Quarterly Board of Health Meeting

September 14, 2023

10:00am

Richmond, VA

Call to Order and Welcome

Gary Critzer

REVIEW OF THE AGENDA

Agenda

Approval of June 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	
Regulations Governing Durable Do Not Resuscitate Orders 12VAC5-66 (Fast Track Amendments)	Gary Brown Director Office of Emergency Medical Services
Regulations for the Licensure of Hospice 12VAC5-391 (Fast Track Amendments)	Rebekah Allen, JD Senior Policy Analyst Office of Licensure and Certification
Regulations for the Certificate of Public Need 12VAC5-220 (Fast Track Amendments)	Rebekah Allen, JD Senior Policy Analyst Office of Licensure and Certification

Agenda

Regulations for Disease Reporting and Control 12VAC5-90 (Final Amendments)	Laura Forlano, DO MPH State Epidemiologist and Director Office of Epidemiology
Certification of Community Health Workers 12VAC5-402 (Proposed Regulations)	Vanessa Walker Harris, MD Director Office of Family Health Services
2024 Travel Meeting Recommendations	Joe Hilbert Deputy Commissioner for Governmental and Regulatory Affairs
2024 Meeting Dates	Alexandra Jansson, MPP Staff to the Board
Report of the Policy Committee	Patricia Kinser, PhD, WHNP-BC, RN Chair, Policy Committee
Other Business	
Adjourn	

APPROVAL OF JUNE 15, 2023 MINUTES

State Board of Health – Nominating Committee
June 15, 2023 - 9:00am
Perimeter Center, Boardroom 2

Members Present: Lee Jones, DMD; Maribel Ramos; Stacey Swartz, PharmD, Chair.

VDH Staff Present: Alexandra Jansson, Staff to the State Board of Health

Dr. Swartz gaveled the meeting to order at 8:30am.

There were no persons signed up for public comment.

Dr. Jones moved to nominate the following slate: Gary Critzer – Chair; Patricia Kinser, PhD – Vice Chair; Anna Jeng, ScD and Michael Desjadon – Executive Committee members. The motion was seconded by Ms. Ramos. The motion was approved by unanimous voice vote.

The meeting adjourned at 8:34am.

State Board of Health
June 15, 2023 - 9:00am
Perimeter Center, Boardroom 2

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

Members Absent: Jim Shuler, DVM.

Ms. Green participated virtually from her home in Bath County due to a temporary medical condition.

Dr. Klein participated virtually from Rhode Island for personal reasons involving pre-existing travel.

VDH Staff Present: 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; Christopher Lindsay, Chief Operating Officer; Maria Reppas, Director, Office of Communications; Anthony Salgado, Medical Reserve Corps Coordinator; Karen Shelton, State Health Commissioner; and Sirah Yoo, Senior Graphic Designer.

Other Staff Present: Robin Kurz, JD, Senior Assistant Attorney General; Allyson Tysinger, Senior Assistant Attorney General/Section Chief; and James Williams, Deputy Secretary for Health and Human Resources.

Ms. Harrison arrived at 9:19 am. Dr. Klein joined the meeting at 9:30 am.

Call to Order
Mr. Critzer called the meeting to order at 9:02 am.

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

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

Approval of March 23rd, 2023 Minutes
The minutes from the March 23 meeting were adopted by unanimous consent, with Mrs. O'Bannon abstaining.

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
- Maternal Health
- Substance Misuse Including EO26/Fentanyl Response
- Partnership for Petersburg
- Projects Funded by the American Rescue Plan Act (ARPA)
- Public Health Infrastructure Grant
- Emergency Preparedness/Hurricane Season
- Public Health Policy Fellows Program
- VDH Follow-up to Joint Commission on Health Care Study of Structure and Financing of Local Health Departments
- Public Health Policy Agenda Development Process

There was discussion regarding maternal mental health screening data, Virginia's national standing as it relates to maternal health and perinatal policy, the methodology associated with the maternal mental health data, and the industry practice of post-partum depression screening, the Board's involvement with the VDH Policy Agenda, the Opioid Impact Reduction Registry, and the Electronic Health Record data system and how that would operate in conjunction with the new Opioid Registry.

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

Since the March 2023 meeting, the Commissioner approved 3 regulatory actions on behalf of the Board while the Board was not in session. All three approved actions for the results of periodic review. The first 2 Periodic Review results for the Commonwealth of Virginia Sanitary Regulations for Marinas and Boat Moorings (12VAC5-570) and the Regulations Implementing the Virginia Donor Registry (12VAC5-475) resulted in "Amend" decision. The third Periodic

Review Result for the Regulations for the Immunization of School Children (12VAC5-110) resulted in a "Retain as is" decision. The Periodic Review Results for 12VAC5-570 were approved by Parham Jaberi, MD during his time as "Acting" Commissioner, while 12VAC5-475 and 12VAC5-110 were approved by Karen Shelton, MD after her appointment as the Virginia State Health Commissioner.

Since the March 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 Program Scholarship Program
- 12 VAC 5-530 Regulations Governing the Virginia Medical Scholarship Program
- 12 VAC 5-542 Rules and Regulations Governing the Virginia Nurse Practitioner / Nurse Midwife 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

There was discussion regarding the regulatory matrix containing all 46 of VDH's current regulatory actions.

Public Comment Period

There were 13 persons signed up for the public comment period. The Board's public comment period allows for a 20 minute period with 2 minutes per person. A motion to extend the public comment period by 6 minutes was made by Mr. Desjadon and seconded by Dr. Puritz. The

motion was passed by unanimous voice vote.

Susan Franz, Carol Sargeant, Jennifer Herget, Lori Leonard, Peter Machem, Ruth Machem, Sheila Furey, Sharon Laundrum, and Kathy Stevens spoke about COVID-19 vaccinations and childhood immunization schedules. Ann Parker, Doris Knick, and Donna Machem spoke about radiation frequencies. Jim Edmondson spoke about health equity concerns. Additional written comments can be found at the end of the minutes document.

Fast Track Amendments to Regulations Governing Vital Records 12 VAC 5-550

Mr. Seth Austin presented the Fast Track Amendments to the Regulations Governing Vital Records. The purpose of the amendments is to reflect several recent changes in the Code of Virginia, including changes to §§ 32.1-258.1, 32.1-269.1, 32.1-261, and 32.1-267. Several sections will be repealed, as these sections are not regulatory in nature.

Chapter 171 (2022) removed the authority to charge a fee to obtain a stillbirth certificate for unintended, intrauterine fetal deaths. Chapters 209, 210, and 211 (2020) removed race from the data to be collected regarding marriages, divorces, and annulments. Chapters 465 and 466 (2020) amended the process to change one's sex on a birth certificate. Chapters 116 and 117 (2022) changed the process and timelines associated with amending a death certificate. Additionally, sections 20, 30, 50, and 60 will be repealed because the provisions do not meet the statutory definition of a "regulation" in § 2.2-4001.

The rulemaking is expected to be non-controversial because the substantive changes being made are to comply with changes to the Code of Virginia. Additionally, the style and form changes are not substantive but will make the regulations clearer and more readable for both the public and agency staff.

There was discussion regarding the processes and language related to amending sex on a birth certificate.

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

Proposed Amendments to Waterworks Operation Fee 12 VAC 5-600

Mr. Dwayne Roadcap presented the Proposed Amendments to the Waterworks Operation Fee Regulations (12VAC5-600). The regulations codify how the Office of Drinking Water (ODW) generates revenue from fees charged to the waterworks that are regulated by the ODW under the federal Safe Drinking Water Act (SDWA) and the Virginia Waterworks Regulations (12VAC5-590). While the regulations have not been amended at all since 2014, there are portions of the regulations, such as the fee assessed for nontransient noncommunity waterworks, which have not changed since the regulations were first promulgated in 1993. In addition to modifying the fee for nontransient noncommunity waterworks and clarifying the method by which operation fees are calculated, the amendments seek to add categories of waterworks, not previously charged a fee, into the regulations. Specifically, transient noncommunity waterworks and wholesale waterworks are proposed to be added to the list of categories of waterworks that are charged a fee for the technical assistance and compliance oversight provided by ODW.

There was discussion regarding the time requirements faced by ODW as it relates to the various waterworks operators, how equity is implemented in the regulations, an overview of the new fee changes, and the potential impacts to localities.

Dr. Jones made a motion to approve the proposed amendments with Ms. Whipple seconding. The motion passed unanimously by voice vote.

Fast Track Amendments to the Regulations for the Patient Level Data System 12 VAC 5-217

Mr. Suresh Soundararajan presented the Fast Track Amendments to the Regulations of the Patient Level Data System. These amendments seek to permanently adopt the emergency regulation promulgated in January 2022 and update the language to reflect current inpatient data reporting practices. Item 307 (D1) of Chapter 552 of the 2021 Acts of Assembly Special Session I ("2021 Appropriation Act") requires inpatient hospitals to report to the Board the admission source of any individuals meeting the criteria for voluntary or involuntary psychiatric commitment. To conform to this mandate, the emergency regulation was promulgated effective January 17, 2022.

