply and sewage disposal system; (ix) personal hygiene standards for employees, particularly those engaged in food handling; (x) the appropriate use of precautions to prevent the transmission of communicable diseases; and (xi) training standards that address food safety and food allergy awareness and safety."
>
> B. In its regulations, the Board may classify restaurants by type and specify different requirements for each classification.
>
> C. The Board may adopt any edition of the Food and Drug Administration's Food Code, or supplement thereto, or any portion thereof, as regulations, with any amendments as it deems appropriate. In addition, the Board may repeal or amend any regulation adopted pursuant to this subsection. No regulations adopted or amended by the Board pursuant to this subsection, however, shall establish requirements for any license, permit, or inspection unless such license, permit, or inspection is otherwise provided for in this title. The provisions of the Food and Drug Administration's Food Code shall not apply to farmers selling their own farm-produced products directly to consumers for their personal use, whether such sales occur on such farmer's farm or at a farmers' market, unless

such provisions are adopted in accordance with the Administrative Process Act (§ 2.2-4000 et seq.)."

Purpose

Explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it is 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.[1] This translates into 1 in 6 Virginians who may become ill each year. The United States Department of Agriculture estimates that foodborne illnesses cost the United States more than $15.6 billion a year.[2]

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 2022 FDA Food Code will ensure the regulation promotes uniformity in administration of the food safety program.

VDH's goals of the regulatory change is to ensure the Food Regulations represent the best practices related to food safety in food establishments, strengthen consumer confidence in the safety of the food served in the Commonwealth, and to ensure administration of the Food Regulations is carried out in the most cost-effective manner.

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.

[1] Center for Disease Control and Prevention (2023, August 9). *Foodborne Germs and Illness.* **https://www.cdc.gov/foodsafety/foodborne-germs.html#:~:text=CDC%20estimates%20that%20each%20year,are%20hospitalized%2C%20and%203%2C000%20die.**

[2] Center for Disease Control and Prevention (2023, March 13). *CDC and Food Safety.* **https://www.cdc.gov/foodsafety/pdfs/cdc-and-food-safety.pdf**

Substance

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

Substantive changes to the Food Regulations are as follows:

A. Definitions
    a. Add and amend definitions to conform with the 2022 FDA Food Code
B. Management and Personnel
    a. Amend the regulations to allow flexibility for food establishments that pose a minimal risk, expand the role of responsible management in the food establishment, and clarify conditions in which food employes shall be excluded or restricted from work duties due to illness.
C. Food
    a. Amend regulations with updated terminology, cross-references, and clarification of handling and tagging of shellfish products.
D. Equipment, Utensils, and Linens
    a. Amend regulations to conform with the 2022 FDA Food Code related to risk categorization.
E. Water, Plumbing, Waste, Physical Facilities
    a. Amend regulations to include new definitions and cross references.
F. Poisonous or Toxic Materials
    a. Amend regulations to conform with 2022 FDA Food Code related to poisonous material storage.
G. Compliance and Enforcement
    a. Amend regulations to conform with 2022 FDA Food Code related to enforcement, variances, and food donation.

Issues

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

The primary advantage of the proposed regulations for the public is the reduction of the risk of foodborne illnesses within food establishments, thus protecting consumers and industry from potentially devastating health consequences and financial losses. The revisions will also make the regulations more understandable and align them with best practices.

The primary advantage to the agency is the regulations will be based on current food science and clarify ambiguous areas relating to enforcement and inspection standards. Staff will have a better understanding of the improved regulatory scheme of food safety thus providing enhanced communication to the public and regulant community on how to prevent foodborne 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 the proposed regulations.

Requirements More Restrictive than Federal

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

There are no requirements in this change that would be more restrictive than those currently required in federal law.

Agencies, Localities, and Other Entities Particularly Affected

Consistent with § 2.2-4007.04 of the Code of Virginia, identify any other state agencies, localities, or other entities particularly affected by the regulatory change. Other entities could include local partners such as tribal governments, school boards, community services boards, and similar regional organizations. "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 state agencies will bear any identified disproportionate material impact not experienced by other agencies, localities, or entities.

Localities Particularly Affected

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

Other Entities Particularly Affected

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

Economic Impact

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

Impact on State Agencies

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	The Board does not expect any changes to costs, savings, fees or revenues as a result of the proposed regulatory change.
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.	The Board does not expect any cost savings by other state agencies as a result of the regulatory change to chapter 421. 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 to chapter 421.
For all agencies: Benefits the regulatory change is designed to produce.	Benefits include alignment with the 2022 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.

Impact on Localities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a or 2) on which it was reported. Information provided on that form need not be repeated here.

Projected costs, savings, fees or revenues resulting from the regulatory change.	Analysis of the proposed regulations on localities has been reported on the ORM Economic Impact form under Table 2.
Benefits the regulatory change is designed to produce.	Analysis of the proposed regulations on localities has been reported on the ORM Economic Impact form under Table 2.

Impact on Other Entities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a, 3, or 4) on which it was reported. Information provided on that form need not be repeated here.

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.	Analysis of the proposed regulations on other entities has been reported on the ORM Economic Impact form under Table 2,3, and 4.
Agency's best estimate of the number of such entities that will be affected. Include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and;	Analysis of the proposed regulations on other entities has been reported on the ORM Economic Impact form under Table 2,3, and 4.

b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	Analysis of the proposed regulations on other entities has been reported on the ORM Economic Impact form under Table 2,3, and 4.
Benefits the regulatory change is designed to produce.	Analysis of the proposed regulations on other entities has been reported on the ORM Economic Impact form under Table 2,3, and 4.

Alternatives to Regulation

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

Analysis of alternatives to the regulation has been reported on the ORM Economic Impact form under Table 1c.

Regulatory Flexibility Analysis

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

Section 35.1-11 of the Code of Virginia requires the Board to make, adopt, promulgate, and enforce regulations necessary to carry out the provisions of Title 35.1 (Hotels, Restaurants, Summer Camps and Campgrounds). No alternative methods are available, as the proposed regulations are necessary and do not impose unreasonably stringent compliance or reporting requirements. The amendments represent the simplest and most effective standards related to compliance and reporting requirements, and they contain exemptions from certain regulatory

requirements to allow flexibility for small businesses as to their operation while protecting public health.

Public Participation

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

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

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

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

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: https://townhall.virginia.gov. Comments may also be submitted by mail, email or fax to: Olivia McCormick, Director of Food and General Environmental Health Services, 109 Governor St, 5th Floor, Richmond, VA 23219, (804)864-7474 (office) (804) 864-7475 (fax) Olivia.Mccormick@vdh.virgnia.gov. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

Detail of Changes

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

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
12VAC5-421-10		**Section Title: "Definitions"** (Amendments) Section provides definitions to terms used throughout the regulations.	**Change:** Amend the definitions of: "Certification Number" "Commingle" "Intact Meat" "Major Food Allergen" "Mechanically Tenderized"

			"Molluscan Shellfish" "Poisonous or Toxic Material" "Ready-to-eat" "Reduced oxygen-packaging" "Shellstock" "Shucked Shellfish" Add new definitions for the following terms: "In-Shell Product" "Tobacco Product" **Intent:** Ensure all technical terms are defined with the most appropriate definitions. **Rationale:** Conformance to the 2022 Edition of the FDA Food Code and update terminology utilized in the food safety industry. **Impact:** Improved understanding and application of the regulations.
12VAC5-421-50		**Section Title: "Assignment of responsibility"** This section assigns responsibility to a member of staff to ensure the continuous presence of someone who is responsible for monitoring and managing all food establishment operations.	**Change/Intent:** Add new subsection, subsection C, to establish an exception where the person-in-charge is not required to be present at all times of the establishment's operation, if the establishment poses a minimal risk to causing or contributing to food borne illness. **Rationale:** Conformance to the 2022 Edition of the FDA Food Code and allows staff to establish criteria for what types of permitted establishments could be exempt from designating a person in charge present at all times during operation. **Impact:** Improved understanding and application of the regulations; reduction of unnecessary regulatory oversight. Food establishments may save money on staff costs.
12VAC5-421-65		**Section Title: "Food protection manager certification"** This section outlines the training standards for a certified food protection manager.	**Change/Intent:** To amend section A and B to correct the title of the Conference for Food Protection Standard to remove the "s" at end of the word 'Standards', and to remove a date, as this is a list that is constantly maintained by the Conference **Rationale:** Conformance to the 2022 Edition of the FDA Food Code and to accurately reflect the name of the

			standardizing organization. Keeping the dated version of the list would restrict industry and provide fewer options. **Impact:** Improved understanding and application of the regulations.
12VAC5-421-70		**Section Title: "Duties of a person in charge"** This section outlines the duties of the Person in Charge.	**Change/Intent:** Add subsection J. The new subsection includes a duty requirement for the Person in Charge to ensure food employees properly maintain the temperatures of time/temperature control for safety foods; amends former subsection '14' (now '15') to indicate what food allergy awareness includes. **Rationale:** Conformance to the 2022 Edition of the FDA Food Code and to ensure the Person in Charge maintains the food operations in a manner to protect the public from food borne illness. **Impact:** Improved understanding and application of the regulations; improved safety and prevention of food borne illness.
12VAC5-421-80		**Section Title: "Responsibility of permit holder, person in charge, and conditional employees"** This section outlines when food employees and conditional employees shall report certain information regarding their health as it relates to diseases transmissible through food.	**Change/Intent:** Correct a cross reference to when an employee should be excluded from working in the food establishment vs. restricted from performing specific types of tasks.(See definitions for "exclude" and "restrict" in 12VAC5-421-10.) **Rationale:** Conformance to the 2022 Edition of the FDA Food Code. **Impact:** Improved understanding and application of the regulations; improved safety and prevention of food borne illness.
12VAC5-421-160		**Section Title: "When to wash"** This section outlines when food employees shall clean their hands and exposed portion of their arms prior to food preparation.	**Change/Intent: R**equire food employees to wash their hands after using tobacco products (see section 220). **Rationale:** Conformance to the 2022 Edition of the FDA Food Code and avoid contamination of food with tobacco products. **Impact:** Improved understanding and application of the regulations; improved safety, prevention of food borne illness and contamination of food.

12VAC5-421-220		**Section Title: "Eating, drinking or using tobacco"** This section outlines the areas in which an employee must eat, drink, or may use tobacco products.	**Change/Intent:** To amend the title and content of section 220: 'tobacco' is now 'tobacco product'. **Rationale:** Conformance to the 2022 Edition of the FDA Food Code and to add the term 'tobacco product' to the list of actions that require usage in designated areas. **Impact:** Improved understanding and application of the regulations; improved safety, prevention of food borne illness and contamination of food.
12VAC5-421-250		**Section Title: "Handling of animals prohibited"** This section restricts food employees from handling animals.	**Change/Intent:** To amend the title of section 250, to add a cross reference which would restrict food employees from handling dogs that are allowed in an outdoor dining area of the food establishment. **Rationale:** Conformance to the 2022 Edition of the FDA Food Code and to restrict handling of dogs in a food establishment. **Impact:** Improved understanding and application of the regulations; improved safety, prevention of food borne illness and contamination of food from handling of animals.
12VAC5-421-270		**Section Title: "Compliance with food law"** This section requires food meet certain standards such being from an approved source, standards for package labeling, and proper food handling.	**Change/Intent:** To correct superscript, change 'priority (P)' to 'priority foundation (Pf)', lessening the severity of this violation, remove cross reference to 12VAC5-421-400; amend section to clarify types of meat obtained from a food processing plant that does not require a consumer advisory; under (E)1 strikes 'labeled by' and replaces it with 'received from'; strikes subsection (E)3.c. **Rationale:** Conformance to the 2022 Edition of the FDA Food Code and to provide clarity to food establishments receiving whole-muscle meats and the appropriate use of consumer advisors. **Impact:** Improved understanding and application of the regulations; improved safety, prevention of food borne illness.
12VAC5-421-400		**Section Title: "Molluscan shellfish, packaging, and identification**	**Change/Intent:** To amend the title of section 400 from "shucked shellfish" to "molluscan shellfish". In addition, the proposed language adds the option to

		This section requires packages or containers for molluscan shellfish to bear a tag or label that contains certain identifying information.	use terminology of “tags” in addition to “labels”, and clarifies what information is required on tags and labels. **Rationale:** Conformance to the 2022 Edition of the FDA Food Code and to ensure tags and labels contain accurate source identification of the harvesting area, harvester, and dealers so that if a shellfish-borne disease outbreak occurs, the information is available to expedite an epidemiological investigation and any necessary regulatory action. **Impact:** Improved understanding and application of the regulations; improved safety, prevention, and investigation of food borne illness.
12VAC5-421-420		**Section Title: Shellstock, condition.** This section requires a food establishment to ensure shellstock is free of mud and in good condition. Any dead or damaged shellstock shall be discarded.	**Change/Intent:** Replace each instance of the word “shellfish” to “shellstock.” **Rationale:** Conformance to the 2022 Edition of the FDA Food Code and to ensure food establishments dispose of dirty, damaged, or dead shellstock which can contaminate and degrade live and healthy shellstock and lead to foodborne illness. **Impact:** Improved understanding and application of the regulations; improved safety, prevention, and investigate of food borne illness.
12VAC5-421-430		**Section Title: Molluscan shellfish, original container.**	**Change/Intent:** To amend text to prohibit the commingling of molluscan shellfish from a different container with different certification dates, different harvest dates and areas. In addition, the proposed text reflects the addition of the terminology “in-shell product” to the regulations. **Rationale:** Conformance to the 2022 Edition of the FDA Food Code and to ensure lot separation of molluscan shellfish. Proper identification is vital for tracing the origin of shellfish in the event of a foodborne outbreak and is helpful when identifying products that require recall or growing waters that may need to be closed to harvesting. **Impact:** Improved understanding and application of the regulations; improved

			safety, prevention, and investigation of food borne illness.
12VAC5-421-440		**Section Title: "Molluscan Shellfish, Maintain Identification"** This section outlines the standards for identification of molluscan shellfish and recordkeeping of tags, labels, and invoices.	**Change/Intent:** Add the following terms: "molluscan shellfish", "invoices", "shucked shellfish" and "in-shell product." **Rationale:** Conformance to the 2022 Edition of the FDA Food Code and to ensure accurate records are maintained in such a manner that allows them to trace molluscan shellfish to its original source. If an outbreak occurs, accurate records are vital to take appropriate actions to prevent further illnesses. **Impact:** Improved understanding and application of the regulations; improved safety, prevention of food borne illness.
	12VAC5-421-445	**Section Title: "Food Donation"** This section requires food offered for donation comply with law and the Food Regulations.	**Change/Intent:** Provide standards for donated food regarding storage, preparation, packaging, display, and labeling. **Rationale:** Conformance to the 2022 Edition of the FDA Food Code and to provide clarity to food establishments that it is permissible to donate food that complies with the Code of Virginia and the Food Regulations. **Impact:** Improved understanding and application of the regulations; to reduce food loss and waste; to reduce food insecurity; improved safety, prevention of food borne illness.
12VAC5-421-470		**Section Title: "Packaged and unpackaged food - separation, packaging, and segregation"** This section outlines standards for the separation of foods in a ready-to-eat form from raw animal foods.	**Change/Intent:** To amend section to include an additional exception as to when raw animal food does not need separation from ready-to-eat food. **Rationale:** Conformance to the 2022 Edition of the FDA Food Code and to provide clarity to food establishments when certain foods do not require separation from raw animal foods. **Impact:** Improved understanding and application of the regulations.
12VAC5-421-510		**Section Title: "Washing fruits and vegetables"** This section outlines when certain fruits and vegetables	**Change/Intent:** To amend section to allow the optional use of a test kit or device to measure wash solution concentration when chemical wash is used.