Additional amendments are proposed to conform the regulations to reflect the data reporting elements currently submitted by inpatient hospitals to Virginia Health Information (VHI). Non-regulatory language is also being removed from 12VAC5-217-20 to conform to the *Form and Style Requirements* set forth by the Virginia Registrar of Regulations.

Dr. Kinser made a motion to approve the Fast Track with Dr. Vaughters seconding. The motion passed unanimously by voice vote.

Final Exempt Amendments to the Regulations for the Licensure of Hospitals in Virginia 12 VAC 5-410

Ms. Rebekah E. Allen presented the Final Exempt Amendments to the Regulations for the Licensure of Hospitals in Virginia. Chapter 417 of the 2023 Acts of Assembly requires the State Board of Health to amend its hospital regulations to require hospitals with emergency departments "to establish a security plan…using standards established by the International Association for Healthcare Security and Safety or other industry standard" and that is "based on the results of a security risk assessment of each emergency department location of the hospital." This security plan must "include the presence of at least one off-duty law-enforcement officer or trained security personnel who is present in the emergency department at all times as indicated to be necessary and appropriate by the security risk assessment." Chapter 417 further enumerates what identified risks that hospitals must consider when developing security plans and training requirements for security personnel. Chapter 417 authorizes the State Health Commissioner to "provide a waiver from the requirement that at least one off-duty law-enforcement officer or trained security personnel be present at all times in the emergency department if the hospital demonstrates that a different level of security is necessary and appropriate for any of its emergency departments based upon findings in the security risk assessment."

The second enactment clause of Chapter 417 exempts this regulatory action from the

Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia), provided that the State Board of Health gives an opportunity for public comment prior to adoption. The State Board of Health published a general notice in The Virginia Register of Regulations on April 10, 2023 containing the proposed regulatory text; this general notice had a 30-day public comment period during which three comments were received. Outside of the public comment period, two written comments were received related to this action for this meeting – they are included at the end of the minutes document.

There was discussion regarding the legal interpretation and intent of the statutory language, security protocols, and liability associated with waivers.

Dr. Kinser made a motion to approve the Final Exempt Amendments with Dr. Vaughters seconding. The motion passed unanimously by voice vote.

Report of the Nominating Committee

Dr. Swartz presented the report of the Nominating Committee. The committee nominated Gary Critzer to continue serving as the chairman of the Board, Patricia Kinser as the Vice Chair of the Board, and Anna Jeng and Michael Desjadon as the Executive Committee members.

Dr. Puritz made a motion to approve the nominations with Ms. Harrison seconding that motion. The motion passed unanimously by voice vote.

Board Bylaws Review

Ms. Jansson reviewed the Board Bylaws to the members as required every four years. Ms. Jansson reviewed the general sections for the bylaws relating to applicability and purpose of the Board, membership, committees, meetings, and elections of members.

There was discussion regarding the Board's involvement in policy work in conjunction with VDH, and how establishing committees to focus on specific topics would occur.

Ms. Whipple made a motion to approve the bylaws as presented with Dr. Swartz seconding that meeting. The motion was passed unanimously by voice vote.

Other Business

Mr. Critzer updated the Board on the progress of the Office of Emergency Medical Services and their study of the Emergency Department off-loading practices. A full report is anticipated at the September meeting.

Mr. Critzer also recommended the creation of a policy committee comprised of interested Board members not to exceed 4 members to communicate policy interests and recommendations to the Agency on behalf of the Board. The members selected at the meeting were Dr. Kinser, Mr. Desjadon, and Ms. Ramos. Mr. Critzer made a motion to approve committee creation. The motion was passed unanimously by voice vote. The group plans to meet prior to the start of the September Board meeting.

Mr. Critzer proposed hosting one of the quarterly meetings per year at a different location than

Richmond. The Board recommended VDH investigate the feasibility of this and to report the findings of this investigation to the Board at the September meeting.

There was discussion regarding the "Right Help Right Now" bills recently signed by Governor Youngkin and how those may impact the current Emergency Department Diversions, the financial costs and budgeting needed to host a meeting in a different area of the State, and the logistics of the presentations at a moving Board meeting and what they may involve.

Adjourn

The meeting adjourned at 12:33pm.

VHHA Public Comment - June 15, 2023 Board of Health

Rawlings, Brent <brawlings@vhha.com>

Tue 6/13/2023 4:23 PM

To:State Board of Health (VDH) <boardofhealth@vdh.virginia.gov>

Cc:Allen, Rebekah (VDH) <Rebekah.Allen@vdh.virginia.gov>;Dime, Julie <jdime@vhha.com>

1 attachments (212 KB)

VHHA Comments - Emergency Department Security (SB 827) Response.pdf;

Please accept the attached public comment on behalf of Virginia Hospital & Healthcare Association to be submitted to the Board of Health in advance of its June 15, 2023, quarterly meeting. This pertains to the agenda item seeking Board approval for Draft Amendments for 12VAC5-410-10 et seq. to Implement SB 827 from 2023 Regular Session (Emergency Department Security).

Please let me know if you have any questions or if you require further information.

Sincerely,

Brent

R. Brent Rawlings
Senior Vice President and General Counsel
Virginia Hospital & Healthcare Association
4200 Innslake Drive, Suite 203
P.O. Box 31394, Richmond, VA 23294
Phone: (804) 965-1228
Mobile: (804) 307-0366
brawlings@vhha.com

VIRGINIA HOSPITAL & HEALTHCARE ASSOCIATION

4200 INNSLAKE DRIVE, SUITE 203, GLEN ALLEN, VIRGINIA 23060-6772
P.O. BOX 31394, RICHMOND, VIRGINIA 23294-1394
(804) 965-1227 FAX (804) 965-0475

SENT VIA EMAIL (boardofhealth@vdh.virginia.gov; rebekah.allen@vdh.virginia.gov)

June 13, 2023

Ms. Rebekah E. Allen, J.D.
Senior Policy Analyst
Virginia Department of Health
Office of Licensure and Certification
9960 Mayland Drive, Suite 401
Henrico, Virginia 23233

RE: **Public Comment on Draft Amendments for 12VAC5-410-10 *et seq.* to Implement SB 827 from 2023 Regular Session**

Dear Ms. Allen,

On behalf of the Virginia Hospital & Healthcare Association (VHHA) and its hospital and health system members across the Commonwealth, please accept these additional comments on draft amendments for 12VAC5-410-10 *et seq.* to implement SB 827 from the 2023 Regular Session for submission to the Board of Health prior to its meeting on June 15, 2023. VHHA previously submitted public comments in response to the notice of public comment on the draft amendments. Those public comments were included in the Agency Background Document for this action prepared by the Virginia Department of Health (VDH) on May 11, 2023.

In its Agency Background Document, VDH provided a response to each of the comments raised by VHHA. We are very appreciative of VDH's thoughtful and thorough analysis and willingness to include modifications to the regulations in certain areas.

One area where we remain in disagreement, however, relates to the security personnel requirement at 12 VAC5-410-280.I.3. SB 827 states that any security plan "shall include the presence of at least one off-duty law-enforcement officer or trained security personnel who is present in the emergency department at all times "*as indicated to be necessary and appropriate by the security risk assessment.*" VHHA was very careful to include this phrase in its negotiations with stakeholders to reach consensus on the legislation. The intent of this phrase was to recognize that there could be instances where the security risk assessment indicates that the presence of at least one trained security personnel is *not* necessary and appropriate, and in such instances, a different security standard could be applied, without obtaining any waiver from the Commissioner.

To apply the statute otherwise creates a presumption that every security risk assessment for every location of every emergency department in Virginia will indicate that the presence of at least one off-duty law-enforcement officer or trained security personnel who is present in the emergency department at all times is necessary and appropriate. This cannot be presumed and the very purpose of requiring the security risk assessment was to insert an objective model for determining whether the presence of security personnel is necessary and appropriate. To apply the statute in this manner would effectively nullify and treat as surplusage the first use of the words "as indicated to be necessary and appropriate by the security risk assessment." Such a determination is inconsistent with the rules of statutory

construction – every part of a statute is presumed to have some meaning and can be rejected as surplusage only if inserted inadvertently or by mistake.

There are plausible reasons why a waiver would be required even where the presence of at least one off-duty law-enforcement officer or trained security personnel who is present in the emergency department at all times is "indicated to be necessary and appropriate by the security risk assessment." For example, in a small critical access hospital, the security plan provides for security personnel to be located within the hospital in some location other than the emergency department. Because of the small size of the facility and concern for threats in other parts of the hospital, the hospital desires not to require a security post in the emergency department, but instead for it to be located in some centralized area that is adjacent to the emergency department. This could effectively be determined by the Commissioner to provide the same level of security as might be available in the emergency department of a larger urban hospital, although it does not meet the technical requirement, making a waiver necessary.

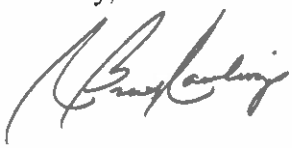
Applying the statute in this manner would not remove the agency's authority to challenge a hospital's determination of whether a security risk assessment does or does not indicate that the presence of at least one off-duty law-enforcement officer or trained security personnel who is present in the emergency department at all times is necessary and appropriate. Just as with any other licensure requirement, the agency would retain the ability to enforce compliance through the licensure process, including requesting to review security plans or security risk assessments for the emergency department as part of inspection or in response to a complaint. So the hospital would remain subject to scrutiny for compliance with the security requirements as a matter of law.

This is not an alternative interpretation and we do not regard it as a "watering down" of the statute as it has been characterized by other stakeholders. Other stakeholders have also suggested that our public comments constituted newly expressed concerns not raised in discussion regarding the legislation. VHHA repeatedly expressed its concerns about the full-time presence of security personnel in emergency departments in its discussions with the patron and all stakeholders. We conveyed concerns over disparate impacts noting that the statute would apply to small rural and critical access hospitals, as well as freestanding emergency departments, in the same manner as it would apply to much larger mid-sized suburban and urban hospitals with much higher volumes and risk profiles. We expressed concerns about existing workforce challenges with security personnel who are already being tasked with managing security details in other parts of the hospital outside of the emergency department. We expressed concerns about the significant costs of the full-time presence of security personnel in emergency departments, which the agency estimates to amount to over $24 million in annual direct and indirect costs. This is in addition to other costs associated with compliance, which the agency estimates to amount to over $117 million in direct and indirect costs for hospitals in total.

It is for these reasons that VHHA was careful to include the phrase "*as indicated to be necessary and appropriate by the security risk assessment*" seeking to reduce regulatory burden involved in requesting waivers – both on behalf of providers and the agency. The safety and security of patients, staff, and the public is of paramount concern for hospitals, but this regulation represents a significant regulatory change bringing with it significant direct and indirect costs that need to be taken into account. This further highlights the importance of ensuring that implementing regulations provide needed flexibility for different levels of risk at various emergency departments across the Commonwealth and avoid imposing unnecessary regulatory burden on hospitals.

We again thank VDH for its thoughtful and thorough analysis and appreciate further consideration of these comments by the Board of Health in its deliberations. Please let us know if we can provide you with any further information on this matter.

Sincerely,



R. Brent Rawlings
Senior Vice President and General Counsel

cc: Ms. Julie M. Dime, Vice President of Government Affairs

Allen, Rebekah (VDH)

From: Apple, Ashley Kathleen (aka5nd) <aka5nd@virginia.edu>
Sent: Thursday, June 15, 2023 8:30 AM
To: State Board of Health (VDH)
Cc: Allen, Rebekah (VDH); Andrew Lamar; Brittany Whitley
Subject: TIME SENSITIVE: VNA Position on 12VACS-410-10 et seq. to implement SB827

With respect to 12VAC5-410-10 *et seq.* to implement SB 827 from the 2023 legislative session, and in response to the public comment submitted by the Virginia Hospital and Healthcare Association (VHHA):

The Virginia Nurses Association agrees that the decision to embed security personnel in healthcare settings is one that requires careful consideration of a number of factors, including the level of risk, legal and regulatory limitations, and community response. In contrast to the VHHA, the Virginia Nurses Association believes that the best way to ensure adequate consideration of these factors is to maintain regulatory oversight of hospital-generated security risk assessments and safety plans for each emergency department location of a hospital. It is our expectation, in accordance with Virginia law, that safety plans include the presence of at least one off-duty law enforcement officer or trained security personnel who is present in the emergency department at all times. If a security risk assessment clearly demonstrates that security personnel are not necessary to ensure the safety of patients and staff, the hospital should submit the risk assessment and supporting documentation for consideration of a waiver of this obligation. Waivers should be issued only with appropriate regulatory oversight, at the discretion of the Commissioner of Health. Our position is directly aligned with both the language and intent of SB 827, which passed both chambers of the Virginia General Assembly unanimously with the full support of the Virginia Hospital and Healthcare Association, the Virginia Nurses Association, the Virginia College of Emergency Physicians, The Medical Society of Virginia, and numerous other stakeholders.

While the physical presence of security personnel is just one component of hospital security, it's a highly effective intervention to reduce the incidence of violence and maintain the safety of patients and staff in the emergency setting. Federal regulations and accrediting bodies have long required hospitals to maintain all-hazards security plans and train staff on violence prevention and de-escalation techniques- and hospitals have long been given autonomy and flexibility to perform safety risk assessments and implement safety plans that meet the industry standard without significant regulatory oversight or approval requirements; Unfortunately, that approach has not adequately protected the healthcare workforce. In 2018, 70% of emergency department nurses and 47% of emergency physicians reported being physically assaulted while on the job (American College of Emergency Physicians, Emergency Nurses Association), and that was before the added stressors brought about by the COVID-19 pandemic. It's clear that additional regulation is required, which is precisely why SB 827 garnered widespread support and received swift legislative and executive approval in 2023.

The Virginia Nurses Association agrees that the security personnel requirement set forth in SB 827 carries substantial financial and workforce implications. The COVID-19 pandemic has exacerbated long-standing problems in hospitals across the United States, resulting in increased violence against healthcare workers and an exodus from the nursing profession. If nurses don't feel safe at work, they will continue to leave the bedside and patient care will suffer. The requirement for security personnel in all emergency departments is not intended to inflict an "administrative burden" on Virginia hospitals- it's meant to reduce the burden of violence against caregivers and the patients we serve. We literally cannot afford to lose any more of our workforce.

The Virginia Nurses Association asks the Board of Health to respect the spirit and intent of SB 827 and put in place robust regulatory oversight to ensure the safety of nurses and patients in the Commonwealth.

Ashley Apple, DNP, RN, FNP-BC

Commissioner on Government Relations

Virginia Nurses Association

COMMENTS OF JIM EDMONDSON TO VIRGINIA BOARD OF HEALTH
JUNE 15, 2023

MY NAME IS JIM EDMONDSON, A RESIDENT OF FAIRFAX COUNTY AND A 13-YEAR BOH MEMBER. AT MY LAST MEETING A YEAR AGO THE BOARD VOTED UNANIMOUSLY TO REJECT THE IDEA THAT HEALTH DISPARITIES IN THE COMMONWEALTH, PARTICULARLY FOR AFRICAN-AMERICAN AND OTHER MINORITY AND LOW-INCOME COMMUNITIES, WERE SUBJECTS NOT TO BE DISCUSSED OR TO BE AGGRESSIVELY REDUCED. EVENTUALLY THE VOICE OF THIS REPUGNANT ATTITUDE, WHICH SEEMS TO HAVE BEEN A REFLECTION OF THE GOVERNOR'S VIEWS, WAS DENIED APPROVAL OF PERMANENT OFFICE AS THE COMMISSIONER OF HEALTH. UNFORTUNATELY FOR THE CITIZENS OF THE COMMONWEALTH, THE "DEPOSED" COMMISSIONER, DR. COLIN GREENE, NOW HAS A ROLE THAT IS SUPPOSED TO REDUCE THE DAMAGE INFLICTED BY THE OPIOID EPIDEMIC. I CAN ONLY WONDER WHAT TYPES OF DAMAGE MIGHT GO UNADDRESSED IN THIS WORTHY EFFORT BECAUSE SOMEHOW THE WHITE CITIZENS OF VIRGINIA OR OTHERS, WHO DO NOT SUFFER FROM OPIOID ADDICTION, MIGHT BE OFFENDED BY POINTING OUT THAT SOME GROUPS -- BLACKS OR RESIDENTS OF APPALACHIA OR POOR WHITES -- ARE MORE LIKELY TO BE AFFECTED.

AS WE LOOK BACK ON THE COVID PANDEMIC AND SEE HOW MINORITIES WERE MUCH MORE LIKELY TO HAVE SUFFERED FROM THE DISEASE AND DEATH FROM IT, WHAT BETTER EXAMPLE FOR THE TRUTH OF THE EXISTENCE OF DISPARITIES IS REQUIRED? THE PREVIOUS COMMISSIONERS AND THIS BOARD HAVE STUDIED, REPORTED ON, AND FULLY APPRECIATED THE REALITY OF DISPARITIES IN HEALTH ACCESS AND OUTCOMES ACROSS A BROAD RANGE OF DISEASES AND CONDITIONS. THE OTHER MOST OBVIOUS DISPARITIES INVOLVE MATERNAL HEALTH, PREGNANCIES AND BIRTHS. HOW CAN ANYONE OF GOOD CONSCIENCE CONTINUE TO HOLD THE VIEWS OF THE GOVERNOR AND THE PREVIOUS, REJECTED COMMISSIONER? MY CHALLENGES TO THIS BOARD, INCLUDING THOSE MEMBERS APPOINTED BY GOV. YOUNGKIN, ARE THESE: 1) TO MAKE SURE, AS LONG AS SHE HOLDS THE POSITION, THAT THE COMMISSIONER'S ACTIONS DO NOT CONTINUE TO CAUSE THE PUBLIC HEALTH OF VIRGINIANS TO DETERIORATE; AND 2) THAT THE BOARD WILL DIRECT HER TO TAKE ACTIONS THAT REDUCE DISPARITIES AND IMPROVE THE EQUALITY OF ACCESS TO CARE AND THE OUTCOMES OF CARE TO ALL VIRGINIANS.