		shall be washed prior to consumption.	**Rationale:** Conformance to the 2022 Edition of the FDA Food Code. **Impact:** Improved understanding and application of the regulations; improved safety, prevention of food borne illness.
12VAC5-421-620		**Section Title: "Food storage; prohibited areas"** This section outlines the areas in which it is prohibited to store food.	**Change/Intent:** To amend section to change storing food in a toilet room from a core violation (to be corrected within 90 days of observation) to a priority foundation violation (corrected within 10 calendar days of observation). **Rationale:** Conformance to the 2022 Edition of the FDA Food Code. In addition, the amendment highlights the increased potential hazard of storing food in a toilet room as trace amounts of refuse or wastes in such areas could contaminate food. **Impact:** Improved understanding and application of the regulations; improved safety, prevention of food borne illness.
12VAC5-421-700		**Section Title: "Raw animal foods"** This section outlines the minimal cooking temperatures based on cooking methods for raw animal foods.	**Change/Intent:** To amend section to delete 'mechanically tenderized and 'injected' and insert 'nonintact meat' and align terminology regarding mechanically tenderized beef products with the Food Code. **Rationale:** Conformance to the 2022 Edition of the FDA Food Code. In addition, the amendments ensure meats, under various types of processing, are cooked at appropriate temperatures to effectively eliminate pathogens. **Impact:** Improved understanding and application of the regulations; improved safety, prevention of food borne illness.
	12VAC5-421-726	**Section Title: "Manufacturer Cooking Instructions"** This section outlines cooking instructions for commercially packaged food.	**Change/Intent:** Add new section, which requires food establishments to cook commercially packaged foods according to manufacturer's instructions or according to a time and temperature appropriate for the food. **Rationale:** Conformance to the 2022 Edition of the FDA Food Code. A food manufacturer may produce and provide food that has a known or reasonably foreseeable hazard (such as Salmonella) without first processing the food(cooking) to control that hazard so

			long as the manufacturer provides a disclosure. This section requires food establishments to cook such foods to control any foodborne illness hazards prior to making the food available for human consumption. **Impact:** Improved understanding and application of the regulations; improved safety, prevention of food borne illness.
12VAC5-421-790		**Section Title: "Thawing"** This section outlines the process to properly thaw time /temperature for safety food.	**Change/Intent:** Add cross references to a new section, "Manufacturer Cooking Instructions", and amend certain subsections from core violations (to be corrected within 90 days of observation) to priority foundation violations (corrected within 10 calendar days of observation). **Rationale:** Conformance to the 2022 Edition of the FDA Food Code. In addition, amendment highlights the increased potential hazard of improper thawing of time/temperature for safety foods. **Impact:** Improved understanding and application of the regulations; improved safety, prevention of food borne illness.
12VAC5-421-830		**Section Title: "Ready-to-eat, time/temperature control for safety food; date marking"** This section outlines the process for date marking certain foods.	**Change/Intent:** Correct a citation to the Code of Federal Regulations. **Rationale:** Conformance to the 2022 Edition of the FDA Food Code; to correctly reflect citations to federal regulations. **Impact:** Improved understanding and application of the regulations; improved safety, prevention of food borne illness.
12VAC5-421-850		**Section Title: "Time as a public health control"** This section outlines food handling when time and not temperature is used as a public health control.	**Change/Intent:** Add a new subsection to address temperatures, within a four-hour window, for ready-to-eat produce or hermetically sealed food that is rendered time/temperature control for safety food. **Rationale:** Conformance to the 2022 Edition of the FDA Food Code; to recognize new technology that continuously monitors temperature control to prevent the grown of C. botulinum and L. monocytogenes, to add additional controlling factors to prevent pathogen growth.

			Impact: Improved understanding and application of the regulations; improved safety, prevention of food borne illness.
12VAC5-421-870		**Section Title: "Reduced oxygen packaging without a variance, criteria"** This section outlines the standards, such as a HACCP plan, for reduced oxygen packaging without a variance.	**Change/Intent:** Add a new subsection to include an additional option to package and seal food products by a cooling or sous-vide process so long as the food meets certain refrigeration standards. Correct cross-references to Section -3630 based on the addition of a new subdivision 4 in that section. **Rationale:** Conformance to the 2022 Edition of the FDA Food Code; to ensure ready-eat-foods are properly handled and disposed of when time and not temperature is used as a public health control prior to pathogen growth and possible toxin production. **Impact:** Improved understanding and application of the regulations; improved safety, prevention of food borne illness.
12VAC5-421-900		**Section Title: "Food labels"** This section outlines what is required on label information for food packaged at a food establishment.	**Change/Intent:** To amend subsection C2 to add a cross reference that would require a food establishment to add a notification regarding potential allergens in bulk food that is available for consumer self-dispensing. **Rationale:** Conformance to the 2022 Edition of the FDA Food Code; to reduce unintended food allergen exposures to consumers with food allergies. **Impact:** Improved understanding and application of the regulations; improved safety, prevention of food borne illness, reduction in serious illness such as anaphylaxis due to contact with an undisclosed food allergen.
12VAC5-421-910		**Section Title: "Other forms of information"** This section outlines requirements for miscellaneous notifications to the consumer.	**Change/Intent:** To add a new subsection that requires the food establishment to notify consumers in writing about major food allergens. **Rationale**: Conformance to the 2022 Edition of the FDA Food Code; to reduce unintended food allergen exposures to consumers with food allergies.

			Impact: Improved understanding and application of the regulations; improved safety, prevention of food borne illness, reduction in serious illness such as anaphylaxis due to contact with an undisclosed food allergen.
12VAC5-421-950		**Section Title: "Pasteurized foods, prohibited reservice, and prohibited food."** This section sets forth the standards for the service of food to highly susceptible populations.	**Change/Intent:** To add subdivision 3(d), a cross reference to manufactured packaged food. Packaged food, as specified in the cross reference, in a ready-to-eat form is prohibited from service to highly susceptible populations. Correct cross-references to Section -3630 based on the addition of a new subdivision 4 in that section. **Rationale:** Conformance to the 2022 Edition of the FDA Food Code; to include additional safeguards to protect those who are particularly vulnerable to foodborne illness. **Impact:** Improved understanding and application of the regulations; improved safety, prevention of food borne illness.
12VAC5-421-1435		**Section Title: "Food equipment, certification and classification"** This section states food equipment meeting certain standards are deemed safe for use in food establishments.	**Change/Intent:** To amend section to clarify that the American National Standards Institute's role is not as an accreditation organization. **Rationale:** Conformance to the 2022 Edition of the FDA Food Code; improved clarity of regulatory requirements. **Impact:** Improved understanding and application of the regulations.
12VAC5-421-1535		**Section Title: "Cleaning Agents and sanitizers, availability"** This section requires cleaning agents be available in the food establishment during hours of operation.	**Change/Intent:** To amend section to add a risk based categorization of "priority foundation" and to remove unnecessary styling. **Rationale:** Conformance to the 2022 Edition of the FDA Food Code; per the FDA this designation was inadvertently 'left off' the 2017 FDA Food Code. **Impact:** Improved understanding and application of the regulations.
12VAC5-421-1540		**Section Title: "Equipment, clothes washers and dryers, and storage cabinets, contamination prevention"**	**Change/Intent:** To amend section to change placing cabinets or equipment used to store food in a toilet room or vestibule from a core violation (to be corrected within 90 days of

		This section restricts the location of cabinets and equipment used to store food.	observation) to a priority foundation violation (corrected within 10 calendar days of observation). **Rationale:** Conformance to the 2022 Edition of the FDA Food Code. In addition, the amendment highlights the increased potential hazard of allowing food storage equipment in a toilet room or its vestibule as trace amounts of refuse or wastes in such areas could contaminate food. **Impact:** Improved understanding and application of the regulations; improved safety, prevention of food borne illness.
12VAC5-421-2010		**Section Title: "Prohibitions"** This section restricts the location of where cleaned and sanitized equipment, utensils, and other items are stored.	**Change/Intent:** To change placing cleaned and sanitized equipment, utensils, and other items in a toilet room or vestibule from a core violation (to be corrected within 90 days of observation) to a priority foundation violation (corrected within 10 calendar days of observation). **Rationale:** Conformance to the 2022 Edition of the FDA Food Code. In addition, the amendment highlights the increased potential hazard of storing cleaned and sanitized equipment, utensils, and other items in a toilet room or its vestibule as trace amounts of refuse or wastes in such areas could contaminate food. **Impact:** Improved understanding and application of the regulations; improved safety, prevention of food borne illness.
12VAC5-421-2190		**Section Title: "Handwashing sinks, water temperature, and flow"** This section outlines standards for the installation of handwashing sinks used in a food establishment that includes the temperature of the water delivered at the sink.	**Change/Intent:** To amend section to reduce the minimum hot water temperature at a handwashing sink from 100°F to 85°F. **Rationale:** Conformance to the 2022 Edition of the FDA Food Code and the International Plumbing Code which defines "tempered water" as having a temperature range between 29.4°C (85°F) and 43°C (110°F). **Impact:** Improved understanding and application of the regulations; alignment of regulatory requirements to industry standard, and reduction of unnecessary regulatory burden.

12VAC5-421-3140		**Section Title: "Employee accommodations, designated areas"** This section requires designated areas for employees to eat, drink, and use tobacco products.	**Change/Intent:** To include the term 'tobacco product.' **Rationale:** Conformance to the 2022 Edition of the FDA Food Code. **Impact:** Improved understanding and application of the regulations; improved safety, prevention of food borne illness, and contamination of food.
12VAC5-421-3360		**Section Title: "Conditions of Use"** This section outlines the proper use and application of poisonous or toxic materials in a food establishment.	**Change/Intent:** To strike reference to "restricted use pesticide." **Rationale:** Conformance to the 2022 Edition of the FDA Food Code; the definition of Poisonous or Toxic Materials with the Code of Federal Regulations was revised. **Impact:** Improved understanding and application of the regulations; improved safety, conformance to changes in federal definitions.
12VAC5-421-3370		**Section Title: "Poisonous or toxic material containers."** This section prohibits the use of poisonous or toxic material containers to store, transport, or dispense food.	**Change/Intent:** To prohibit the storage of linens, single-service, or single-use articles in in containers that previously stored poisonous or toxic materials. **Rationale:** Conformance to the 2022 Edition of the FDA Food Code and to reduce the risk of potential contamination of food or food contact surfaces with poisonous or toxic material. **Impact:** Improved understanding and application of the regulations; improved safety, prevention of food contamination.
12VAC5-421-3510		**Section Title: "Poisonous or toxic material containers."** This section prohibits the use of poisonous or toxic material containers to store, transport, or dispense food.	**Change/Intent:** To require the department to apply the regulations to donated food. **Rationale:** Conformance to the 2022 Edition of the FDA Food Code and to ensure donated food products are served, stored, and prepared safely. **Impact:** Improved understanding and application of the regulations; improved safety, and prevention of food borne illness.
12VAC5-421-3595		**Section Title: "Conformance with approved procedures."**	**Change/Intent:** To require the permit holder to maintain any approved variance at the food establishment. Correct cross-reference to Section -

		This section outlines the requirements of the permit holder when a variance is granted, or a HACCP plan is required.	3630 based on the addition of a new subdivision 4 in that section. **Rationale:** Conformance to the 2022 Edition of the FDA Food Code and to ensure a copy of an approved variance is on the premise of the food establishment available for inspection. **Impact:** Improved understanding and application of the regulations; improved safety, and improved compliance with approved variances.
12VAC5-421-3630		**Section Title: "Contents of a HACCP Plan."** This section outlines the information permit holders or applicants shall submit to the department when seeking the approval of a HACCP plan.	**Change/Intent:** To clarify and merge text to highlight items required for submission to the department. **Rationale:** Conformance to the 2022 Edition of the FDA Food Code. **Impact:** Improved understanding and application of the regulations; improved safety, and to improve the approval process of HACCP plans.
12VAC5-421-3700		**Section title: "Contents of the application."** This section outlines the requirements for a permit application.	**Change/Intent:** To correct a cross-reference to Section -3630. **Rationale:** A new subdivision 4 was added to section -3630 in this action.. **Impact:** Correct cross-references ensure proper interpretation and enforcement of the chapter.
12VAC5-421-3860		**Section title: "Documenting information and observations."** This section outlines the department's responsibilities during inspections.	**Change/Intent:** To correct a cross-reference to Section -3630. **Rationale:** New subdivisions 4 and 5 b are added to section -3630 in this action. **Impact:** Correct cross-references ensure proper interpretation and enforcement of the chapter.
Throughout			**Change/Intent:** Non-substantive edits were made throughout, such as correcting use of "must," "shall," and "may;" changing passive constructions to active voice; adding or clarifying definite/indefinite articles; correcting use of singular vs. plural; "if" vs. "when"; and other minor updates for readability. The intent is to conform to the Registrar of Regulations' *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code.*

			Rationale: The rationale is that proper style and format, grammatical correctness, and consistency of language are required to conform to the journalistic style of the Virginia Register of Regulations. **Likely Impact:** The likely impact is that the chapter will be more readable.

Office of Regulatory Management

Economic Review Form

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-421
VAC Chapter title(s)	Food Regulations
Action title	Amend Chapter 421 to Adopt 2022 FDA Food Code
Date this document prepared	November 1, 2023
Regulatory Stage (including Issuance of Guidance Documents)	Fast Track

Cost Benefit Analysis

Complete Tables 1a and 1b for all regulatory actions. You do not need to complete Table 1c if the regulatory action is required by state statute or federal statute or regulation and leaves no discretion in its implementation.

Table 1a should provide analysis for the regulatory approach you are taking. Table 1b should provide analysis for the approach of leaving the current regulations intact (i.e., no further change is implemented). Table 1c should provide analysis for at least one alternative approach. You should not limit yourself to one alternative, however, and can add additional charts as needed.

Report both direct and indirect costs and benefits that can be monetized in Boxes 1 and 2. Report direct and indirect costs and benefits that cannot be monetized in Box 4. See the ORM Regulatory Economic Analysis Manual for additional guidance.

Table 1a: Costs and Benefits of the Proposed Changes (Primary Option)

(1) Direct & Indirect Costs & Benefits (Monetized)	**Direct Costs:** The majority of the changes in this regulatory action are to terminology and have no direct or indirect associated costs. Exceptions are listed below. **Addition of sesame as a major allergen (section 10):** This addition requires the permit holder to notify customers by written notification of the presence of major food allergens in unpackaged foods. Costs associated with this amendment are indeterminate but are expected to be minor based on feedback from the National Restaurant Association via Virginia Restaurant Lodging and Travel Association. Establishments that add sesame to foods will have one-time costs to provide written notification of any allergens present (section 910), which may vary depending on the type of menu offered. Establishments using QR Code

	digital menus or that change a limited paper menu regularly may bear no costs. **Addition of requirements to the duties of the Person In Charge (PIC)** may require limited costs for initial training, but are unlikely to require staffing changes. **Additional requirements for hazard control plans** may result in very limited but indeterminate costs. **Other amendments are not estimated to result in direct costs.** **Indirect Costs:** Indeterminate. There are no monetizable indirect costs associated with this change unless food establishments choose to change existing recipes or food product sources to avoid sesame products. Other amendments are not estimated to result in indirect costs. **Direct Benefits:** Indeterminate. There may be direct monetizable benefits associated with amendments to sections 50, 80, and 2190: **Section 50** allows certain low-risk food establishments to operate without a designated Person In Charge (PIC). While there is no direct cost associated with a PIC, these establishments may benefit monetarily from an increased flexibility in scheduling. **Section 80** reclassifies certain ill employees that were previously required to be excluded from work as those who are allowed to work in a restricted capacity. These employees will benefit as they will not lose wages, and employers will benefit from a reduced impact on staffing. **Section 2190** reduces the requirement for the temperature of hot water required in food establishments. This may reduce energy costs or costs borne in the maintenance or replacement of hot water heaters. **Indirect Benefits:** Indeterminate, however, indirect monetizable benefits to food establishments may occur due to reduction in foodborne illness and outbreak. One 2018 study estimated the cost of a single outbreak "ranged from $3,968 to $1.9 million for a fast-food restaurant, $6,330 to $2.1 million for a fast-casual restaurant, $8,030 to $2.2 million for a casual-dining restaurant, and $8,273 to $2.6 million for a fine-dining restaurant". The indirect benefit to the individual may be significant as well. The Centers for Disease Control estimate that 48 million people get sick, 128,000 are hospitalized, and 3,000 die from foodborne diseases each year in the United States. A 2010 estimate placed the cost to an affected (ill) individual at $1,850 on average nationwide. The United States Department of Agriculture estimates the negative impact of foodborne pathogens at 17.6 billion dollars in 2018.