ADDITIONAL COMMENTS NOT MADE DURING THE PUBLIC COMMENT PERIOD:

I and other Board members, especially Anna Jung, were deeply involved in fighting the regulations drafted by former AG Ken Cuccinelli that were intended to shut all women's health clinics that offered abortion care. After the victories of Terry McAuliffe and Mark Herring in the election of 2013, those indefensible regulations, which had been in effect for approximately one year, were overturned. The Commonwealth lost approximately

seven clinics as a result of the TRAP regulations, but the leadership of three Commissioners, Drs. Karen Remley, Marissa Levine and Norm Oliver, prevented there being a greater loss. Now, the treatment of abortion clinics as hospitals or outpatient surgery clinics is not permitted under state law, and we hope it remains that way. Many of the former members of the BOH, and perhaps some current members, do not object to the regulation of abortion clinics, nor do all support abortion access during the very late term. We did, and I hope you still do, object strongly to ignoring the precedent of applying regulations to operating clinics rather than imposing them only when new clinics are constructed or substantially renovated....and that you would apply logic to any regulations you may impose in the future -- for example, making parking places a criterion for the granting of permission to operate or requiring that medical abortions be treated exactly as surgical abortions. I remind you that both surgical and medical abortions are safer than giving birth.

Even if the current Attorney General were to draft regulations comparable to the Cuccinelli regulations, the Board has the power to reject them. Mr. Cuccinelli threatened not to represent any Board members who voted to reject his regs, if they were sued by anti-abortion advocates, a clear violation of his duties under the Administrative Procedures law. Enough of the members of the Board in 2012 were intimidated by his threat that, when presented to the Board a second time, those regs were adopted, with only a few holdouts such as Anna and me. If the opportunity to defy the AG occurs again (and I hope it doesn't) , be strong and take the position of a vast majority of Virginians -- abortion access is a basic right.

Ruth Machen, Mathews. I come before you today to ask that you not recommend the Covid jab for children. There are thousands of stories like this one that I am about to share written by Maddie's mother.

"Maddie de Garay was a healthy and vibrant 12-year-old. She was a normal pre-teen who loved dancing and spending time with friends. Maddie's life changed forever when she received her second dose of the Pfizer Covid vaccine in January 2021 while participating in the trial for 12-15-year-olds.

In less than 24 hours of her second dose, Maddie had a severe systemic adverse reaction. She developed crippling body pain, her fingers and toes ice cold and turned white and she said she felt like someone was "ripping her heart out though her neck."

A life of soccer games and school was replaced with 11 ER trips totaling more than 65 days. Maddie has suffered numerous systemic injuries, she is still in a wheelchair, receives all her nutrition and medicine through a feeding tube, cannot control her neck, has constant stomach, back, neck and body pain, vision problems, tinnitus, can't feel from the waist down, allergic reactions, and more. She's not improving but declining.

After reporting everything to the Pfizer clinical trial Principal Investigator and being brushed aside, we started documenting Maddie's injury. Cincinnati Children's first tried to treat Maddie as "a mental patient," telling us it was anxiety and it was all in Maddie's head. Pfizer listed her traumatic systemic adverse reaction as "functional abdominal pain" when reporting to the FDA. A day before Pfizer submitted their request for emergency approval for the Covid vaccine for 12-15-year-olds and before necessary testing was done, they put Functional Neurological Disorder as a diagnosis in her chart.

It's been over two years and a half, time and options are running out for Maddie. I can't even explain how hard it is to see your child suffer while watching doctor after doctor refuse to help her. We have exhausted all options available through insurance. Pfizer has zero financial obligation for Maddie's injury and they have not offered any assistance. Despite all that she has been through, she has remained strong and optimistic. We trust God and know that he will heal Maddie, he chose her for a reason and will continue to give her strength."

Dear Members of the Board,

Peter Machen, Mathews, VA

I am here today to speak against adding the Covid-19 shot to the schedule. Here is the updated VAERS data:

35,347 DEATHS

17,048 BELL'S PALSY

5,009 Miscarriages

19,915 Heart Attacks

27,113 Myocarditis

66,462 Permanently Disabled

37,785 Life Threatening

15,751 Shingles

Total two and a half million adverse events.

I would like you leave you with a few question, how many more people have to die before you stop recommending the Covid-19 shot? Do any of your close family members have to die before you stop? How much lower does the torch of freedom have to burn before you act to save my generation, or will you wait until the torch of freedom is completely extinguished and you yourself has no freedom either? One of our founding fathers John Adams said: "Freedom once lost, is lost forever." So either you can defend our rights or you can blow out the torch forever. Thank you

Dear Members of the Board,

I am Donna Machen of Mathews, Virginia, and I am concerned about the adverse effects of technology on my body. 5G has rolled out in my community, and Miss Judy Rowe has vowed that she will reach every person in Mathews with it, like it or not. Smart meters have rolled out into my neighborhood, and Dominion has vowed to upgrade every meter, like it or not. I have done my homework and learned that with 5G and smart meters, surveillance in my home will be an invasion of my privacy at the cost of my health. Not only that, it will be a violation of my fourth amendment right against searches and seizures. I urge you to do everything within your power to educate yourself and others on the dangers of technology and on ways to limit the danger for the sake of all Virginians. The effects include increased risk of cancer. How many people do you know or have you known with cancer? My husband has cancer. My mother has cancer. My father-in-law was diagnosed with cancer and put on hospice this week. My mother-in-law died from cancer. My deceased father had cancer. My neighbor, Miss Joan, has cancer and her deceased husband did, too. Will you pay attention? Will you listen? Will you do the right thing? Will you take action? Will you verify whether or not this technology is safe? Please face this, like it or not.

Good morning. I am Susan Franz and I'm from Williamsburg Virginia. The VDH continues to promote the Covid injection as safe and effective for pregnant women. I assume that as a public health board you are aware of Pfizer's own data demonstrating the injection is not safe for pregnant women or their babies. In their own document titled "cumulative analysis of adverse event reports, " 5.3.6 page 12, they demonstrate an 80 percent miscarriage rate in injection recipients. This study was conducted from Dec 2021 to Feb 2021. This one piece of information alone should cause the VDH to stop promoting this vaccine as safe and effective for pregnant women. Are you even aware of this information? If not, why not? It is your job to know the data that affects the decisions you make. Additional data is available that clearly demonstrates fetal death, malformation, blood clots and heart attacks in babies. Apparently you choose not to look at it. Worse, you know the truth and you choose not to act. It is pure evil to continue to promote this injection. I am calling for you, the VDH, to take a stand and stop promoting this injection as safe and effective. It clearly is not. The public is not stupid. We know when we have been lied to. We have lost complete faith and trust in those charged with keeping us safe and healthy. You have a chance to redeem your reputation by stopping this injection from being administered to anyone.

I am leaving you with a copy of the Pfizer results to review for yourselves.

5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021

Report Prepared by:

Worldwide Safety

Pfizer

Table 6. Description of Missing Information

Topic	Description
Missing Information	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**
Use in Pregnancy and lactation	• Number of cases: 413[3] (0.98% of the total PM dataset): 84 serious and 329 non-serious: • Country of incidence: US (205), UK (64), Canada (31), Germany (30), Poland (13), Israel (11); Italy (9), Portugal (8), Mexico (6), Estonia, Hungary and Ireland, (5 each), Romania (4), Spain (3), Czech Republic and France (2 each), the remaining 10 cases were distributed among 10 other countries. Pregnancy cases: 274 cases including: • 270 mother cases and 4 foetus/baby cases representing 270 unique pregnancies (the 4 foetus/baby cases were linked to 3 mother cases: 1 mother case involved twins). • Pregnancy outcomes for the 270 pregnancies were reported as spontaneous abortion (23), outcome pending (5), premature birth with neonatal death, spontaneous abortion with intrauterine death (2 each), spontaneous abortion with neonatal death, and normal outcome (1 each). No outcome was provided for 238 pregnancies (note that 2 different outcomes were reported for each twin, and both were counted). • 146 non-serious mother cases reported exposure to vaccine in utero without the occurrence of any clinical adverse event. The exposure PTs coded to the PTs Maternal exposure during pregnancy (111), Exposure during pregnancy (29) and Maternal exposure timing unspecified (6). Trimester of exposure was reported in 21 of these cases: 1st trimester (15 cases), 2nd trimester (7), and 3rd trimester (2). • 124 mother cases, 49 non-serious and 75 serious, reported clinical events, which occurred in the vaccinated mothers. Pregnancy related events reported in these cases coded to the PTs Abortion spontaneous (25), Uterine contraction during pregnancy, Premature rupture of membranes, Abortion, Abortion missed, and Foetal death (1 each). Other clinical events which occurred in more than 5 cases coded to the PTs Headache (33), Vaccination site pain (24), Pain in extremity and Fatigue (22 each), Myalgia and Pyrexia (16 each), Chills (13) Nausea (12), Pain (11), Arthralgia (9), Lymphadenopathy and Drug ineffective (7 each), Chest pain, Dizziness and Asthenia (6 each), Malaise and COVID-19 (5 each). Trimester of exposure was reported in 22 of these cases: 1st trimester (19 cases), 2nd trimester (1 case), 3rd trimester (2 cases). • 4 serious foetus/baby cases reported the PTs Exposure during pregnancy, Foetal growth restriction, Maternal exposure during pregnancy, Premature baby (2 each), and Death neonatal (1). Trimester of exposure was reported for 2 cases (twins) as occurring during the 1st trimester. Breast feeding baby cases: 133, of which: • 116 cases reported exposure to vaccine during breastfeeding (PT Exposure via breast milk) without the occurrence of any clinical adverse events: • 17 cases, 3 serious and 14 non-serious, reported the following clinical events that occurred in the infant/child exposed to vaccine via breastfeeding: Pyrexia (5), Rash (4), Infant irritability (3), Infantile vomiting, Diarrhoea, Insomnia, and Illness (2 each), Poor feeding infant, Lethargy, Abdominal discomfort, Vomiting, Allergy to vaccine, Increased appetite, Anxiety, Crying, Poor quality sleep, Eructation, Agitation, Pain and Urticaria (1 each). Breast feeding mother cases (6): • 1 serious case reported 3 clinical events that occurred in a mother during breast feeding (PT Maternal exposure during breast feeding); these events coded to the PTs Chills, Malaise, and Pyrexia • 1 non-serious case reported with very limited information and without associated AEs.

Horowitz: Confidential Pfizer document shows the company observed 1.6 million adverse events covering nearly every organ system

Over 10,000 *categories* of nearly 1.6 million adverse events – many of them serious and debilitating – brought to you by Pfizer!

You might not have heard it in the news, but in recent months, Pfizer's pharmacovigilance documents requested by the European Union's drug regulator, the European Medicines Agency, have been released. They show that Pfizer knew about a sickening level of injury early on. An August 2022 document shows that the company already had observed the following scope of vaccine injury:

- 508,351 individual case reports of adverse events containing 1,597,673 events;
- One-third of the AEs were classified as serious, well above the standard for safety signals usually pegged at 15%;
- Women reported AEs at three times the rate of men;
- 60% of cases were reported with either "outcome unknown" or "not recovered," so many of the injuries were not transient;

Highest number of cases occurred in the 31-50 year age group, and 92% did not have any comorbidities, which makes it very likely it was the vaccine causing such widespread, sudden injury.

These numbers alone suggest that all COVID shots should be defunded and Congress must immediately remove liability protections from the manufacturers. But a more recent document released by the Europeans is even more devastating, because it breaks down the 1.6 million adverse events observed by Pfizer by category and subcategory of ailment and injury.

The 393-page confidential Pfizer document, dated Aug. 19, 2022, shows that Pfizer observed over 10,000 categories of diagnosis, many of them very severe and very rare. For example:

- Pfizer was aware of 73,542 cases of 264 categories of vascular disorders from the shots. Many of them are rare conditions.
- There were hundreds of categories of nervous system disorders, totaling 696,508 cases.
- There were 61,518 AEs from well over 100 categories of eye disorders, which is unusual for a vaccine injury.
- Likewise, there were over 47,000 ear disorders, including almost 16,000 cases of tinnitus, which even Mayo Clinic researchers observed as a common but often devastating side effect early on.
- There were roughly 225,000 cases of skin and tissue disorders.
- There were roughly 190,000 cases of respiratory disorders.
- Disturbingly, there were over 178,000 cases of reproductive or breast disorders, including disorders you wouldn't expect, such as 506 cases of erectile dysfunction in men.

- Very disturbingly, there were over 77,000 psychiatric disorders observed following the shots, lending credence to Dr. Peter McCullough's research observing case studies showing psychosis correlating with vaccination.
- 3,711 cases of tumors – benign and malignant
- Of course, there were almost 127,000 cardiac disorders, running the gamut of about 270 categories of heart damage, including many rare disorders, in addition to myocarditis.
- There were over 100,000 blood and lymphatic disorders, for both of which there's a wealth of literature linking them to the spike protein.

When reading what Pfizer knew early on juxtaposed to independent studies, it's clear that nobody could have mistaken most of these AEs for mere incidental ailments. Here is a list of 3,129 case studies chronicling vaccine injury in every organ system observed in this Pfizer document.

What is so jarring is that there are hundreds of very rare neurological disorders that reflect something so systemically wrong with the shots, a reality that was clearly of no concern to the manufacturers and regulators alike. One of the infamous cases of vaccine injury was Maddie de Garay, an Ohio teen who became disabled for life immediately after participating in the Pfizer clinical trial. Her story is chronicled in chapter 16 of my book. I checked this confidential document and found that they knew of 68 cases of her rare diagnosis, chronic inflammatory demyelinating polyneuropathy.

Preferred Term	Total # of Spontaneous AE	I	C	I	C	I	C
Cerebral venous thrombosis	235	68	235			2	6
Cerebral ventricle dilatation	15	5	11	1	4	1	2
Cerebral ventricular rupture	14	3	14				
Cerebrosclerosis	1	1	1				
Cerebrospinal fluid circulation disorder	4		2	1	2		
Cerebrospinal fluid leakage	21	7	21				
Cerebrospinal fluid retention	1	1	1				
Cerebrovascular accident	4389	1331	4389			28	42
Cerebrovascular disorder	120	29	95	10	25	1	2
Cerebrovascular insufficiency	3	1	3				
Cerebrovascular stenosis	3	2	3				
Cervical cord compression	3	1	3				
Cervical radiculopathy	121	17	46	20	75		
Cervical spinal cord paralysis	3	2	3				
Cervicobrachial syndrome	158	19	60	35	98		
Cervicogenic headache	21	1	5	3	16		
Cervicogenic vertigo	6		1	2	5		
Change in seizure presentation	2		2				
Cholinergic syndrome	20	4	20				
Chorea	27	5	21	3	6		
Choreoathetosis	3			1	3		
Chronic inflammatory demyelinating polyradiculoneuropathy	68	39	66				
Chronic lymphocytic inflammation with pontine perivascular	1		1				
Chronic paroxysmal hemicrania	1	1	1				
Circadian rhythm sleep disorder	35	5	11	6	24		1
Claude's syndrome	3	1	3				
Clinically isolated syndrome	18	6	18				

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

The broad scope of injuries affecting every single organ system is simply extraordinary. Yet to this day, the FDA continues to criminally label the Pfizer shot as safe and effective. To this day, the label indicates the shot is a fully protective vaccine and also fails to mention all of these side effects, as required by law.

Recently, Peter Doshi, editor of the British Medical Journal, wrote a letter to the FDA requesting that the agency update its labeling to reflect the reality of what we've learned about the shots. Specifically, he asked that they include the following side effects on the label: multisystem inflammatory syndrome in children, pulmonary embolism, sudden cardiac death, neuropathic and autonomic disorders, decreased sperm concentration, heavy menstrual bleeding, and detection of vaccine mRNA in breast milk. The

causal relationship of all these AEs to the vaccine is backed by substantial research, surveys, and adverse event reporting systems.