(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits

	(a) Indeterminate	(b) Indeterminate
(3) Net Monetized Benefit	Indeterminate; however, given the potential costs for foodborne illness to industry and individuals, the agency estimates that the benefits of the action outweigh costs.	
(4) Other Costs & Benefits (Non-Monetized)	Alignment of the Virginia Food Regulations to the 2022 Food Code may benefit chain establishments that operate in other states and localities that also use the most up to date version of the Food Code. Many large chain operations use the most recent edition of the Food Code as an operational standard to ensure they reduce liability and operate consistently throughout their operational region. By adopting current changes to FDA Food Code, there is consistency with VDACS Retail Food Regulations.	
(5) Information Sources	Bartsch SM, Asti L, Nyathi S, Spiker ML, Lee BY. Estimated Cost to a Restaurant of a Foodborne Illness Outbreak. Public Health Rep. 2018 May/Jun;133(3):274-286. doi: 10.1177/0033354917751129. Epub 2018 Apr 15. PMID: 29656701; PMCID: PMC5958383. https://www.cdc.gov/foodborneburden/estimates-overview.html https://www.pewtrusts.org/en/research-and-analysis/reports/0001/01/01/healthrelated-costs-from-foodborne-illness-in-the-united-states https://www.ers.usda.gov/amber-waves/2021/april/economic-cost-of-major-foodborne-illnesses-increased-2-billion-from-2013-to-2018/	

Table 1b: Costs and Benefits under the Status Quo (No change to the regulation)

(1) Direct & Indirect Costs & Benefits (Monetized)	**Direct Costs:** There are no direct or indirect monetized costs or benefits associated with not updating the regulation to align to the 2022 FDA Food Code.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) None	(b) None
(3) Net Monetized Benefit	None	
(4) Other Costs & Benefits (Non-Monetized)	None	

(5) Information Sources	N/A

Table 1c: Costs and Benefits under Alternative Approach(es)

(1) Direct & Indirect Costs & Benefits (Monetized)	**One alternative would be to amend the respective sections in the regulation in a way that is not to align with the 2022 FDA Food Code.** The direct and indirect monetized costs associated with this alternative are that the Board of Health and the Board of Agriculture and Consumer Services would be inconsistent, and food establishments may have to navigate and comply with differing sets of requirements, potentially increasing the total number of requirements imposed on them and the associated cost of compliance. There are no direct or indirect costs or benefits associated with this alternative.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) N/A	(b) N/A
(3) Net Monetized Benefit	N/A	
(4) Other Costs & Benefits (Non-Monetized)	The non-monetized costs associated with this alternative are the confusion and frustration for regulated entities, the public, and VDH and VDACS staff in reading, interpreting, enforcing, and complying with inconsistent regulations. It would jeopardize the success of the two agencies' joint oversight over food establishments.	
(5) Information Sources	N/A	

Impact on Local Partners

Use this chart to describe impacts on local partners. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

Table 2: Impact on Local Partners

(1) Direct & Indirect Costs & Benefits (Monetized)	There are no known direct or indirect, monetized costs or benefits that impact local partners.

(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) None	(b) None
(3) Other Costs & Benefits (Non-Monetized)	None	
(4) Assistance	N/A	
(5) Information Sources	N/A	

Impacts on Families

Use this chart to describe impacts on families. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

Table 3: Impact on Families

(1) Direct & Indirect Costs & Benefits (Monetized)	**Direct Costs:** There are no direct costs to families that do not operate a food establishment (see Table 1a for impacts on those operating a food establishment). **Indirect Costs:** There are no indirect costs to families that do not operate a food establishment (see Table 1a for impacts on those operating a food establishment). **Direct Benefits:** Indeterminate. A reduced risk of foodborne illness may result in reduced healthcare costs and reduced loss of wages associated with foodborne illness. See Table 1a. **Indirect Benefits:** Indeterminate. It is possible that improvement in food safety as a result of the fast track amendments may lead to greater economic stability in the food service sector in the Commonwealth, as high profile outbreaks weaken consumer confidence in restaurants. A significant outbreak may have deleterious effects on the economic performance of the food service or tourism sectors, which may have trickle-down effects on the economy of the Commonwealth at large. These effects may impact the family economy, especially if the employment and wages of the family are dependent on the food service or tourism sectors.

(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) None	(b) Indeterminate
(3) Other Costs & Benefits (Non-Monetized)	Improvements in food safety associated with the amendments help ensure families avoid the pain, suffering, and potential death associated with foodborne illness.	
(4) Information Sources	N/A	

Impacts on Small Businesses

Use this chart to describe impacts on small businesses. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

Table 4: Impact on Small Businesses

(1) Direct & Indirect Costs & Benefits (Monetized)	Almost all the approximately 30,000 food establishments in the Commonwealth are estimated to be small businesses. None of the proposed changes are anticipated to have any particular or disproportionate impact on food establishments that are small businesses. See Table 1a for more information.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) See Table 1a	(b) See Table 1a
(3) Other Costs & Benefits (Non-Monetized)	None of the proposed changes are anticipated to have any particular or disproportionate impact on food establishments that are small businesses. See Table 1a for more information.	
(4) Alternatives	None of the proposed changes are anticipated to have any particular or disproportionate impact on food establishments that are small businesses. See Table 1a for more information. Thus, no alternatives to these changes is being considered.	
(5) Information Sources	See Table 1a	

Changes to Number of Regulatory Requirements

Table 5: Regulatory Reduction

For each individual action, please fill out the appropriate chart to reflect any change in regulatory requirements, costs, regulatory stringency, or the overall length of any guidance documents.

Change in Regulatory Requirements

VAC Section(s) Involved*	Authority of Change	Initial Count	Additions	Subtractions	Net Change
12VAC5-421-10	**Statutory:**	**0**	0	0	0
	Discretionary:	**0**	0	0	0
12VAC5-421-50	**Statutory:**	**1**	0	0	0
	Discretionary:	**2**	0	2	-2
12VAC5-421-65	**Statutory:**	**0**	0	0	0
	Discretionary:	**2**	0	0	0
12VAC5-421-70	**Statutory:**	**0**	0	0	0
	Discretionary:	**74**	3	0	3
12VAC5-421-80	**Statutory:**	**0**	0	0	0
	Discretionary:	**183**	0	1	-1
12VAC5-421-160	**Statutory:**	**0**	0	0	0
	Discretionary:	**12**	0	0	0
12VAC5-421-220	**Statutory:**	**0**	0	0	0
	Discretionary:	**30**	0	0	0
12VAC5-421-250	**Statutory:**	**0**	0	0	0
	Discretionary:	**4**	0	0	0
12VAC5-421-270	**Statutory:**	**0**	0	0	0
	Discretionary:	**28**	0	1	-1
12VAC5-421-400	**Statutory:**	**0**	0	0	0
	Discretionary:	**7**	0	0	0
12VAC5-421-420	**Statutory:**	**0**	0	0	0
	Discretionary:	**4**	0	0	0
12VAC5-421-430	**Statutory:**	**0**	0	0	0
	Discretionary:	**15**	3	0	3
12VAC5-421-440	**Statutory:**	**0**	0	0	0
	Discretionary:	**9**	0	1	-1
12VAC5-421-445	**Statutory:**	**0**	0	0	0
	Discretionary:	**0**	5	0	5
12VAC5-421-470	**Statutory:**	**0**	0	0	0
	Discretionary:	**69**	0	1	-1
12VAC5-421-510	**Statutory:**	**0**	0	0	0
	Discretionary:	**9**	0	0	0
12VAC5-421-620	**Statutory:**	**0**	0	0	0
	Discretionary:	**12**	0	0	0
12VAC5-421-700	**Statutory:**	**0**	0	0	0
	Discretionary:	**68**	0	0	0
12VAC5-421-720	**Statutory:**	**0**	0	0	0
	Discretionary:	**1**	0	0	0
12VAC5-421-726	**Statutory:**	**0**	0	0	0
	Discretionary:	**0**	3	0	3
	Statutory:	**0**	0	0	0

12VAC5-421-790	**Discretionary:**	**20**	0	1	-1
12VAC5-421-830	**Statutory:**	**0**	0	0	0
	Discretionary:	**30**	0	0	0
12VAC5-421-850	**Statutory:**	**0**	0	0	0
	Discretionary:	**28**	0	1	-1
12VAC5-421-870	**Statutory:**	**0**	0	0	0
	Discretionary:	**111**	0	1	-1
12VAC5-421-900	**Statutory:**	**0**	0	0	0
	Discretionary:	**42**	1	0	1
12VAC5-421-910	**Statutory:**	**0**	0	0	0
	Discretionary:	**3**	1	0	1
12VAC5-421-950	**Statutory:**	**0**	0	0	0
	Discretionary:	**47**	1	0	1
12VAC5-421-1435	**Statutory:**	**0**	0	0	0
	Discretionary:	**1**	0	0	0
12VAC5-421-1535	**Statutory:**	**0**	0	0	0
	Discretionary:	**8**	0	0	0
12VAC5-421-1540	**Statutory:**	**0**	0	0	0
	Discretionary:	**63**	0	0	0
12VAC5-421-2010	**Statutory:**	**0**	0	0	0
	Discretionary:	**46**	0	0	0
12VAC5-421-2190	**Statutory:**	**0**	0	0	0
	Discretionary:	**4**	0	1	-1
12VAC5-421-3140	**Statutory:**	**0**	0	0	0
	Discretionary:	**22**	0	0	0
12VAC5-421-3360	**Statutory:**	**0**	0	0	0
	Discretionary:	**46**	0	0	0
12VAC5-421-3370	**Statutory:**	**0**	0	0	0
	Discretionary:	**3**	5	0	5
12VAC5-421-3510	**Statutory:**	**0**	0	0	0
	Discretionary:	**10**	1	0	1
12VAC5-421-3595	**Statutory:**	**0**	0	0	0
	Discretionary:	**7**	1	0	1
12VAC5-421-3630	**Statutory:**	**0**	0	0	0
	Discretionary:	**30**	4	0	4
				Total Net Change of Statutory Requirements:	**0**
				Total Net Change of Discretionary Requirements:	**18**

Cost Reductions or Increases (if applicable)

VAC Section(s) Involved*	Description of Regulatory Requirement	Initial Cost	New Cost	Overall Cost Savings/Increases
12VAC5-421-10	Adds sesame to the list of what constitutes a major allergen	Indeterminate	Indeterminate (see Table 1a)	Indeterminate

Other Decreases or Increases in Regulatory Stringency (if applicable)

VAC Section(s) Involved*	Description of Regulatory Change	Overview of How It Reduces or Increases Regulatory Burden
12VAC5-421-50	Removes the requirement for a Person In Charge (PIC) at establishments deemed to be at low risk for causing illness.	Reduces cost burden on low risk food establishments.
12VAC5-421-80	Ill employees previously excluded from work may now work in a restricted capacity.	Positive effect on both employee income and food establishment staffing.
12VAC5-421-440	Adds 'invoice' as a recordkeeping option.	Allows greater flexibility while maintaining food safety rigor.
12VAC5-421-850	Establishes standards for an exemption for the initial temperature of received food product.	Allows greater flexibility while maintaining food safety rigor.
12VAC5-421-870	Creates additional option for the cold holding of food that requires refrigeration.	Allows additional options for food holding while maintaining rigor of food safety
12VAC5-421-2190	Reduction in the temperature required for hot water.	Indeterminate but positive effect on potential costs for hot water heater upkeep and power costs associated with hotter water use.

Project 7483 – Fast Track

Department of Health

Amend Chapter 421 to Adopt 2022 FDA Food Code

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.

"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.

"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 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.~~ means the unique identification number issued by the shellfish control authority to each dealer for each location. Each certification number shall consist of a one-to-five digit Arabic number preceded by the two letter State abbreviation and followed by a two-letter abbreviation for the type of activity or activities the dealer is qualified to perform in accordance with this provision of the National Shellfish Sanitation Program.

Table A. Certifications	
Acronym	**Term**
SP	Shucker Packer
RP	Repacker
SS	Shellstock Shipper
RS	Reshipper
DP	Depuration

Table B. Permits	
Acronym	**Term**
PHP	Post-Harvest Processing
AQ	Aquaculture
WS	Wet Storage

"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.~~ means the act of combining different lots of shellfish.

"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 food establishment in which food, food containers, or supplies are kept, handled, prepared, packaged, or stored for distribution to satellite operations.

"Commonwealth" means the Commonwealth of Virginia.

"Conditional employee" means a potential food employee to whom a job offer is made , conditional on 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 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).

"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 , 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 in this definition 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, ratites, 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.

"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 an 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, 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.

"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.

"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.

"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, 2017 Revision (U.S. Food and Drug Administration), with which certain fluid and dry milk and milk products comply.

"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.

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

"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 that are referred to as "injecting," "pump marinating," or "stitch pumping."

"In-shell Product" means non-living, processed shellfish with one or both shells present.

"Intact meat" means a cut of whole ~~muscle~~ muscle(s) meat that has not undergone comminution, injection, mechanical tenderization, ~~or reconstruction.~~ vacuum tumbling with solutions, reconstruction, cubing, or pounding.

"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 sesame; 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 w~~ith 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.~~ by piercing with a set of needles, pins, blades, or any mechanical device, which breaks up muscle fiber and tough connective tissue to increase tenderness. This includes injection, scoring, and processes which may be referred to as "blade tenderizing," “jaccarding,” “pinning,” or “needling”.

"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. Molluscan shellfish includes shellstock, shucked shellfish, and in-shell products.

"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 department that authorizes a person to operate a food establishment.

"Permit holder" means person that is legally responsible for the operation of the food establishment 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 indicate acidity and values between 7 and 14 indicate alkalinity. The value for pure distilled water is 7, 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~~ five 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~~.~~ ; and

5. Restricted use pesticides.

"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-^{Pf}.

"Priority item" means a provision in this chapter whose application contributes directly to the elimination, prevention or reduction to an acceptable level , 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-^{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, 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."

"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 12VAC5-421-700 D 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~~ Plant foods 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 Article 4 (12VAC5-421-700 et seq.) of Part III 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

9. Food manufactured as specified in 21 CFR Part 113.

"Ready-to-eat food" does not include:

1. Commercially packaged food that bears a manufacturer's cooking instructions; and

2. Food for which the manufacturer has provided information that it has not been processed to control pathogens.

"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 of 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 psychotrophic 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 psychotropic pathogens.

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

"Regulatory authority" means the local, state, or federal enforcement body or 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.

"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, or 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 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 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 allow 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 r~~aw, in-shell molluscan shellfish.~~ live molluscan shellfish in the shell.

"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, 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.~~ 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 that 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 cleanability 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 A. Interaction of pH and A_w for control of spores in food heat treated to destroy vegetative cells and subsequently packaged.

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

*TCS food means time/temperature control for safety food

**PA means product assessment required

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

A_w values	pH values			
	< 4.2	4.2 - 4.6	> 4.6 - 5.0	> 5.0
<0.88	non-TCS food*	non-TCS food	non-TCS food	non-TCS food
0.88 - 0.90	non-TCS food	non-TCS food	non-TCS food	PA**
>0.90 - 0.92	non-TCS food	non-TCS food	PA	PA
>0.92	non-TCS food	PA	PA	PA

*TCS food means time/temperature control for safety food

**PA means product assessment required

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

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.

"Tobacco Product" has the meaning stated in the Federal Food, Drug and Cosmetic Act §201(rr) (21 U.S.C. 321(rr)).

"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 department that authorizes a modification or waiver of one or more requirements of this chapter if, in the opinion of the 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, 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 pure 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.

12VAC5-421-50. Assignment of responsibility.

Article 1
Supervision

A. Except as specified in ~~subsection~~ subsections B and C of this section, the permit holder shall be the person in charge or shall designate a person in charge and shall ensure that a person in charge is present at the food establishment during all hours of operation.[Pf]

B. In a food establishment with two or more separately permitted departments that are the legal responsibility of the same permit holder and that are located on the same premises, the permit holder may, during specific time periods when food is not being prepared, packaged, or

served, designate a single person in charge who is present on the premises during all hours of operation, and who is responsible for each separately permitted food establishment on the premises.[Pf]

C. This section shall not apply to certain types of food establishments deemed by the department to pose minimal risk of causing, or contributing to, foodborne illness based on the nature of the operation and extent of the food preparation.[Pf]

12VAC5-421-65. Food protection manager certification.

A. A person in charge who demonstrates knowledge by being a food protection manager who is certified by a food protection manager certification program that is evaluated and listed by a Conference for Food Protection-recognized accrediting agency as conforming to the Conference for Food Protection ~~Standards~~ Standard for Accreditation of Food Protection Manager Certification Programs ~~, April 2012,~~ (Conference for Food Protection) is deemed to comply with subdivision 2 of 12VAC5-421-60.

B. A food establishment that has an employee who is certified by a food protection certification program that is evaluated and listed by a Conference for Food Protection-recognized accrediting agency as conforming to the Conference for Food Protection ~~Standards~~ Standard for Accreditation of Food Protection Manager Certification Programs ~~, April 2012,~~ (Conference for Food Protection) is deemed to comply with 12VAC5-421-55.

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;[Pf]

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;[Pf]

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;[Pf]

4. Employees are effectively cleaning their hands, by routinely monitoring the employees' handwashing;[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;[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;[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;[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;[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;[Pf]

10. Food employees are properly maintaining the temperature of time/temperature control for safety foods during thawing through daily oversight of the food employees' routine monitoring of food temperatures;[Pf]

~~10.~~ 11. 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;[Pf]

~~11.~~ 12. 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;[Pf]

~~12.~~ 13. 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;[Pf]

~~13.~~ 14. Except when approval is obtained from the 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; [Pf]

~~14.~~ 15. Employees are properly trained in food safety, including food allergy awareness, as it relates to their assigned duties~~;~~[Pf]. Food allergy awareness includes describing 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;[Pf]

~~15.~~ 16. 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;[Pf] and

~~16.~~ 17. Written procedures and plans, where specified by this chapter and as developed by the food establishment, are maintained and implemented as required.[Pf]

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;[P]

b. Diarrhea;[P]

c. Jaundice;[P]

d. Sore throat with fever;[P] 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;[P]

(2) On exposed portions of the arms, unless the lesion is protected by an impermeable cover;[P] or

(3) On other parts of the body, unless the lesion is covered by a dry, durable, tight-fitting bandage;[P]

2. Has an illness diagnosed by a health practitioner due to:

a. Norovirus;[P]

b. Hepatitis A virus;[P]

c. Shigella spp.;[P]

d. Shiga toxin-producing Escherichia coli; [P]

e. Typhoid fever (caused by Salmonella typhi);[P] or

f. Salmonella (nontyphoidal);[P]

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

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; [P]

b. Shiga toxin-producing Escherichia coli, or Shigella spp. within the past three days of the last exposure;[P]

c. Typhoid fever (caused by Salmonella typhi) within the past 14 days of the last exposure;[P] or

d. Hepatitis A virus within the past 30 days of the last exposure;[P] 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, an individual diagnosed with an illness caused by:

a. Norovirus within the past 48 hours of the last exposure;[P]

b. Shiga toxin-producing Escherichia coli or Shigella spp. within the past three days of the last exposure;[P]

c. Typhoid fever (caused by Salmonella typhi) within the past 14 days of the last exposure;[P] or

d. Hepatitis A virus within the past 30 days of the last exposure.[P]

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

1. Jaundiced;[Pf] or

2. Diagnosed with an illness due to a pathogen as specified under subdivisions A 2 a through f of this section.[Pf]

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;[P] 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.[P]

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 subdivision 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;[P] or

2. Restricted as specified under subdivision 4 b, 5 b, 6 b, 7, 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.[P]

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

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;[P] or

2. Comply with a restriction as specified under subdivision 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.[P]

12VAC5-421-160. When to wash.

Food employees shall clean their hands and exposed portions of their arms as specified under 12VAC5-421-140 immediately before engaging in food preparation including working with exposed food, clean equipment and utensils, and unwrapped single-service and single-use articles[P] , and:

1. After touching bare human body parts or hair other than clean hands and clean, exposed portions of arms;[P]

2. After using the toilet room;[P]

3. After caring for or handling service animals or aquatic animals as allowed under 12VAC5-421-250 B;[P]

4. Except as specified in 12VAC5-421-220 B, after coughing, sneezing, using a handkerchief or disposable tissue, using tobacco products, eating, or drinking;[P]

5. After handling soiled equipment or utensils;[P]

6. During food preparation, as often as necessary to remove soil and contamination and to prevent cross contamination when changing tasks;[P]

7. When switching between working with raw foods and working with ready-to-eat foods;[P]

8. Before donning gloves to initiate a task that involves working with foods;[P] and

9. After engaging in other activities that contaminate the hands.[P]

12VAC5-421-220. Eating, drinking, or using tobacco products.

Article 4

Hygienic Practices

A. Except as specified in subsection B of this section, an employee shall eat, drink, or use any form of tobacco products only in designated areas where the contamination of exposed food; clean equipment, utensils, and linens; unwrapped single-service and single-use articles; or other items needing protection cannot result.

B. A food employee may drink from a closed beverage container if the container is handled to prevent contamination of:

1. The employee's hands;

2. The container; and

3. Exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles.

12VAC5-421-250. Handling of animals prohibited.

A. Except as specified in subsection B of this section, ~~food employees shall~~ a food employee may not care for or handle animals that may be present such as patrol dogs, service animals, or pets that are allowed under 12VAC5-421-3310 B 2, 3, ~~and 4.~~[~~Pf~~] 4, and 6.[Pf]

B. ~~Food employees~~ A food employee with a service ~~animals~~ animal may handle or care for ~~their~~ the service ~~animals and food employees~~ animal and a food employee may handle or care for fish in aquariums or molluscan shellfish or crustacea in display tanks ~~if they wash their~~ the food employee washes his hands as specified under 12VAC5-421-140 and subdivision 3 of 12VAC5-421-160.

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~~] [Pf]

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

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

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

1. Obtained from a food processing plant that ~~, upon request by the purchaser, packages the steaks and labels them to indicate that they meet the definition of~~ does not mechanically tenderize, vacuum tumble with solutions, reconstruct, cube or pound the whole-muscle, intact beef steaks;[Pf] or

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

3. If individually cut in a food establishment:

a. Cut from whole-muscle intact beef that is ~~labeled by~~ received from a food processing plant as specified in subdivision 1 of this subsection or identified as specified in subdivision 2 of this subsection; [P] and

b. Prepared so they remain intact ~~;~~[Pf] ~~and~~ .[Pf]

~~c. If packaged for undercooking in a food establishment, labeled as specified in subdivision 1 of this subsection or identified as specified in subdivision 2 of this subsection.~~[Pf]

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

G. 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).

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

A. ~~Raw shucked~~ Molluscan shellfish shall be obtained in nonreturnable packages or containers that bear a legible tag or label that identifies:[Pf]

1. The ~~name, address, and certification number of the shucker-packer, or repacker of the molluscan shellfish~~ source, and are affixed by a dealer that depurates, packs, ships, or reships the molluscan shellfish, as specified in the National Shellfish Sanitation Program Guide for Control of Molluscan Shellfish;[Pf] and

2. The "sell by" or "best if used by" date for shucked shellfish packages with a capacity of less than 64 fluid ounces (1.89L) or the date shucked for packages with a capacity of 64 fluid ounces (1.89L) or more.[Pf]

B. A ~~package~~ container of raw ~~shucked shellfish~~ molluscan shellfish that does not bear a tag or label or that bears a tag or label ~~which~~ 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.

12VAC5-421-420. Shellstock; condition.

When received by a food establishment, shellstock shall be reasonably free of mud, dead ~~shellfish~~ shellstock, and ~~shellfish~~ shellstock with broken shells. Dead ~~shellfish or~~ shellstock and shellstock with badly broken shells shall be discarded.

12VAC5-421-430. Molluscan shellfish; original container.

A. Except as specified in subsections ~~B, C, and D~~ C, D and E of this section, molluscan shellfish ~~shall~~ may not be removed from the container in which they were received other than immediately before sale or preparation for service.

B. Molluscan shellfish from one tagged or labeled container may not be commingled with molluscan shellfish from another container with different certification numbers, different harvest dates, or different harvest areas identified on the tag or label before being ordered by the consumer.[Pf]

~~B.~~ C. For display purposes, shellstock or in-shell product may be removed from the container in which they are received, displayed on drained ice, or held in a display container, and a quantity specified by a consumer may be removed from the display or display container and provided to the consumer if:

1. The source of the shellstock or in-shell product on display is identified as specified under ~~12VAC5-421-410~~ 12VAC5-421-400 and recorded as specified under 12VAC5-421-440; and

2. The shellstock or in-shell product are protected from contamination.

~~C.~~ D. Shucked shellfish may be removed from the container in which they were received and held in a display container from which individual servings are dispensed upon a consumer's request if:

1. The labeling information for the shellfish on display as specified under 12VAC5-421-400 is retained and correlated to the date when, or dates during which, the shellfish are sold or served; and

2. The shellfish are protected from contamination.

~~D.~~ E. Shucked shellfish may be removed from the container in which they were received and repacked in consumer self-service containers where allowed by law if:

1. The labeling information for the shellfish is on each consumer self-service container as specified under 12VAC5-421-400 and 12VAC5-421-900 A and B 1 through 5;

2. The labeling information as specified under 12VAC5-421-400 is retained and correlated with the date when, or dates during which, the shellfish are sold or served;

3. The labeling information and dates specified under subdivision ~~D~~ E 2 of this section are maintained for 90 days; and

4. The shellfish are protected from contamination.

12VAC5-421-440. ~~Shellstock; maintaining identification~~ Molluscan shellfish; maintain identification.

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

B. The date when the last ~~shellstock~~ molluscan shellfish from the container is sold or served shall be recorded on the ~~tag or label.~~[Pf] tag, label, or invoice.[Pf]

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

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

2. If ~~shellstock~~ shellstock, shucked shellfish, or in-shell product are removed from ~~its~~ the tagged or labeled

container:

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

b. Ensuring that ~~shellstock or shucked shellfish~~ shellstock, shucked shellfish, or in-shell product from one tagged or labeled container are not commingled with ~~shellstock or shucked shellfish~~ shellstock, shucked shellfish, or in-shell product 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.[Pf]

12VAC5-421-445. Food Donation.

Food that is stored, prepared, packaged, displayed, and labeled in accordance to law and this chapter may be offered for donation.

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 d of this subsection, or if combined as ingredients, 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;[P]

b. Cooked ready-to-eat food;[P]

c. Fruits and vegetables before they are washed;[P] and

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~~ if 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;[P] or

b. Arranging each type of food in equipment so that cross contamination of one type with another is prevented;[P] and

c. Preparing each type of food at different times or in separate areas.[P]

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~~ shall 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.

12VAC5-421-510. Washing fruits and vegetables.

A. Except as specified in subsection B of this section and except for whole, raw fruits and vegetables that are intended for washing by the consumer before consumption, raw fruits and vegetables shall be thoroughly washed in water to remove soil and other contaminants before

being cut, combined with other ingredients, cooked, served, or offered for human consumption in ready-to-eat form.

B. Fruits and vegetables may be washed by using chemicals as specified under 12VAC5-421-3390 and a test kit or other device that accurately measures the active ingredient concentration of the fruit and vegetable wash solution may be provided .

C. ~~Devices~~ A device used for onsite generation of chemicals meeting the requirements specified in 21 CFR 173.315 shall be used in accordance with the manufacturer's instructions.[Pf]

12VAC5-421-620. Food storage; prohibited areas.

Food shall not be stored:

1. In locker rooms;
2. In toilet rooms or their vestibules; [Pf]
3. In dressing rooms;
4. In garbage rooms;
5. In mechanical rooms;
6. Under sewer lines that are not shielded to intercept potential drips;
7. Under leaking water lines, including leaking automatic fire sprinkler heads, or under lines on which water has condensed;
8. Under open stairwells; or
9. Under other sources of contamination.

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:[P]

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

   b. ~~Except as~~ Unless otherwise specified ~~under~~ in 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;[P]

2. 155°F (68°C) for 17 seconds or the temperature specified in the following chart that corresponds to the holding time for ratites , ~~mechanically tenderized meats, and injected meats;~~ and nonintact 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:[P]

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

; or

3. 165°F (74°C) or above for less than one 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.[P]

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

1. 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:[P]

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

; and

2. If cooked in an oven, ~~use~~ using 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.[Pf]

~~f~~

Oven Type	Oven Temperature Based on Roast Weight	
	Less than 10 lbs (4.5 kg)	10 lbs (4.5 kg) or more
Still Dry	350°F (177°C) or more	250°F (121°C) or more
Convection	325°F (163°C) or more	250°F (121°C) or more
High Humidity[1]	250°F (121°C) or less	250°F (121°C) or less
[1]Relative humidity greater than 90% for at least one hour as measured in the cooking chamber or exit of the oven; or in a moisture-impermeable bag that provides 100% humidity.		

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"~~ prepared so that it remains intact ; 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~~ Pursuant to subdivisions 3 a and 3 b of 12VAC5-421-950 , the food establishment serves a population that is not a highly susceptible population; ~~2. The~~ the food, if served or offered for service by consumer selection from a children's menu, does not contain comminuted meat;[Pf] and ~~3. The~~ the consumer is informed ~~as specified under~~ , pursuant to 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.~~ 2. The department grants a variance from subsection A or B of this section ~~as specified in~~ pursuant to 12VAC5-421-3570 based on a HACCP plan that:

a. Is submitted by the permit holder and approved ~~as specified under~~ pursuant to 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.

12VAC5-421-726. Manufacturer cooking instructions.

A. Commercially packaged food that bears a manufacturer's cooking instructions shall be cooked according to those instructions before use in ready-to-eat foods or offered in unpackaged form for human consumption, unless the manufacturer's instructions specify that the food may be consumed without cooking. [P]

B. Food for which the manufacturer has provided information that it has not been processed to control pathogens, when used in read-to-eat foods or offered for human consumption, shall be cooked according to a time and temperature appropriate for the food. [P]

12VAC5-421-790. Thawing.

A. Except as specified in subdivision 4 of this subsection, time/temperature control for safety food shall be thawed:

1. Under refrigeration that maintains the food temperature at 41°F (5°C) or less; [Pf]

2. Completely submerged under running water:

a. At a water temperature of 70°F (21°C) or below; [Pf]

b. With sufficient water velocity to agitate and float off loose particles in an overflow; [Pf] and

c. For a period of time that does not allow thawed portions of ready-to-eat food to rise above 41°F (5°C); [Pf] or

d. For a period of time that does not allow thawed portions of a raw animal food requiring cooking ~~as specified under~~ pursuant to 12VAC5-421-700 A or B to be above 41°F (5°C) for more than four hours including:

(1) The time the food is exposed to the running water and the time needed for preparation for cooking; Pf or

(2) The time it takes under refrigeration to lower the food temperature to 41°F (5°C); Pf

3. As part of a cooking process if the food that is frozen is:

a. Cooked ~~as specified under~~ pursuant to 12VAC5-421-700 A or B ~~or~~ , 12VAC5-421-710 or, 12VAC5-421-726 ; Pf or

b. Thawed in a microwave oven and immediately transferred to conventional cooking equipment, with no interruption in the process; Pf or

4. Using any procedure if a portion of frozen ready-to-eat food is thawed and prepared for immediate service in response to an individual consumer's order.