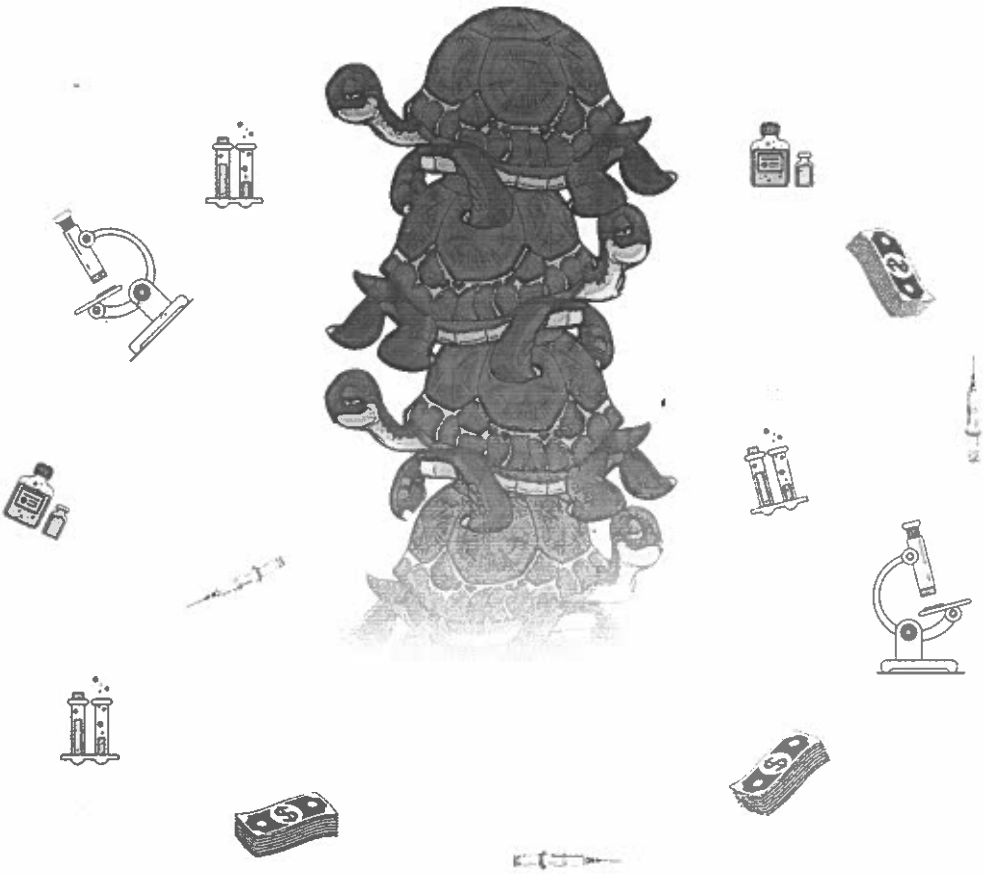
Unfortunately, the FDA denied the causal relationship between any of these side effects and the COVID shots. Even with regard to the request that officials clarify on the label that the shots don't stop transmission, the FDA replied, "We are not convinced that there is any widespread misconception about this."

"Product labeling should be informative and accurate, not promotional. The law requires it, and following the law shouldn't be optional," bemoaned Doshi and the other authors in a piece at TheHill.com.

The question is whether Republicans in the House will force the FDA to comply with the law by using the leverage of the appropriations bills for the FDA and HHS. So far, there has been no reckoning for their false marketing and the devastating human toll it has cost. Oh, and that is just the short-term human toll.

TURTLES ALL THE WAY DOWN

Vaccine Science and Myth



FOREWORD BY MARY HOLLAND, J.D.

EDITED BY ZOEY O'TOOLE AND MARY HOLLAND

Let's protect our kids.
Let's hardwire our schools.

TechSafeSchools

Information for Administrators

Legal Responsibility of School Administrators - Multiple state and federal laws confer legal responsibility on school administrators to ensure a safe and healthy learning environment for all students and staff. Understanding the risks of radiofrequency (RF) radiation and knowing exposure levels in classrooms is part of that legal responsibility. For more information, visit the **Legal** tab on our website.

Emerging Science on RF Radiation Exposure - Recent studies document serious biological harm from RF radiation at levels *below* current FCC safety guidelines. Exposure is cumulative and additive. Children and developing fetuses are at increased risk due to their unique physiologic vulnerability. To learn more, visit the **Science** tab on our website.

Three Easy Ways to Reduce Exposures

1. Have classrooms tested to determine RF radiation exposure levels. Test at task level with all devices operating.

2. Ask IT staff to reduce output power levels and adjust beacon frequency of routers and access points to reduce exposure levels.

3. Stop all purchases of wireless technology pending new exposure level recommendations from federal agencies.

For more ways to reduce radiation levels in classrooms, please visit the **Mitigation** tab *on our website.*

"We wired all our classrooms with Ethernet, and were able to reduce the power output of our few wireless access points by 75% without any noticeable impact on performance. From our perspective, even though we don't have all the answers, it's much better to take precautionary measures than to take the risk, especially when it comes to our students."

- Frances Cameron, Head of School, The Hartsbrook School, Hadley, MA

www.TechSafeSchools.org

Children's Radiofrequency (RF) Radiation Health Survey

Child's Age: _____ **Known Health Conditions Prior to Exposure:** _____

Symptoms	**Duration**			**Severity**		
	Rare	Intermittent	Chronic	High	Medium	Low
Cardiovascular Problems						
Arrhythmia	☐	☐	☐	☐	☐	☐
Blood Pressure Abnormalities	☐	☐	☐	☐	☐	☐
Heart Palpitations	☐	☐	☐	☐	☐	☐
Eye Pain, Pressure or Visual Disturbances	☐	☐	☐	☐	☐	☐
Fatigue	☐	☐	☐	☐	☐	☐
Hearing Loss, Ear Pain or Ringing in the Ears	☐	☐	☐	☐	☐	☐
Nausea	☐	☐	☐	☐	☐	☐
Neurological Problems						
Anxiety	☐	☐	☐	☐	☐	☐
Behavioral Problems	☐	☐	☐	☐	☐	☐
Concentration and Memory Problems	☐	☐	☐	☐	☐	☐
Dizziness	☐	☐	☐	☐	☐	☐
Headaches	☐	☐	☐	☐	☐	☐
Hyperactivity	☐	☐	☐	☐	☐	☐
Nose Bleeds	☐	☐	☐	☐	☐	☐
Seizures	☐	☐	☐	☐	☐	☐
Skin Rashes	☐	☐	☐	☐	☐	☐
Sleep Problems	☐	☐	☐	☐	☐	☐
Tingling or Burning Sensations of the Skin	☐	☐	☐	☐	☐	☐
Other _____	☐	☐	☐	☐	☐	☐

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Hearing Loss, Ear Pain or Ringing in the Ears	☐	☐	☐	☐	☐	☐
Nausea	☐	☐	☐	☐	☐	☐
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Headaches	☐	☐	☐	☐	☐	☐
Hyperactivity	☐	☐	☐	☐	☐	☐
Nose Bleeds	☐	☐	☐	☐	☐	☐
Seizures	☐	☐	☐	☐	☐	☐
Skin Rashes	☐	☐	☐	☐	☐	☐
Sleep Problems	☐	☐	☐	☐	☐	☐
Tingling or Burning Sensations of the Skin	☐	☐	☐	☐	☐	☐
Other _____	☐	☐	☐	☐	☐	☐

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Children's Radiofrequency (RF) Radiation Health Survey

Cancer

- Adrenal Gland ☐
- Brain ☐
- Breast ☐
- Heart ☐
- Parotid Gland ☐
- Testicular ☐
- Thyroid ☐
- Vestibular ☐

Exposures

- Alexa/Google/Siri ☐
- Baby Monitors and Accessories ☐
- Cell Phone ☐
- Cell Tower ☐
- Computer/Computer Components ☐
- Cordless or DECT Phone ☐
- Small Cell Antenna ☐
- Smart Home Fixtures/Appliances ☐
- Tablet ☐
- Utility Smart Meter ☐
- VR Headsets ☐
- Wi-Fi Router ☐
- Wireless Games/Toys ☐
- Wireless Wearables (Smart Watches/ Earbuds) ☐

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EMF Points of Confusion vs. Fact

Many are surprised to learn the **electromagnetic fields (EMFs)** emitted by wireless technology are biologically hazardous, and one often gets push-back when they open the conversation. This fact sheet provides information to help sort fact from misinformation and identifies solutions for safer technology use. For those reading this in print format, please see https://sites.google.com/site/understandingemfs/ma-emf-bills for an electronic copy to access the links below.

Point of Confusion	FACT
The FCC says wi-fi is fine.	FCC guidelines are outdated. The U.S. Government Accountability Office in 2012 instructed the FCC to bring their public radiation exposure limits in line with current science. Hundreds of formal comments were submitted to the FCC by EMF scientists, doctors and the American Academy of Pediatrics. The FCC has failed to respond and continues to promote wireless technology. See Harvard's *Captured Agency: How the Federal Communications Commission is Dominated by the Industries it Presumably Regulates*. They appear to be using the tobacco industry playbook. See also the Mobile Communications and Health study by T-Mobil.
The manufacturers make it look like all wi-fi all the time is the way to go.	Most consumers, and even many who work in the industry, are unaware of the manufacturers' fine print that comes with each device indicating one should never keep an active device on one's body or radiation exposure may exceed even the FCC's outdated non-protective guidelines. Additionally, science indicates we should have invoked the Precautionary Principle decades ago when evidence of harm was first found, and not exposed the public until proven safe. We have not done this in the U.S. but other countries have. This table illustrates the disparity in allowable public radiation exposure levels.
There are studies showing no evidence of harm.	No evidence of harm is not the same as safe. This technology was brought to market with no safety testing and a safe level of microwave radiation has never been identified. The telecommunications industry produces its own scientific studies designed to show no evidence of harm. This creates doubt among consumers so they will continue to purchase wireless products. Dr. Henry Lai provides insights here. In 2018 the U.S. National Institutes of Health found clear evidence of cancer, as did a large Italian study at the Ramazzini Institute.
There are not many studies done on wi-fi.	There didn't used to be, but there are now. See this 2018 meta-study on Wi-Fi by Dr. Martin Pall. Cell phones came first so that is why the majority of studies, which can take years to complete, use cell phones. However, all wireless operates in the biologically hazardous microwave segment of the electromagnetic radiation spectrum. So, what cell phone studies reveal holds true for 2G, 3G, 4G, 5G, wi-Fi and the Internet of Things too. We have thousands of studies showing man-made EMFs are hazardous to all biological species-- humans, plants, animals, and insects -- including the pollinators needed to grow our food.