B. Reduced oxygen packaged fish that bears a label indicating that it is to be kept frozen until time of use shall be removed from the reduced oxygen environment:

1. ~~Prior to its~~ Before thawing under refrigeration ~~as specified in~~ pursuant to subdivision A 1 of this section.

2. ~~Prior to~~ Before , or immediately upon completion of, ~~its~~ thawing using procedures specified in subdivision A 2 of this section.

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

A. Except ~~when~~ if packaging food using a reduced oxygen packaging method ~~as specified under~~ pursuant to 12VAC5-421-870, and except as specified in ~~subsections~~ subsection E ~~and F~~ of this section, refrigerated ready-to-eat time/temperature control for safety food that is 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~~ if held at a temperature ~~of~~ at or below 41°F (5°C) ~~or less~~ for a maximum of seven days. The day of preparation shall be counted as day 1.Pf

B. Except as specified in subsections E ~~,~~ and F ~~, and G~~ of this section, refrigerated ready-to-eat, time/temperature control for safety food that is 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~~ . If the food is held for more than 24 hours, ~~to~~ the date marking shall 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:Pf

1. The day the original container is opened in the food establishment shall be counted as day 1;Pf and

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.Pf

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.Pf

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 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~~ shall be disclosed to the department upon request.

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

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

~~G.~~ Subsection B of this section ~~does~~ shall 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;~~ 21 CFR 117;

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 department upon request that specify:[Pf]

1. Methods of compliance with subsection B or C of this section;[Pf] and

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.[Pf]

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

1. ~~The~~ Unless otherwise specified in subdivision B 2 of this this section, 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; [P]

2. The food may have an initial temperature of 70°F (21°C) of less if:

a. It is a ready-to-eat fruit or vegetable that upon cutting is rendered a time/temperature control for safety food; or

b. It is a ready-to-eat hermetically sealed food that upon opening is rendered a time/temperature control for safety food;

c. The food temperature does not exceed 70°F (21°C) within a maximum time period of 4 hours from the time it was rendered a time/temperature control for safety food; and

d. The food is marked or otherwise identified to indicate the time that is 4 hours after the food is rendered a time/temperature control for safety food as specified in subdivisions B 2 a and B 2 b of this section.

~~2.~~ 3. The food shall be marked or otherwise identified to indicate the time that is four hours ~~past the point in time when~~ after the food is removed from temperature control; Pf

~~3.~~ 4. 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;P and

~~4.~~ 5. The food in unmarked containers or packages, or marked to exceed a four-hour limit shall be discarded.P

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 41ºF (5ºC) or less when removed from temperature control and the food temperature may not exceed 70ºF (21ºC) within ~~a maximum time period of~~ the six ~~hours~~ hour period ;P

2. The food shall be monitored or an ambient air temperature shall be maintained to ensure that the warmest portion of the food does not exceed 70ºF (21ºC) during the six-hour period ~~, unless an ambient air temperature is maintained that ensures the food does not exceed 70ºF (21ºC) during the six-hour holding period~~ ;Pf

3. The food shall be marked or otherwise identified to indicate:Pf

a. The time when the food is removed from 41ºF (5ºC) or less cold-holding temperature control,Pf and

b. The time that is six hours ~~past the point in time when~~ after the food is removed from 41ºF (5ºC) or less cold-holding temperature control;Pf

4. The food shall be:

a. Discarded if the temperature of the ~~foods~~ food exceeds 70ºF (21ºC);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 41ºF (5ºC) or less cold-holding temperature control;P and

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

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

A. Except for a food establishment that obtains a variance ~~as specified under~~ pursuant to 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.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 implement a HACCP plan that contains the information specified under subdivisions 3 and ~~4~~ 5 of 12VAC5-421-3630 and that:[Pf]

1. Identifies the food to be packaged;[Pf]

2. Except as specified in subsections C, D, and E 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:[Pf]

a. Has an A_w of 0.91 or less;[Pf]

b. Has a pH of 4.6 or less;[Pf]

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;[Pf] or

d. Is a food with a high level of competing organisms such as raw meat, raw poultry, or raw vegetables ~~.~~ ; [Pf]

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:[Pf]

a. Maintain the food at 41°F (5°C) or ~~below~~ less ;[Pf] and

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;[Pf]

4. Limits the refrigerated shelf life to (i) no more than 30 calendar days from packaging to consumption, except the time the product is maintained frozen, or (ii) the original manufacturer's "sell by" or "use by" date, whichever occurs first;[P]

5. Includes operational procedures that:

a. Prohibit contacting ready-to-eat food with bare hands as specified in 12VAC5-421-450 B;[Pf]

b. Identify a designated work area and the method by which:[Pf]

(1) Physical barriers or methods of separation of raw foods and ready-to-eat foods minimize cross contamination;[Pf] and

(2) Access to the processing equipment is limited to responsible trained personnel familiar with the potential hazards of the operation;[Pf] and

c. Delineate cleaning and sanitization procedures for food contact surfaces;[Pf] and

6. Describes the training program that ensures that the individual responsible for the reduced oxygen packaging operation understands the:[Pf]

a. Concepts required for safe operation;[Pf]

b. Equipment and facilities;[Pf] and

c. Procedures specified under subdivision B 5 of this section and subdivisions 3 and ~~4~~ 5 of 12VAC5-421-3630 ~~;~~ . [Pf] and

7. Is provided to the department ~~prior to~~ before implementation ~~as specified under~~ pursuant to 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.[P]

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~~ Submit to the department ~~prior to~~ before implementation a HACCP plan that contains the information ~~as specified under~~ required pursuant to subdivisions 3 and ~~4~~ 5 of 12VAC5-421-3630;[Pf]

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;[Pf]

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

c. Protected from contamination before and after cooking ~~as specified in~~ pursuant to 12VAC5-421-450 through 12VAC5-421-765;[P]

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);[P]

e. Cooled to 41°F (5°C) in the sealed package ~~as specified under~~ pursuant to 12VAC5-421-800; and:[P]

(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;[P]

(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;[P] ~~or~~

(3) Cooled to 34°F (1°C) within 48 hours of reaching 41°F (5°C), removed from refrigeration equipment that maintains at 34°F (1°C) food temperature and then held at 41°F (5°C) or less for no more than 7 days not to exceed 30 days from its date of packaging, at which time the food must be consumed or discarded;[P] or

~~(3)~~ (4) Held frozen with no shelf-life restriction while frozen until consumed or used;[P]

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;[Pf]

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;[Pf] and

h. Labeled with the product name and the date packaged; [Pf] ~~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, maintained ~~and: a. Made~~ , made available to the department upon request ~~;~~ , [Pf] and ~~b. Held~~ held for six months;[Pf] 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.[Pf]

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 (i) are commercially manufactured in a food processing plant with no ingredients added in the food establishment and ~~that~~ (ii) meet the Standards of Identity as specified in 21 CFR 133.150, 21 CFR 133.169, or 21 CFR 133.187;[P]

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;[Pf]

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;[Pf] 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.[Pf]

F. A HACCP plan ~~is~~ shall not be required ~~when~~ if 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;[Pf]

6. Except as exempted in the Federal Food, Drug, and Cosmetic Act § 403(Q)(3) through (5), nutrition labeling as specified in 21 CFR Part 101 and 9 CFR Part 317, Subpart B; and

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, 5, and 6 of this section.

D. Bulk, unpackaged foods such as bakery products and unpackaged foods that are portioned to consumer specification shall not need ~~not~~ to 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.

12VAC5-421-910. Other forms of information.

A. If required by law, consumer warnings shall be provided.

B. ~~Food establishment~~ No person may conceal or alter a food establishment's or ~~manufacturers'~~ manufacturer's dating information on foods ~~shall not be concealed or altered~~.

C. The permit holder shall notify consumers by written notification of the presence of major food allergens as an ingredient in unpackaged food items that are served or sold to the consumer.

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~~ subdivision 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) or a packaged juice or beverage containing juice that bears a warning label ~~as specified under~~ pursuant to subdivision 2 of 12VAC5-421-765 may not be served or offered for sale;[P] 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~~ pursuant to subdivisions 3, ~~4, and~~ 5 , and 6 of 12VAC5-421-3630 and ~~as specified in~~ pursuant to 21 CFR 120.24.[P]

2. Pasteurized eggs or egg products shall be substituted for raw eggs in the preparation of:[P]

a. Foods such as Caesar salad, hollandaise or bèarnaise sauce, mayonnaise, meringue, eggnog, ice cream, and egg-fortified beverages;[P] 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.[P]

3. The following foods shall not be served or offered for sale in a ready-to-eat form:[P]

a. Raw animal foods such as raw fish, raw-marinated fish, raw molluscan shellfish, and steak tartare;[P]

b. A partially cooked animal food such as lightly cooked fish, rare meat, soft-cooked eggs that are made from raw eggs, and meringue;[P] ~~and~~

c. Raw seed sprouts ~~.~~ ; [P] and

d. Packaged food as specified in 12VAC5-421-726.

4. ~~Food employees shall~~ A food employee may not contact ready-to-eat food ~~as specified in~~ pursuant to 12VAC5-421-450 B and E.[P]

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

6. Subdivision 2 b of this section ~~does~~ shall 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~~ required by 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~~ pursuant to 12VAC5-421-680 B 1 and 2.

8. Food may not be re-served under the following conditions:

a. ~~Any food~~ Food served to ~~patients or clients who are~~ a patient or client under contact precautions in medical isolation or quarantine ~~,~~ or protective environment isolation may not be re-served to others outside.

b. ~~Packages~~ A package of food from ~~any patients, clients, or other consumers should~~ a patient, client, or other consumer may not be re-served to ~~persons~~ a person in protective environment isolation.

12VAC5-421-1435. Food equipment, certification and classification.

Food equipment that is certified or classified for sanitation ~~by an~~ in conformance to a recognized American National Standards Institute (ANSI)-accredited certification program is deemed to comply with the requirements of Articles 1 (12VAC5-421-960 et seq.) and 2 (12VAC5-421-1080 et seq.) of this part.

12VAC5-421-1535. Cleaning agents and sanitizers, availability.

A. ~~Cleaning agents that are~~ A cleaning agent that is used to clean equipment and utensils ~~as specified under~~ pursuant to Article 6 (12VAC5-421-1770 et seq.) of this part shall be provided and available for use during all hours of operation. Pf

B. Except for a chemical ~~sanitizers that are~~ sanitizer that is generated on site at the time of use, a chemical ~~sanitizers that are~~ sanitizer that is used to sanitize equipment and utensils ~~as specified under~~ pursuant to Article 7 shall be provided and available for use during all hours of operation. Pf

12VAC5-421-1540. Equipment, clothes washers and dryers, and storage cabinets, contamination prevention.

~~Article 4~~

~~Location and Installation~~

A. ~~Except as specified in subsection B of this section, equipment,~~ Equipment, cabinets used for the storage of food, or cabinets used to store cleaned and sanitized equipment, utensils, laundered linens, and single-service and single-use articles ~~shall~~ may not be located:

1. In locker rooms , except pursuant to subsection B of this section ;

2. In toilet rooms or vestibules; Pf

3. In garbage rooms;

4. In mechanical rooms;

5. Under sewer lines that are not shielded to intercept potential drips;

6. Under leaking water lines including leaking automatic fire sprinkler heads or under lines on which water has condensed;

7. Under open stairwells; or

8. Under other sources of contamination.

B. A storage cabinet used for linens or single-service or single-use articles may be stored in a locker room.

C. If a mechanical clothes washer or dryer is provided, it shall be located only where there is no exposed food; clean equipment, utensils, and linens; unwrapped single-service and single-use articles; and so that the washer or dryer is protected from contamination.

12VAC5-421-2010. Prohibitions.

A. ~~Except as specified in subsection B of this section, cleaned~~ Cleaned and sanitized equipment, utensils, laundered linens, and single-service and single-use articles ~~shall~~ may not be stored:

1. In locker rooms , except pursuant to subsection B of this section ;

2. In toilet rooms or vestibules; Pf

3. In garbage rooms;

4. In mechanical rooms;

5. Under sewer lines that are not shielded to intercept potential drips;

6. Under leaking water lines including leaking automatic fire sprinkler heads or under lines on which water has condensed;

7. Under open stairwells; or

8. Under other sources of contamination.

B. Laundered linens and single-service and single-use articles that are packaged or in a facility such as a cabinet may be stored in a locker room.

12VAC5-421-2190. Handwashing sinks, water temperature, and flow.

A. A handwashing sink shall be equipped to provide water at a temperature of at least ~~100°F (38°C)~~ 85°F (29.4°C) through a mixing valve or combination faucet.Pf

B. A steam mixing valve ~~shall~~ may not be used at a handwashing sink.

C. A self-closing, slow-closing, or metering faucet shall provide a flow of water for at least 15 seconds without the need to reactivate the faucet.

D. An automatic handwashing facility shall be installed in accordance with the manufacturer's instructions.

12VAC5-421-3140. Employee accommodations, designated areas.

A. Areas designated for employees to eat, drink, and use tobacco products shall be located so that food, equipment, linens, and single-service and single-use articles are protected from contamination.

B. Lockers or other suitable facilities shall be located in a designated room or area where contamination of food, equipment, utensils, linens, and single-service and single-use articles can not occur.

12VAC5-421-3360. Conditions of use.

Poisonous or toxic materials shall be:

1. Used according to:

a. Law and this chapter;

b. Manufacturer's use directions included in labeling, and, for a pesticide, manufacturer's label instructions that state that use is allowed in a food establishment;[P]

c. The conditions of certification, if certification is required, for use of the pest control materials;[P] and

d. Additional conditions that may be established by the department; and

2. Applied so that:

a. A hazard to employees or other persons is not constituted;[P] 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:[P]

(1) Removing the items;[P]

(2) Covering the items with impermeable covers;[P] or

(3) Taking other appropriate preventive actions;[P] and

(4) Cleaning and sanitizing equipment and utensils after the application.[P]

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.[Pf]

12VAC5-421-3370. Poisonous or toxic material containers.

A container previously used to store poisonous or toxic materials ~~shall~~ may not be used to store, transport, or dispense food ~~.~~[P] , equipment, utensils, linens, single-service, or single-use articles.[P]

12VAC5-421-3510. Public health protection.

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

B. In enforcing the provisions of this ~~regulation~~ chapter , the department shall assess existing facilities or equipment that were in use before June 10, 2021, 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.

12VAC5-421-3595. Conformance with approved procedures.

If the commissioner or the commissioner's designee grants a variance ~~as specified in~~ pursuant to 12VAC5-421-3570 ~~,~~ or a HACCP plan is otherwise required ~~as specified under~~ pursuant to 12VAC5-421-3620, the permit holder shall:

1. Maintain the approved variance at the food establishment; [Pf]

~~1.~~ 2. Comply with the HACCP plans and procedures that are submitted ~~as specified under~~ pursuant to 12VAC5-421-3630 and approved as a basis for the variance;[P] and

~~2.~~ 3. Maintain and , upon request, provide to the department ~~, upon request,~~ records specified under subdivisions ~~4 and~~ 5 and 6 c of 12VAC5-421-3630 that demonstrate that the following are routinely employed:

a. Procedures for monitoring the critical control points;[PF]

b. Monitoring of the critical control points;[PF]

c. Verification of the effectiveness of the operation or process;[PF] and

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

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

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

1. General information ~~such as~~ including 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;[Pf]

3. A flow diagram or chart for each specific food or category type that identifies:

a. Each step in the process,[Pf] and

~~b. The hazards and controls for each step in the flow diagram or chart,[Pf]~~

~~c.~~ b. The steps that are critical control points,[Pf]

~~d. The ingredients, materials, and equipment used in the preparation of that food,[Pf] and~~

~~e. Formulations or recipes that delineate methods and procedural control measures that address the food safety concerns involved.[Pf]~~

4. The ingredients, recipes or formulations, materials and equipment used in the preparation of each specific food or category type and the methods and procedural control measures that address the food safety concerns involved;[Pf]

~~4.~~ 5. A critical control points summary for each specific food or category type that clearly identifies:

a. Each critical control point;[Pf]

b. The significant hazards for each critical control point, [Pf]

~~b.~~ c. The critical limits for each critical control point;[Pf]

~~c.~~ d. The method and frequency for monitoring and controlling each critical control point by the designated food employee ~~designated by~~ or the person in charge;[Pf]

~~d.~~ e. The method and frequency for the person in charge or food employee to routinely verify that the food employee is following standard operating procedures and monitoring critical control points;[Pf]

~~e. Action~~ f. The action to be taken by the food employee or person in charge if the critical limits for each critical control point are not met;[Pf] and

~~f.~~ g. Records to be maintained by the person in charge to demonstrate that the HACCP plan is properly operated and managed;[Pf]

~~5.~~ 6. Supporting documents such as ~~such as~~ , including :

a. Food employee and supervisory training plan addressing food safety issues;[Pf]

b. Copies of blank records forms that are necessary to implement the HACCP plan;[Pf]

c. Additional scientific data or other information, as required by the department , supporting the determination that food safety is not compromised by the proposal;[Pf] and

~~6.~~ 7. Any other information required by the department.

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. Attests 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 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 5 of 12VAC5-421-3630; and

8. Other information required by the department.

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

The 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 , 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 department as specified under 12VAC5-421-60;

e. Failure of the person in charge to provide records required by the department for determining conformance with a HACCP plan as specified under subdivision ~~4 f~~ 5 g of 12VAC5-421-3630; and

f. Nonconformance with critical limits of a HACCP plan.

Regulations for the Certificate of Public Need
12VAC5-220
Fast Track Amendments

Rebekah E. Allen
Senior Policy Analyst
Office of Licensure and Certification

COMMONWEALTH of VIRGINIA

Department of Health

Karen Shelton, MD
State Health Commissioner

P O BOX 2448
RICHMOND, VA 23218

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

MEMORANDUM

DATE: October 20, 2023

TO: State Board of Health

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

SUBJECT: Fast Track Action – Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations – Promulgation of Fee Schedule

---

Enclosed for your review are fast track amendments to Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations (12VAC5-220-10 *et seq.*).

This Fast Track action is being utilized to conform 12VAC5-220-10 *et seq*. to the Code of Virginia. Chapter 1271 (2020 Acts of Assembly) removed the statutory cap on fees and included authority for the State Board of Health to establish a fee schedule for the applications that it receives. The State Board of Health previously approved a Fast Track action to create a fee schedule on March 18, 2021. After this Fast Track was published, the Virginia Hospital & Healthcare Association and the Virginia Health Care Association approached the agency during the public comment period requesting that the fee schedule be reconsidered; otherwise, the Fast Track would receive enough objections to move it from a Fast Track to a standard regulatory action. VDH withdrew the stage and has been in discussions with those stakeholders about revisions to the fee schedule, which is before you today. This regulatory action creates a fee schedule for the COPN program and revises the fee cap on applications, removes the definition of "application fee", replaces the repealed definition with a new section number 125 that sets out the fee schedule for COPN applications and registration applications, and updates the regulatory text for internal consistency with the new fee schedule.

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

townhall.virginia.gov

Fast-Track Regulation
Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC 5-220-10 *et seq.*
VAC Chapter title(s)	Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations
Action title	Promulgation of Fee Schedule
Date this document prepared	October 20, 2023

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code.*

Brief Summary

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

Chapter 1271 of the 2020 Acts of Assembly made extensive revisions to Article 1.1 (§ 32.1-102.1 *et seq.*) of Chapter 4 of Title 32.1 of the Code of Virginia, which governs the Certificate of Public Need program in VDH. The amendments removed the prior statutory cap on fees and included authority for the State Board of Health to establish a fee schedule for the applications that it receives. This regulatory action creates a fee schedule for the COPN program and revises the fee cap on applications.

Acronyms and Definitions

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

"Agency" means the Virginia Department of Health.

"Board" means the State Board of Health.

"COPN" means Certificate of Public Need.

"ICF/IID" means intermediate care facility for individuals with intellectual disabilities.

"RHPA" means regional health planning agency.

"SHSP" means the State Health Services Plan.

"VDH" means the Virginia Department of Health.

Statement of Final Agency Action

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

Enter statement here

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, "mandate" has the same meaning as defined in the ORM procedures, "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."

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

Chapter 1271 (2020) made extensive revisions to Article 1.1 (§ 32.1-102.1 *et seq.*) of Chapter 4 of Title 32.1 of the Code of Virginia, which governs the COPN program in VDH. Va. Code § 32.1-102.2(A)(5) previously granted the Board the authority to establish a fee schedule for COPN applications, but the fees were capped at "the lesser of one percent of the proposed expenditure for the project or $20,000"; this fee cap was created in 1996 and was an increase from the prior fee cap of $10,000. With the amendments introduced by Chapter 1271 (2020), the authority to establish a fee schedule has been renumbered as Va. Code § 32.1-102.2(A)(5), expanded to include registration applications, and removed the fee cap. Chapter 1271 (2020) also increased the review interval for the SHSP (formerly the State Medical Facilities Plan) from four years to two years and placed new requirements on VDH to have a publicly available electronic inventory of COPN-authorized capacity. These changes require an additional two FTEs and the Board is establishing a new fee schedule to support the existing COPN program, the new program obligations, and the new FTEs.

It's anticipated that this action will be noncontroversial and appropriate for the fast-track process because:

- the fee being charged for registration applications is nominal;
- the fee being charged for COPN applications retains a fee cap (though it has been adjusted higher) and still utilizes a formula of the lesser of 1.5 percent of the proposed project expenditure or the fee cap; and
- the changes to the fee schedule proposed in this action were developed with robust stakeholder engagement.

Legal Basis

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

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

Va. Code § 32.1-102.2(A)(4) states that the Board shall promulgate regulations that are consistent with this article and "…[m]ay establish a schedule of fees for applications for certificates or registration of a project to be applied to expenses for the administration and operation of the Certificate of Public Need Program[.]"

Purpose

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

The rationale or justification of the regulatory change is that the COPN program should be primarily, if not entirely, supported by fee revenue rather than general funds. The specific reasons the regulatory change is essential to protect the health, safety, or welfare of citizens is that the continued financial health of the COPN program ensures that the healthcare marketplace is not characterized by unneeded medical facilities or equipment and that charity care is being provided to indigent patients. There is a minimum patient volume needed to ensure continued competency of staff providing care, which is a consideration of COPN programs staff when evaluating COPN requests; COPNs are also conditioned on the provision of a prescribed amount of charity care to indigent patients, which allows healthcare to be accessible to more patients. The goals of the regulatory change are to ensure that VDH receives sufficient revenue to support its COPN program and the mandated activities that the COPN program carries out. The problem the regulatory change is intended to solve is to update a fee cap that has not been changed in over 20 years and to create a fee for the registration process that currently lacks one.

Substance

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

12VAC5-220-10. *Definitions.*
Repeal of the definition for "application fee."

12VAC5-220-105. *Requirements for registration of the replacement of existing medical equipment.*
Specifies that the registration has to be accompanied by the fee prescribed in 12VAC5-220-125.

12VAC5-220-110. *Requirements for registration of certain capital expenditures.*
Specifies that the registration has to be accompanied by the fee prescribed in 12VAC5-220-125.

12VAC5-220-125. *Fee schedule.*
A new section; creates a fee schedule for COPN applications and registration applications.

12VAC5-220-180. *Application forms.*
Specifies that the registration has to be accompanied by the fee prescribed in 12VAC5-220-125.

12VAC5-220-355. *RFA project application forms.*
Specifies that the registration has to be accompanied by the fee prescribed in 12VAC5-220-125.

Issues

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

The primary advantages to the public are a sufficiently funded COPN program that can regulate the healthcare marketplace, that maintains and updates the SHSP, and that monitors compliance with charity care conditions on COPNs. The primary disadvantage to the public is the assessment of higher fees for COPN projects if the project cost is in excess of $1.33 million. The primary advantages to VDH and the Commonwealth are that the COPN program will have sufficient fee revenue to support its current staff, the two new FTEs, and the new mandates that the COPN program must meet. There are no primary disadvantages to the Commonwealth. There are no other pertinent matters of interest to the regulated community, government officials, and the public.

Requirements More Restrictive than Federal

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

There are no applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Consistent with § 2.2-4007.04 of the Code of Virginia, identify any other state agencies, localities, or other entities particularly affected by the regulatory change. Other entities could include local partners such as tribal governments, school boards, community services boards, and similar regional organizations. "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

The two licensed nursing homes operated by the Department of Veterans Services, the licensed general hospital operated by Virginia Commonwealth University (VCU) Health Systems Authority, the general hospital operated by the University of Virginia (UVA) Medical Center, and any state agency wishing to begin a project that would require either a COPN or registration with the COPN program are particularly affected by this proposed regulatory change.

Localities Particularly Affected

The County of Bedford, Lee County Hospital Authority, and Chesapeake Hospital Authority may be particularly affected by this proposed regulatory change since Bedford operates a nursing home and the two hospital authorities operate a licensed general hospital each and would be particularly affected by this proposed regulatory change. Additionally, any locality wishing to begin a project that would require either a COPN or registration with the COPN program would be particularly affected by this proposed regulatory change.

Other Entities Particularly Affected

Any person wishing to begin a project that would require either a COPN or registration with the COPN program are particularly affected by this proposed regulatory change.

Economic Impact

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

Impact on State Agencies

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	There are no projected costs, savings, or revenue loss resulting from the regulatory change. Fee calculations are based on the average annual number of projects and project costs for SFYs2015-2020 due to the variability in the number of project applications and capital expenditure costs observed by the COPN program after the start of the COVID-19 pandemic in 2020. The data for SFYs2021-2023 do not reflect anticipated typical COPN expenditure and revenue, and therefore were not utilized in these fee calculations. The SFY2020 budget to administer the COPN program was $981,368. COPN application fee revenue in SFY2020 was $1,022,030, a 4.1% margin ($40,662) over budget. The SFY2024 budget includes an additional two FTEs for the COPN program to provide support to the production of the State Health Services Plan and to provide community outreach and education on the COPN program; therefore, there is not

	sufficient revenue from the current fee structure to support the COPN program. The annual number of COPN applications cannot be accurately predicted and the number of applications received for SFY15-SFY20 has varied from a low of 38 applications to a high of 61 applications. In SFY1995 (the year before the last increase in COPN application fees), the average proposed capital expenditure for a proposed COPN project was $3,132,053 (range $0 - $54,524,000) and the average COPN application fee was $6,215 (range $0 - $10,000). In SFY1995, only 37% of COPN application fees were at the maximum allowed. In SFY2020, the average proposed capital expenditure for a proposed COPN project was $9,100,992 (range $0 - $155,764,458) and the average COPN application fee was $15,254 (range $1,000 - $20,000). In SFY2020, 63% of projects seeking COPN authorization had estimated capital costs greater than $2,000,000. With the inclusion of two new FTEs, the COPN program budget's "annual revenue target" is now $1,704,141. Item 300 of the State Budget provides that any COPN application fees in excess of the amount required to operate the COPN program (less than one month's operating expenses) shall be provided to RHPAs as supplemental funding, which in a year with an average number of expected applications would result in $52,432 ($74,622 less than one month's operating expenses) being provided to the RHPAs. The projected fees resulting from the regulatory change are a fee of $70 for registration and a fee of 1.5% of the estimated capital expenditure for the project (with a minimum of $1,600 and maximum of $44,000) for all other projects. The projected total revenue resulting from the regulatory change is at least $1,704,141 annually, which is an increase of $682,471 compared to SFY2020's fee revenue.
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.	There are no projected savings, fees or revenues resulting from the regulatory change resulting from the regulatory change for other state agencies. The projected costs for other state agnecies are identical to those being assessed on other entities, which is a fee of $70 for registration and a fee of 1.5% of the estimated capital expenditure for the project (with a

	minimum of $1,600 and maximum of $44,000) for all other projects.
For all agencies: Benefits the regulatory change is designed to produce.	VDH will have sufficient fee revenue to support its COPN program activities and staff.

Impact on Localities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a or 2) on which it was reported. Information provided on that form need not be repeated here.

Projected costs, savings, fees or revenues resulting from the regulatory change.	There are no projected savings, fees or revenues resulting from the regulatory change resulting from the regulatory change for localities. The projected costs for localities are identical to those being assessed on other entities, which is a fee of $70 for registration and a fee of 1.5% of the estimated capital expenditure for the project (with a minimum of $1,600 and maximum of $44,000) for all other projects.
Benefits the regulatory change is designed to produce.	VDH will have sufficient fee revenue to support its COPN program activities and staff.

Impact on Other Entities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a, 3, or 4) on which it was reported. Information provided on that form need not be repeated here.

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.	The individuals, business, or other entities likely to be affected by the regulatory change are any that seek to apply for a COPN for a project or for registration of qualified projects. This potentially includes hospitals, nursing homes, ICF/IIDs, and some physician offices.
Agency's best estimate of the number of such entities that will be affected. Include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	There are 103 general hospitals, 73 outpatient surgical hospitals, 8 psychiatric hospitals, 289 nursing homes, 61 ICF/IIDs, and 22,874 doctors of medicine. There is not data available about how many doctors of medicine operate a physician's office and how many of that number would be engaging in services or utilizing equipment that would require either registration or a COPN; however, it is likely that all doctors of medicine would qualify as a small business if they did operate a physician's office, unless the physician's office is owned by a health system or other larger entity that is not a small business. Over SFYs2015-2020, COPN requests from physician groups make up an average of 18.8% of all requests (an average of 8.8 requests per year).
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to:	There are no projected savings, fees or revenues resulting from the regulatory change resulting from the regulatory change for affected individuals, businesses, or other entities. The

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.	projected costs are a fee of $70 for registration and a fee of 1.5% of the estimated capital expenditure for the project (with a minimum of $1,600 and maximum of $44,000) for all other projects.
Benefits the regulatory change is designed to produce.	VDH will have sufficient fee revenue to support its COPN program activities and staff.

Alternatives to Regulation

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

There are no viable alternatives to the regulatory change as the Board has no other method other than the promulgation of regulations to create a fee schedule.

Regulatory Flexibility Analysis

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

There are no alternative regulatory methods. The Board is required by the General Assembly to regulate the COPN program. The Board has no other method other than the promulgation of regulations to create a fee schedule.

Public Participation

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

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

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

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

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

Detail of Changes

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

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
220-10	N/A	This section contains the definitions for 12VAC5-220.	**Change:** The Board is proposing to remove the definition of “application fee”. **Intent:** The intent of this change is to remove the previous application fee requirements from the definitions section **Rationale:** The rationale of this change is that there is no need to keep this outdated definition because a fee schedule is being created. **Likely Impact:** The likely impact of this change is that the regulation will not contain conflicting information.
220-105	N/A	This section contains the requirements for the registration of the replacement of existing medical equipment.	**Change:** The Board is proposing to add language to require the payment of a $70 fee for registrations.