Point of Confusion	FACT
Surely we would know if this were an issue.	Advertising dollars influence media content, and telecommunications, energy and technology companies are among the top advertisers. Media executives will not allow true investigative journalism into this issue or their revenues will drop so we rarely hear of wi-fi harm in mainstream media. When there is coverage, they typically say more research is needed, which appeases industry advertisers and keeps consumers buying their toxic products. Industry influence on public servants can also be a factor. In 2017, it took a lawsuit for the California Department of Public Health to finally release a long-suppressed fact sheet on cell phone radiation.
Our education agencies do not see this as an issue.	Few agencies have investigated because the industry has been so effective at suppressing evidence of harm while offering financial incentives to adopt EMF products and infrastructure. In our top-down education system, local schools often do not feel empowered to act. However, legal precedents are being set that leave schools, public agencies and companies at risk. The insurance industry has identified EMFs as one of the top emerging hazards. Lloyds of London and other insurers do not cover EMF damages so schools and businesses can be held directly responsible for harm. Workers compensation cases have also been awarded for EMF damages in the workplace, and teachers unions are beginning to request hard-wired work environments. Click here for additional information. Ashland Public Schools, MA has become the first in the nation to adopt Best Practices for Mobile Devices and Maryland is the first state to recommend hard-wiring in schools with wi-fi off.
We need wireless for the 21st century classroom.	The industry identified children as an untapped market and began their 21st Century Classroom campaign to put a wireless device in the hands of every child. In addition to biological harm from wi-fi, studies are showing excessive screen time is harming neurological brain development. This is causing impaired social and emotional skills, digital addiction and poorer educational outcomes. See the Reykjavik Appeal.
Some say electrosensitivity doesn't exist.	The United States Access Board's IEQ Indoor Environmental Quality Project indicates electromagnetic sensitivities may be considered disabilities under the ADA and recommends accommodations. Just as Lyme Disease was dismissed by medical practitioners before it was widely understood, today's doctors, nurses, psychologists and social workers in many countries have yet to be trained to diagnose and treat electrosensitivity (ES). School nursing records often indicate an increase in one or more common symptoms among students and staff following the installation of wireless systems: headaches, tachycardia, bloody noses, ear bleeds, skin rashes, nausea, tinnitus (loud ringing in the ears), vertigo, inability to concentrate, depression, anxiety, insomnia. See also the *EUROPAEM EMF Guideline 2016 for the prevention, diagnosis and treatment of EMF-related health problems and illnesses* and the *Guideline of the Austrian Medical Association for the diagnosis and treatment of EMF related health problems and illnesses (EMF syndrome)*.

Point of Confusion	FACT
The radiation drops off with distance.	This is true, in physics the inverse-square law states the intensity is inversely proportional to the square of the distance from the source of that physical quantity. However, it is the pulsed, spiked, erratic signal that causes biological damage. Many routers and cell antennas send and receive data at long distances, and those erratic pulses, though spread out with distance, hit our bodies as they go through buildings, walls, ceilings, etc. Further, if not stopped, the industry will put cell antennas right in our neighborhoods every 2-12 houses for 5G and the Internet of Things. These will pulse close range toxic radiation at our families 24x7.
Respected engineers, physicists, medical professionals and technologists in our community want our children to have wi-fi in schools.	Most professionals were taught in school and in their work that there must be enough heat from a wireless device to raise the temperature of skin tissue in order to cause harm. Non-industry funded science has now proven this thermal effect premise is false. Thousands of studies show biological effects at the non-thermal, non-ionizing level; most recently the U.S. National Toxicology Program study found DNA damage as well as brain and heart tumors. Professionals in all sectors will benefit from updated education on EMFs.
There is nothing we can do, wi-fi is everywhere.	Leading non-industry funded EMF scientists from around the world have already sent a formal appeal to the World Health Organization and United Nations to address this "emerging public health crisis". They succinctly outline specific measures to solve this problem, the first of which is to protect children and pregnant women. Until public policy catches up with science and biologically safe technology is brought to market: • Use hard-wired connections with antennas turned off (cell, data, Bluetooth, wi-fi, hotspot) to access the internet safely and avoid legal exposure. Hard-wired is not only safer, it is faster, more reliable and more secure than wireless. Use Ethernet cables and adapters to hard-wire routers, laptops, tablets, etc. Clear sleeping areas of EMFs, and never give to or use an active device near a child. • Choose corded baby monitors, gaming devices, entertainment systems; turn off any wi-fi antennas. • Use corded landline phones, they are safer and more reliable, especially during power outages. Avoid DECT cordless phones, they have high EMF emissions. Cell phones can be forwarded to landlines. • Keep analog utility meters, they do not emit the electromagnetic radiation that "smart" meters do. • Work with public servants to keep wireless infrastructure away from where we live, work, learn, play. The U.S. Collaborative for High Performance Schools provides Low-EMF Best Practices to establish a hard-wired school environment and prohibit use of personal wi-fi devices in school, except during emergencies. See WirelessEducation.org, a non-profit charity that distills the science and medical recommendations into easy-to-learn concepts in affordable 30-minute e-learning courses for families, schools, and workplaces.

Americans for Responsible Technology
184 Main Street • Port Washington • New York • 516.883.0887 • www.AmericansForResponsibleTech.org

May 24, 2023

[Submitted Electronically]

Division of Dockets Management
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION AND REQUEST FOR LEGAL COMPLIANCE

Legal Obligations of FDA Regarding Public Exposure to Non-Ionizing Radiation from Electronic Products

Pursuant to 21 C.F.R. §§ 10.20, 10.30 (Citizen Petitions), Petitioner Americans for Responsible Technology and other petitioners Grassroots Environmental Education, Consumers for Safe Cell Phones, California Brain Tumor Association, Manhattan Neighbors for Safer Telecommunications, Michelle Lewis, Zen Honeycutt, Michele Hertz, and Laurie Brown hereby respectfully request that the Secretary of Health and Human Services (HHS) and the Commissioner of the Food and Drug Administration (FDA) fully execute, implement, fulfill and carry out their administrative obligations under 21 USC Federal Food, Drug and Cosmetic Act, Subchapter V, Part C Electronic Product Radiation Control, Section 360ii - Program of Control, regarding public exposure to non-ionizing radiation, a part of the electromagnetic spectrum. We further petition the FDA to produce and make public information detailing its activities and administrative actions that demonstrate full compliance with the specifications of the statute, especially as they relate to non-medical products and devices emitting this radiation.

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SECTION 1. STATEMENT OF GROUNDS

Petitioners are individuals and non-profit organizations representing individuals who are, or have been directly, negatively, and substantially affected by the failure of FDA to adhere to basic and fundamental principles and requirements of its organic statute (21 U.S.C., Subchapter V) and administrative law, or to engage in the on-going risk assessment required.[1] FDA's repeated failure to fully comply with the plainly worded requirements in Subchapter V as it relates to electronic products and devices has resulted in a void of public information and exerted a serious and negative influence on medical practitioners and their patients, local, state, and federal officials, school administrators, parents, and other individuals, resulting in a clear and present danger to public health and a violation of public trust.

SECTION 2. ISSUES INVOLVED

In 1968, Congress passed Public Law 90-602, "An Act to Amend the Public Health Service Act to provide for the protection of the public health from radiation emissions from electronic products," also known as the Radiation Control for Health and Safety Act of 1968. In its Declaration of Purpose, Congress wrote, "*The Congress hereby declares that the public health and safety must be protected from the dangers of electronic product radiation.*" The law was updated and codified into the current law in 1991,[2] with no significant change in its underlying purpose of minimizing the public's exposure to both ionizing and non-ionizing radiation.

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[1] As the Secretary has customarily delegated authority over these matters to the Food and Drug Administration, in this document we will hereafter refer only to FDA except when quoting the law.