			Intent: The intent of this change is to require a fee for the registration of medical equipment. **Rationale:** The rationale for this change is that Chapter 1271 of the 2020 Act of Assembly authorizes the Board to collect an fee for registration of equipment and collection of a fee will partially offset administrative costs to the agency for processing registration applications. **Likely Impact:** The likely impact of this change is that regulants will now pay a fee to register medical equipment.
220-110	N/A	This section contains the requirements for the registration of certain capital expenditures.	**Change:** The Board is proposing to add language to require the payment of a $70 fee for registrations. **Intent:** The intent of this change is to require a fee for the registration of certain capital expenditures. **Rationale:** The rationale for this change is that Chapter 1271 of the 2020 Act of Assembly authorizes the Board to collect a fee for the registration of certain capital expenditures and collection of a fee will partially offset administrative costs to the agency for processing registration applications. **Likely Impact:** The likely impact of this change is that regulants will now pay a fee to register medical equipment.
N/A	220-125		**Change:** The Board is proposing to create a new section for the fee schedule. This new section: • Increases the fee percentage from 1% to 1.5% of the total capital expenditure; • Increases the minimum and maximum fee caps to $1,600 and $44,000; • Requires a $70 registration fee for certain capital expenditures and medical equipment and services; and • Prescribes a $50 dishonored payment fee as authorized by Va. Code § 2.2-4805. **Intent:** The intent of this change is to update the fees for the COPN program.

			Rationale: The rationale for this change is that Chapter 1271 of the 2020 Act of Assembly authorizes the Board to change the fee amounts in order to ensure sufficient operating costs for the COPN division and these amounts are calculated to achieve that goal. **Likely Impact:** The likely impact of this change is that VDH will have sufficient fee revenue to support its COPN program activities and staff.
220-180		This section contains the application requirements for a certificate of public need.	**Change:** The Board is proposing to remove the previous fee language and add a cross-reference to the new fee schedule in 12VAC5-220-125. **Intent:** The intent of this change is to update the COPN fees. **Rationale:** The rationale for this change is that Chapter 1271 of the 2020 Act of Assembly authorizes the Board to change the fee amounts in order to ensure sufficient operating costs for the COPN division and that the fees should be located in a single regulatory section and cross-referenced. **Likely Impact:** The likely impact of this change is that VDH will have sufficient fee revenue to support its COPN program activities and staff.
220-355		This section contains the application requirements for an RFA project.	**Change:** The Board is proposing to remove the previous fee language and add a cross-reference to the new fee schedule in 12VAC5-220-125. **Intent:** The intent of this change is to update the COPN fees. **Rationale:** The rationale for this change is that Chapter 1271 of the 2020 Act of Assembly permits the Board to change the fee amounts in order to ensure sufficient operating costs for the COPN division and that the fees should be located in a single regulatory section and cross-referenced. **Likely Impact:** The likely impact of this change is that VDH will have sufficient fee revenue to support its COPN program activities and staff.

Office of Regulatory Management

Economic Review Form

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC 5-220-10 *et seq*.
VAC Chapter title(s)	Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations
Action title	Promulgation of Fee Schedule
Date this document prepared	October 20, 2023
Regulatory Stage (including Issuance of Guidance Documents)	Fast Track

Cost Benefit Analysis

Table 1a: Costs and Benefits of the Proposed Changes (Primary Option)

(1) Direct & Indirect Costs & Benefits (Monetized)	**Amended to include the new COPN fee cap, fee rate, registration fee, and fee schedule:** • **Direct Monetized Benefit**: VDH will have sufficient fee revenue to support its COPN program activities and staff due to the projected annual revenue of $1,704,141; this calculation is based on the average annual number of projects and project costs for SFYs2015-2020 due to the variability in the number of project applications and capital expenditure costs observed by the COPN program after the start of the COVID-19 pandemic in 2020. The data for SFYs2021-2023 do not reflect anticipated typical COPN expenditure and revenue moving forward, and therefore were not utilized in these fee calculations. The COPN personnel budget, escalated to reflect the SFY 22, SFY 23 a and b raises, plus other operating line items, escalated for inflation, estimates a budget need of $1,524,655, including the addition of the two authorized FTEs, state raises, inflation, and operating costs; this leaves VDH with an additional $179,486 after the operating budget needs from the total fee revenue. • **Direct Monetized Cost**: All COPN projects will incur higher fees due to the increase to the COPN capital expenditure fee cap amount and fee rate from 1% estimated capital cost of the project and a maximum project application fee of $20,000 to a fee rate of

	1.5% estimated capital cost of the project and a maximum project application fee of $44,000. This action will also increase the minimum application fee for a project from $1,000 to $1,600, so projects with an estimated capital expenditure amount of less than $106,700 will need to pay a higher application fee than they previously would have. Fees were not previously charged for registrations, so regulants who are registering medical equipment that requires a registration will incur an initial $70 registration fee. The total annual expected registration cost to regulants is expected to be approximately $2,452 annually. • **There are no monetized indirect costs or benefits associated with this regulatory action.** There are no monetized direct or indirect costs or benefits associated with the following regulatory changes: • **Updated the text to cross-reference the new "schedule of fees" section.**

(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	The identified monetized costs represent fees, which are a transfer payment and cancel out.	The identified monetized costs represent fees, which are a transfer payment and cancel out.
(3) Net Monetized Benefit		

(4) Other Costs & Benefits (Non-Monetized)	**There are no non-monetized costs or benefits associated with this action.**
(5) Information Sources	VDH COPN Division

Table 1b: Costs and Benefits under the Status Quo (No change to the regulation)

(1) Direct & Indirect Costs & Benefits (Monetized)	• **Direct Monetized Benefit:** Without the regulatory change in the fee cap, the COPN capital expenditure fee cap would remain at $20,000, and the department would not require a registration fee. The cost to regulants would remain the same. • **Direct Monetized Cost:** Without the change in fee cap and additional registration fee, VDH will not be able to support its current COPN program activities and staffing levels due to the necessity to hire two new staff. The annual estimate for fee revenue currently, based on the numbers from SFY15-SFY20, is only $572,287, which is far below the operating budget needed to support this program.

	• **There are no monetized indirect costs or benefits associated with the status quo.**	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $0
(3) Net Monetized Benefit	$0	
(4) Other Costs & Benefits (Non-Monetized)	There are no non-monetized costs and benefits associated with this regulatory change.	
(5) Information Sources	VDH COPN Division	

Table 1c: Costs and Benefits under Alternative Approach(es)

(1) Direct & Indirect Costs & Benefits (Monetized)	An alternative approach would be to revive a previous fast track stage that raised the 1% capital expenditure fee cap to $60,000 and required a $70 registration fee. • **Direct Monetized Benefit**: The direct monetized benefit of this change is that the projected revenue of $1,189,489 annually would be an increase in the total fee revenue collected by the COPN program. • **Direct Monetized Cost**: The monetized cost of this regulatory change is that regulants would be required to pay a registration fee of $70 for each registration, and projects with an estimated capital expenditure of $2 million will pay a higher application fee. There is a cost to the department as well due to the fact that an annual fee revenue of $1,189,489 is no longer sufficient to support the COPN program due to employee raises, interest, and an increase in the workload for the COPN program employees as a result of new mandates. • **There are no indirect costs or benefits of this alternative regulatory change.**	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) The identified monetized costs represent fees, which are a transfer payment and cancel out.	(b) The identified monetized costs represent fees, which are a transfer payment and cancel out.
(3) Net Monetized Benefit		
(4) Other Costs & Benefits (Non-Monetized)	This alternative was proposed in a previous fast-track action, however, this change received negative feedback from some stakeholders, and the	

	stage was withdrawn so that further discussions about a mutually acceptable fee schedule could be had.
(5) Information Sources	VDH COPN Division

Impact on Local Partners

Table 2: Impact on Local Partners

(1) Direct & Indirect Costs & Benefits (Monetized)	**Amended to include the new COPN fee cap, fee rate, registration fee, and fee schedule:** • **Direct Monetized Benefit**: VDH will have sufficient fee revenue to support its COPN program activities and staff due to the projected annual revenue of $1,704,141; this calculation is based on the average annual number of projects and project costs for SFYs2015-2020 due to the variability in the number of project applications and capital expenditure costs observed by the COPN program after the start of the COVID-19 pandemic in 2020. The data for SFYs2021-2023 do not reflect anticipated typical COPN expenditure and revenue moving forward, and therefore were not utilized in these fee calculations. The COPN personnel budget, escalated to reflect the SFY 22, SFY 23 a and b raises, plus other operating line items, escalated for inflation, estimates a budget need of $1,524,655, including the addition of the two authorized FTEs, state raises, inflation, and operating costs; this leaves VDH with an additional $179,486 after the operating budget needs from the total fee revenue. • **Direct Monetized Cost**: All COPN projects will incur higher fees due to the increase to the COPN capital expenditure fee cap amount and fee rate from 1% estimated capital cost of the project and a maximum project application fee of $20,000 to a fee rate of 1.5% estimated capital cost of the project and a maximum project application fee of $44,000. This action also increased the minimum application fee for a project from $1,000 to $1,600, so projects with an estimated capital expenditure amount of less than $106,700 will need to pay a higher application fee than they previously would have needed to. Fees were not previously charged for registrations, so regulants who are registering medical equipment that requires a registration will incur an initial $70 registration fee. The total annual expected registration cost to regulants is expected to be approximately $2,452 annually. • **There are no monetized indirect costs or benefits associated with this regulatory action.** There are no monetized direct or indirect costs and benefits associated with the following regulatory changes:

	• **Updated the text to cross-reference the new "schedule of fees" section.**	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	The identified monetized costs represent fees, which are a transfer payment and cancel out.	The identified monetized benefits represent fees, which are a transfer payment and cancel out.
(3) Other Costs & Benefits (Non-Monetized)	There are no non-monetized costs and benefits associated with this regulatory change.	
(4) Assistance	Regulants will not require additional assistance from VDH to meet the requirements of this regulatory change.	
(5) Information Sources	VDH COPN Division	

Impacts on Families

Table 3: Impact on Families

(1) Direct & Indirect Costs & Benefits (Monetized)	**Families will not be affected by direct or indirect costs and benefits of the regulatory change as they are not subject to the requirements contained in this regulatory chapter and thus will incur no direct cost or benefit.**	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $0
(3) Other Costs & Benefits (Non-Monetized)	None.	
(4) Information Sources		

Impacts on Small Businesses

Table 4: Impact on Small Businesses

(1) Direct & Indirect Costs & Benefits (Monetized)	Based on anecdotal information, VDH does not believe any general hospital or nursing home meets the definition of "small business." VDH is unable to quantify how many Physician Offices and Outpatient Surgical Hospitals qualify as small businesses; however, entities that qualify as a "small business" can anticipate the impacts below: **Amended to include the new COPN fee cap, fee rate, registration fee, and fee schedule:**

	• **Direct Monetized Benefit**: There are no monetized benefits for small businesses associated with this regulatory action. • **Direct Monetized Cost**: All COPN projects will incur higher fees due to the increase to the COPN capital expenditure fee cap amount and fee rate from 1% estimated capital cost of the project and a maximum project application fee of $20,000 to a fee rate of 1.5% estimated capital cost of the project and a maximum project application fee of $44,000. This action also increased the minimum application fee for a project from $1,000 to $1,600, so projects with an estimated capital expenditure amount of less than $106,700 will need to pay a higher application fee than they previously would have needed to. Fees were not previously charged for registrations, so regulants who are registering medical equipment that requires a registration will incur an initial $70 registration fee. The total annual expected registration cost to regulants is expected to be approximately $2,452 annually. • **There are no monetized indirect costs or benefits associated with this regulatory action.** There are no monetized direct or indirect costs and benefits associated with the following regulatory changes: • **Updated the text to cross-reference the new "schedule of fees" section.**

(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	The identified monetized costs represent fees. VDH is unable to quantify the total amount of the overall projected fee revenue that would be paid by small businesses.	$0

(3) Other Costs & Benefits (Non-Monetized)	There are no non-monetized costs and benefits associated with this regulatory change.
(4) Alternatives	The State Board of Health was not able to identify any alternatives for small businesses that would be more equitable while still protecting the health, safety, and welfare of the public, and has put forth thoughtful consideration about the burdens of the new substantiative regulatory requirements that have a cost to regulants.
(5) Information Sources	VDH COPN Division

Changes to Number of Regulatory Requirements

Table 5: Regulatory Reduction

For each individual action, please fill out the appropriate chart to reflect any change in regulatory requirements, costs, regulatory stringency, or the overall length of any guidance documents.

Change in Regulatory Requirements

VAC Section(s) Involved	Authority of Change	Initial Count	Additions	Subtractions	Net Change
12.5.220.105	**Statutory:**	8 (R/S)	+1 (R/S)		+1
	Discretionary:				
12.5.220.110	**Statutory:**	2 (G/S) 2(R/S)	+1 (R/S)		+1
	Discretionary:	2 (G/D) 4(R/D)			
12.5.220.125	**Statutory:**		+3 (R/S)		+3
	Discretionary:		+1 (R/D)		+1
12.5.220.180	**Statutory:**	1 (G/S) 1 (R/S)	+1 (R/S)	- 1 (R/S)	0
	Discretionary:	2 (G/D) 6 (R/S)			
12.5.220.355	**Statutory:**	1 (G/S) 1 (R/S)	+1 (R/S)	-1 (R/S)	0
	Discretionary:	2 (G/D) 6 (R/D)		-1 (R/D)	-1

Cost Increases

VAC Section(s) Involved	Description of Regulatory Requirement	Initial Cost	New Cost	Overall Cost Savings/Increases
12.5.220.125	The COPN minimum fee, COPN fee cap, and COPN fee rate have been increased. A registration fee has been established.	-Minimum fee: $1,000 -Fee cap: $20,000 -Fee rate: 1% of the estimated capital expenditure cost	-Minimum fee: $1,600 -Fee cap: $44,000 -Fee rate: 1.5% of the estimated capital expenditure cost -Registration fee: $70	-Registration fee: $2,452 annually -Projected COPN fee revenue: $1,704,141 annually

Project 6433 - Fast-Track

Department of Health

Promulgation of Fee Schedule

12VAC5-220-10. Definitions.

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

"Acquisition" means an expenditure of $600,000 or more that changes the ownership of a medical care facility. It shall also include the donation or lease of a medical care facility. An acquisition of a medical care facility shall not include a capital expenditure involving the purchase of stock. See 12VAC5-220-120.

"Amendment" means any modification to an application that is made following the public hearing and prior to the issuance of a certificate and includes those factors that constitute a significant change as defined in this chapter. An amendment shall not include a modification to an application that serves to reduce the scope of a project.

"Applicant" means the owner of an existing medical care facility or the sponsor of a proposed medical care facility project submitting an application for a certificate of public need.

"Application" means a prescribed format for the presentation of data and information deemed necessary by the board to determine a public need for a medical care facility project.

~~"Application fees" means fees required for a project application and application for a significant change. Fees shall not exceed the lesser of 1.0% of the proposed capital expenditure or cost increase for the project or $20,000.~~

"Board" means the State Board of Health.

"Capital expenditure" means any expenditure by or in behalf of a medical care facility that, under generally accepted accounting principles, is not properly chargeable as an expense of operation and maintenance. Such expenditure shall also include a series of related expenditures during a 12-month period or a financial obligation or a series of related financial obligations made during a 12-month period by or in behalf of a medical care facility. Capital expenditures need not be made by a medical care facility so long as they are made in behalf of a medical care facility by any person. See definition of "person."

"Certificate of public need" means a document that legally authorizes a medical care facility project as defined herein and which is issued by the commissioner to the owner of such project.

"Clinical health service" means a single diagnostic, therapeutic, rehabilitative, preventive, or palliative procedure as defined in § 32.1-102.1 of the Code of Virginia.

"Commissioner" means the State Health Commissioner who has authority to make a determination respecting the issuance or revocation of a certificate.

"Competing applications" means applications for the same or similar services and facilities that are proposed for the same planning district or medical service area and which are in the same review cycle. See 12VAC5-220-220.

"Completion" means conclusion of construction activities necessary for substantial performance of the contract.

"Construction" means the building of a new medical facility or the expansion, remodeling, or alteration of an existing medical care facility.

"Construction, initiation of" means that a project shall be considered under construction for the purpose of certificate extension determinations upon the presentation of evidence by the

owner of: (i) a signed construction contract; (ii) the completion of short term financing and a commitment for long term (permanent) financing when applicable; (iii) the completion of predevelopment site work; and (iv) the completion of building foundations.

"Date of issuance" means the date of the commissioner's decision awarding a certificate of public need.

"Department" means the Virginia Department of Health.

"Designated medically underserved areas" means (i) areas designated as medically underserved areas pursuant to § 32.1-122.5 of the Code of Virginia; (ii) federally designated Medically Underserved Areas (MUA); or (iii) federally designated Health Professional Shortage Areas (HPSA).

"Ex parte" means any meeting that takes place between (i) any person acting in behalf of the applicant or holder of a certificate of public need or any person opposed to the issuance or in favor of the revocation of a certificate of public need and (ii) any person who has authority in the department to make a decision respecting the issuance or revocation of a certificate of public need for which the department has not provided 10 days written notification to opposing parties of the time and place of such meeting. An ex parte contact shall not include a meeting between the persons identified in clause (i) and staff of the department.

"Gamma knife surgery" means stereotactic radiosurgery, where stereotactic radiosurgery is the noninvasive therapeutic procedure performed by directing radiant energy beams from any source at a treatment target in the head to produce tissue destruction. See definition of "project."

"Health planning region" means a contiguous geographical area of the Commonwealth as defined in § 32.1-102.1 of the Code of Virginia.

"Informal fact-finding conference" means a conference held pursuant to § 2.2-4019 of the Code of Virginia.

"Inpatient beds" means accommodations within a medical care facility with continuous support services (such as food, laundry, housekeeping) and staff to provide health or health-related services to patients who generally remain in the medical care facility in excess of 24 hours. Such accommodations are known by varying nomenclatures including but not limited to: nursing beds, intensive care beds, minimal or self care beds, isolation beds, hospice beds, observation beds equipped and staffed for overnight use, and obstetric, medical, surgical, psychiatric, substance abuse, medical rehabilitation, and pediatric beds, including pediatric bassinets and incubators. Bassinets and incubators in a maternity department and beds located in labor or birthing rooms, recovery rooms, emergency rooms, preparation or anesthesia inductor rooms, diagnostic or treatment procedures rooms, or on-call staff rooms are excluded from this definition.

"Medical care facility" means any institution, place, building, or agency as defined in § 32.1-102.1 of the Code of Virginia.

"Medical service area" means the geographic territory from which at least 75% of patients come or are expected to come to existing or proposed medical care facilities, the delineation of which is based on such factors as population characteristics, natural geographic boundaries, and transportation and trade patterns, and all parts of which are reasonably accessible to existing or proposed medical care facilities.

"Modernization" means the alteration, repair, remodeling, replacement, or renovation of an existing medical care facility or any part thereto, including that which is incident to the initial and subsequent installation of equipment in a medical care facility. See definition of "construction."

"Operating expenditure" means any expenditure by or in behalf of a medical care facility that, under generally accepted accounting principles, is properly chargeable as an expense of operation and maintenance and is not a capital expenditure.

"Operator" means any person having designated responsibility and legal authority from the owner to administer and manage a medical care facility. See definition of "owner."

"Other plans" means any plan(s) which is formally adopted by an official state agency or regional health planning agency and which provides for the orderly planning and development of medical care facilities and services and which that is not otherwise defined in this chapter.

"Owner" means any person who has legal responsibility and authority to construct, renovate, or equip or otherwise control a medical care facility as defined herein.

"Person" means an individual, corporation, partnership, association, or any other legal entity, whether governmental or private. Such person may also include the following:

1. The applicant for a certificate of public need;

2. The regional health planning agency for the health planning region in which the proposed project is to be located;

3. Any resident of the geographic area served or to be served by the applicant;

4. Any person who regularly uses health care facilities within the geographic area served or to be served by the applicant;

5. Any facility or health maintenance organization (HMO) established under § 38.2-4300 et seq. of the Code of Virginia that is located in the health planning region in which the project is proposed and that provides services similar to the services of the medical care facility project under review;

6. Third party payors who provide health care insurance or prepaid coverage to 5.0% or more patients in the health planning region in which the project is proposed to be located; and

7. Any agency that reviews or establishes rates for health care facilities.

"Physician's office" means a place, owned, or operated by a licensed physician or group of physicians practicing in any legal form whatsoever, which is designed and equipped solely for the provision of fundamental medical care whether diagnostic, therapeutic, rehabilitative, preventive, or palliative to ambulatory patients and which does not participate in cost-based or facility reimbursement from third party health insurance programs or prepaid medical service plans excluding pharmaceuticals and other supplies administered in the office. See definition of "medical care facility."

"Planning district" means a contiguous area within the boundaries established by the Department of Housing and Community Development as set forth in § 15.2-4202 of the Code of Virginia, except that for purposes of this chapter, Planning District 23 shall be divided into two planning districts: Planning District 20, consisting of the counties of Isle of Wight and Southampton and the cities of Chesapeake, Franklin, Norfolk, Portsmouth, Suffolk, and Virginia Beach; and Planning District 21, consisting of the counties of James City and York and the cities of Hampton, Newport News, Poquoson, and Williamsburg.

"Predevelopment site work" means any preliminary activity directed towards preparation of the site prior to the completion of the building foundations. This includes, but is not limited to, soil testing, clearing, grading, extension of utilities, and power lines to the site.

"Primary medical care services" means first-contact, whole-person medical and health services delivered by broadly trained, generalist physicians, nurses, and other professionals, intended to include, without limitation, obstetrics/gynecology, family practice, internal medicine, and pediatrics.

"Progress" means actions that are required in a given period of time to complete a project for which a certificate of public need has been issued. See 12VAC5-220-450, Demonstration of progress.

"Project" means any plan or proposal as defined in § 32.1-102.1 of the Code of Virginia that is subject to Certificate of Public Need approval.

"Public hearing" means a proceeding conducted by a regional health planning agency at which an applicant for a certificate of public need and members of the public may present oral or written testimony in support or opposition to the application that is the subject of the proceeding and for which a verbatim record is made. See subsection A of 12VAC5-220-230.

"Regional health plan" means the regional plan adopted by the regional health planning agency board.

"Regional health planning agency" means the regional agency as defined in § 32.1-102.1 of the Code of Virginia.

"Rural" means territory, population, and housing units that are classified as "rural" by the Bureau of the Census of the United States Department of Commerce, Economics and Statistics Administration.

"Schedule for completion" means the timetable that identifies the major activities required to complete a project as identified by the applicant and set forth on the certificate of public need. The timetable is used by the commissioner to evaluate the applicant's progress in completing an approved project.

"Significant change" means any alteration, modification, or adjustment to a reviewable project for which a certificate of public need has been issued or requested following the public hearing which:

1. Changes the site;

2. Increases the capital expenditure amount authorized by the commissioner on the certificate of public need issued for the project by 10% or more;

3. Changes the service(s) proposed to be offered;

4. Extends the schedule for completion of the project beyond three years (36 months) from the date of certificate issuance or beyond the time period approved by the commissioner at the date of certificate issuance, whichever is greater. See 12VAC5-220-440 and 12VAC5-220-450.

"Standard review process" means the process utilized in the review of all certificate of public need requests with the exception of:

1. Certain bed relocations as specified in 12VAC5-220-280;

2. Certain projects that involve an increase in the number of beds in which nursing facility or extended care services are provided as specified in 12VAC5-220-325.

"State Medical Facilities Plan" means the planning document as contained in Article 1.1 (§ 32.1-102.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia, used to make medical care facilities and services needs decisions.

Statutory Authority

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

Historical Notes

Derived from VR355-30-000 § 1.1, eff. June 30, 1993; amended, Volume 10, Issue 17, eff. June 15, 1994; amended, Virginia Register Volume 13, Issue 07, eff. January 24, 1997; Volume 14, Issue 12, eff. April 2, 1998; Volume 19, Issue 08, eff. February 3, 2003; Volume 20, Issue 26,

eff. September 27, 2004; Volume 24, Issue 11, eff. March 5, 2008; Volume 38, Issue 19, eff. June 23, 2022.

12VAC5-220-105. Requirements for registration of the replacement of existing medical equipment.

A. Within 30 days of any person contracting to make, or otherwise legally obligating to make, a capital expenditure for the replacement of medical equipment or otherwise acquiring replacement medical equipment for the provision of services listed in subdivision 7 of the definition of "project" in 12VAC5-220-10, the person shall register in writing such equipment replacement with the commissioner and the appropriate regional health planning agency. Such registration shall be made on forms provided by the department. The registration shall identify the specific unit of equipment to be replaced and the estimated capital cost of the replacement, and shall include documentation that the equipment to be replaced has previously been authorized or exempted as allowed by law.

B. A person shall submit the fee prescribed by subsection D of 12VAC5-220-125.

Statutory Authority

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

Historical Notes

Derived from Virginia Register Volume 14, Issue 12, eff. April 2, 1998; amended, Virginia Register Volume 19, Issue 8, eff. February 3, 2003; Volume 26, Issue 2, eff. November 1, 2009; Volume 38, Issue 19, eff. June 23, 2022.

12VAC5-220-110. Requirements for registration of certain capital expenditures.

A. At least 30 days before ~~any~~ a person contracts to make or is otherwise legally obligated to make a capital expenditure by or on behalf of a medical care facility as defined in this chapter that has not been previously authorized by the commissioner, such expenditure shall be registered in writing with the commissioner. The threshold amount for capital expenditure project registration shall be determined using the formula contained in subsection B of this section.

B. The threshold contained in subsection A of this section shall be adjusted annually using the percentage increase listed in the Consumer Price Index for All Urban Consumers (CPI-U) for the most recent year as follows:

A x (1 + B)

where:

A = the capital expenditure threshold amount for the previous year

and

B = the percent increase for the expense category "Medical Care" listed in the most recent year available of the CPI-U of the U.S. Bureau of Labor Statistics.

C. The format for registration shall include information concerning the purpose of such expenditure and projected impact that the expenditure will have upon the charges for services. For purposes of registration, the owner shall include any person making the affected capital expenditure. See definition of "project."

D. Annually, the department shall (i) publish the threshold amount in the General Notices section of the Virginia Register of Regulations and (ii) post the threshold amount on its website.

E. A person shall submit the fee prescribed by subsection C of 12VAC5-220-125.

Statutory Authority

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

Historical Notes

Derived from VR355-30-000 § 3.2, eff. June 30, 1993; amended, Virginia Register Volume 10, Issue 17, eff. June 15, 1994; Volume 13, Issue 7, eff. January 24, 1997; Volume 24, Issue 11, eff. March 5, 2008; Volume 25, Issue 1, eff. October 15, 2008; Volume 26, Issue 2, eff. November 1, 2009; Volume 26, Issue 26, eff. September 30, 2010; Volume 27, Issue 24, eff. September 1, 2011; Volume 30, Issue 8, eff. February 3, 2014; Volume 38, Issue 19, eff. June 23, 2022.

12VAC5-220-125. Fee schedule.

A. Unless otherwise provided, fees established by the board in this chapter shall not be refundable.

B. The fee for an application that requests a certificate of public need shall be 1.5% of the proposed expenditure for the project but not less than $1,600 and no more than $44,000.

C. The fee for an application that requests registration of certain capital expenditures under 12VAC5-220-110 shall be $70.

D. The fee for an application that requests registration of medical equipment or services shall be $70.

E. If a check, money draft, or similar instrument for payment of a fee is not honored by the bank or financial institution named, the applicant shall remit funds sufficient to cover the original fee amount, plus a $50 dishonored payment fee.

Statutory Authority

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

12VAC5-220-180. Application forms.

A. Letter of intent. An applicant shall file a letter of intent with the commissioner to request appropriate application forms, and submit a copy of that letter to the appropriate regional health planning agency, by the later of (i) 30 days prior to the submission of an application for a project included within a particular batch group or (ii) 10 days after the first letter of intent is filed for a project within a particular batch group for the same or similar services and facilities which are proposed for the same planning district or medical service area. The letter shall identify the owner, the type of project for which an application is requested, and the proposed scope (size) and location of the proposed project. The department shall transmit application forms to the applicant within seven days of the receipt of the letter of intent. A letter of intent filed with the department shall be considered void one year after the date of receipt of such letter. (See 12VAC5-220-310 C.)

B. ~~Application fees. The department shall collect application fees for applications that request a certificate of public need. The~~ An applicant shall pay the fee ~~required~~ prescribed by subsection B of 12VAC5-220-125 for an application ~~shall be 1.0% of the proposed expenditure for the project, but not less than $1,000 and no more than $20,000~~ that requests a certificate of public need.

No application will be deemed to be complete for review until the required application fee is paid. (See 12VAC5-220-310 C.)

C. Filing application forms. Applications must be submitted at least 40 days prior to the first day of a scheduled review cycle to be considered for review in the same cycle. In order to verify the date of the department's and the appropriate regional health planning agency's receipt of the application, the applicant shall transmit the document electronically, or prepare in triplicate two copies to be submitted to the department and one copy to be submitted to the appropriate regional health planning agency and sent by certified mail or a delivery service, return receipt requested, or by hand, with a signed receipt to be provided. No application shall be deemed to have been submitted until required copies have been received by the department and the appropriate regional health planning agency. (See 12VAC5-220-200.)

Statutory Authority

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

Historical Notes

Derived from VR355-30-000 § 5.2, eff. June 30, 1993; amended, Volume 10, Issue 17, eff. June 15, 1994; amended, Virginia Register Volume 14, Issue 12, eff. April 2, 1998; Volume 19, Issue 08, eff. February 3, 2003; Volume 26, Issue 02, eff. November 1, 2009; Volume 38, Issue 19, eff. June 23, 2022.

12VAC5-220-355. RFA project application forms.

A. ~~Letter of intent.~~ A RFA project applicant shall file a letter of intent with the commissioner to request appropriate application forms, and shall submit a copy of ~~that~~ the letter to the appropriate regional health planning agency by the letter of intent deadline specified in the RFA. The letter shall identify the owner, the type of project for which an application is requested, and the proposed scope (size) and location of the proposed project. The department shall transmit the application forms to the applicant within seven days of the receipt of the letter of intent. A letter of intent filed with the department shall be considered void if an application is not filed for the project by the application deadline specified in the RFA.

B. ~~Application fees. The department shall collect application fees for RFA applications that request a certificate of public need. The fee required for an application is 1.0% of the proposed capital expenditure for the project but no less than $1,000 and no more than $20,000. No application will be deemed to be complete for review until the required application fee is paid.~~ An applicant shall submit the application fee prescribed pursuant to subsection B of 12VAC5-220-125.

C. ~~Filing application forms. Applications must be submitted~~ An applicant shall submit an application to the department and the appropriate regional health planning agency by the application filing deadline specified in the RFA. No application shall be deemed to have been submitted until required copies have been received by the department and the appropriate regional health planning agency. In order to verify the department and the appropriate regional health planning agency's receipt of the application, the applicant shall ~~transmit~~ :

1. Submit the document electronically ~~,~~ ; or

~~prepare in triplicate~~ 2. Submit three copies of the application as follows: two copies ~~to be submitted~~ to the department and one copy ~~to be submitted~~ to the appropriate regional health planning agency ~~and sent~~ . The applicant shall send the copies by certified mail or a delivery service, return receipt requested, or by hand, with a signed receipt to be provided. ~~No application shall be deemed to have been submitted until required copies have been received by the department and the appropriate regional health planning agency.~~

Statutory Authority

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

Historical Notes

Derived from Volume 13, Issue 07, e; Volume 38, Issue 19, eff. June 23, 2022ff. January 24, 1997; amended, Virginia Register Volume 19, Issue 08, eff. February 3, 2003; Volume 26, Issue 02, eff. November 1, 2009; Volume 38, Issue 19, eff. June 23, 2022.

2024 MEETING TRAVEL RECOMMENDATIONS

POLICY COMMITTEE DISCUSSION

OTHER BUSINESS

ADJOURN