[2] The Radiation Control for Health and Safety Act, P.L. 90-62, Subpart 3 (enacting then 42 U.S.C. Sec. 354) provided that "The Congress hereby declares that the public health and safety must be protected from the dangers of electronic product radiation. Thus, it is the purpose of this subpart to provide for the establishment by the Secretary of an electronic product radiation control program which shall include the development and administration of performance standards to control the emission of electronic product radiation from electronic products and the undertaking by public and private organizations of research and investigation into the effects and control of such radiation emissions." The Section 354 purpose and policy statement was repealed in P.L. 101-629, the Safe Medical Devices Act of 1990, Sec. 19(a)(3), but the underlying understanding of risks remains given the still-effective duty to "protect the public health and safety from electronic product radiation" by requiring "activities to minimize the emissions of and the exposure of people to, unnecessary electronic product radiation." (§ 360ii(a)(2)).

Over the past two decades the ubiquity of personal wireless devices, the deployment of hundreds of thousands of new small cell wireless antennas, the installation of millions of wireless utility meters, the outfitting of school classrooms with wireless routers, tablets, and smart boards, and the surge of popularity of personal wireless wearables and the myriad of other wireless devices now in near-constant use by the public has created a level of exposure to radiation unfathomable to the drafters of the 1968 law. Their belief that exposure to non-ionizing radiation would constitute an on-going and significant risk to public health was prescient.

The issue we address in this Petition is that FDA has failed to execute the clear obligations imposed by Congress, placing the agency in violation of the law. The determination of ***risk*** regarding human exposure to non-ionizing radiation has already been made by Congress. Because of the risk involved, Congress instructed FDA to ***minimize*** that risk by actively participating in the development of publicly available materials designed to help the public reduce its exposures to radiation emanating from electronic products. Despite acknowledging its authority in this area and its responsibility for protecting the public from hazardous and unnecessary exposure to radiation from electronic products,[3] Petitioners assert that these actions have not been, and continue not to be, properly taken by FDA, resulting in an escalating risk and significant harm to public health.

Administrative agencies such as FDA must adhere to their governing statutes and, like all agencies and individuals, obey the law. While the statute is equivocal as to whether the Commissioner has a mandatory duty to promulgate "standards" for human exposure, or whether a predicate finding is required,[4] no such leeway exists regarding the other clear obligations of FDA to carry out the activities enumerated in the law. These include:

- [P]lanning, conducting, coordinating, and/or supporting research, development, training, and operational activities to minimize the emissions of, and the

[3] See, *inter alia*, https://www.fda.gov/radiation-emitting-products/electronic-product-radiation-control-program.

[4] *Compare* 21 U.S.C. § 360ii(a)(1) ("shall" "develop and administer performance standards…"); § 360kk(a)(1) "shall by regulation prescribe performance standards for electronic products to control the emission of electronic product radiation from such products if he determines that such standards are necessary for the protection of the public health and safety." (Emphasis added).

exposure of people to, unnecessary electronic product radiation [21 USC 360ii (a) (2)]

- [S]tudying and evaluating emissions of, and conditions of exposure to, electronic product radiation and intense magnetic fields [21 USC 360ii (a) (4)]
- [D]eveloping, testing and evaluating the effectiveness of procedures and techniques for minimizing exposure to electronic product radiation [21 USC 360ii (a) (5)].

These obligations are not dependent on an FDA determination of risk, or any arbitrary exposure level established by FDA or any other entity, and cannot be extinguished by other means. Congress understood that **any** reduction to a known health hazard will inevitably have a beneficial impact on public health. Petitioners note that FDA does have a Technical Electronic Product Radiation Safety Standards Committee, established in 1968.[5] But as if to underscore its failure to recognize its responsibilities under the law or take them seriously, the Committee has not met since 2016, and FDA has allowed the committee's membership to dwindle to just five out of the required 15 members. This situation has only recently been addressed by FDA after the matter was brought to the attention of the Court in *EHT v. FCC*.[6]

Moreover, because the purpose of the prescribed activities in Section 360ii is to protect public health and safety by having the FDA produce and make public materials to help members of the public reduce their exposure, activities that take place out of public view, such as private deliberations or discussions within FDA with no public record, public notice, or public participation, do not and will not satisfy the requirements of the statute.

[5] This advisory committee was established in accordance with Section 21 U.S.C. 360kk(f)(1) of the Radiation Control for Health and Safety Act. The committee is supposed to advise FDA regarding proposed performance standards for electronic products which emit radiation.

[6] *Envtl. Health Tr. v. FCC*, 9 F.4th 893, 904-906 (D.C. Cir. 2021) "EHT v. FCC")

SECTION 3. SPECIFIC ACTIONS REQUESTED

Petitioners hereby respectfully request that the Commissioner direct the Centers for Devices and Radiological Health (CDRH), or such other new or existing division as he may designate, to take the following three actions to bring FDA into full compliance with the law.

A. REQUESTED ACTION NO. 1

21USC 360ii (a) (2) requires FDA to "plan, conduct, coordinate, and/or support research, development, training, and operational activities to minimize the emissions of and the exposure of people to, unnecessary electronic product radiation."

1. Planning, conducting, coordinating and/or supporting research

In its own "*Review of Published Literature between 2008 and 2018 of Relevance to Radiofrequency Radiation and Cancer*"[7] published in 2020, FDA fails to identify a single peer-reviewed study designed to help the public reduce its exposure in which FDA has been actively engaged regarding the planning, coordination, or support of the study.[8] Instead, FDA claims it regularly "monitors" scientific studies performed by others,[9] as if such passive activity satisfies the demands of the law. It does not.

The one study on non-ionizing radiation in which FDA actually played a role was the study conducted at FDA's request to determine whether or not non-thermal levels of radiation such as that from cell phones posed a cancer risk to humans.[10] That study, which fails to meet the requirements of the law since it is not about reducing

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[7] https://www.fda.gov/media/135043/download

[8] The review ignored hundreds of published, peer-reviewed independent scientific studies which demonstrated biological harm from exposure.

[9] See, *inter alia*, https://www.fda.gov/radiation-emitting-products/cell-phones/do-cell-phones-pose-health-hazard "The FDA's physicians, scientists, and engineers regularly analyze scientific studies and publications for evidence of health effects of exposure to radio frequency energy from cell phones."

[10] "The existing exposure guidelines are based on protection from acute injury from thermal effects of [non-ionizing] exposure, and may not be protective against any non-thermal effects of chronic exposures." FDA Nomination letter to National Toxicology Program, May 19, 1999. https://ntp.niehs.nih.gov/ntp/htdocs/chem_background/exsumpdf/wireless051999_508.pdf

exposures, was nominated by FDA to the National Institutes of Health in 1999.[11] Preliminary results were released by the NIH's National Toxicology Program (NTP) in 2016, with an independent peer review panel releasing its own findings in 2018. The panel found that the study results showed "clear evidence" of an increased risk of cancer,[12] the highest level of scientific confidence. FDA, however, immediately disputed the study's findings, claiming, among other things, that the results were not conclusive.

The NTP study could have been useful in meeting the law's requirements, if FDA had alerted the public that exposure to non-ionizing radiation could increase their own risk of cancer. Instead, CDRH's Director Dr. Jeffrey Shuren issued a statement[13] in response to the independent panel's conclusion, asserting that the study's findings "*should not be applied to human cell phone usage*," when, in fact, determining whether or not there was a potential risk to humans was the whole purpose guiding the study's design.[14] Dr. Shuren's statement, unsupported by any documentation, drew a sharp rebuke from the U.S. Court of Appeals for the District of Columbia Circuit in Washington, DC[15] for its "conclusory" nature, when the Court stated:

> *"Such conclusory statements 'cannot substitute for a reasoned explanation,' for they provide 'neither assurance that the [FDA] considered the relevant factors nor [do they reveal] a discernable path to which the court may defer.' Am. Radio, 524 F.3d at 241. They instead represent a failure by the FDA to address the implication of Petitioners' studies: The factual premise — the non-existence of*

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[11] https://ntp.niehs.nih.gov/getinvolved/nominate/summary/nm-n99019.html

[12] https://ntp.niehs.nih.gov/whatwestudy/topics/cellphones/index.html

[13] https://www.fda.gov/news-events/press-announcements/statement-jeffrey-shuren-md-jd-director-fdas-center-devices-and-radiological-health-recent-national

[14] The original 1999 FDA nomination of the subject for study defined its rationale as follows: "Little is known about the possible health effects of repeated long-term exposure to low levels of radio frequency radiation (RFR) of the types emitted by wireless communication devices, like cellular phones." See https://ntp.niehs.nih.gov/getinvolved/nominate/summary/nm-n99019.html

[15] *Envtl. Health Tr. v. FCC*, 9 F.4th 893, 904-906 (D.C. Cir. 2021) "EHT v. FCC"). See, *inter alia*, https://www.fda.gov/radiation-emitting-products/home-business-and-entertainment-products/cell- phones

non-thermal biological effects — underlying the current radio-frequency guidelines may no longer be accurate."

We note here that FDA seems to believe its responsibility for planning, supporting or conducting research on reducing exposures is limited to the radiation emitted by mobile phones.[16] In its 2020 literature review, the agency goes to great lengths to explain how difficult it is to study the effect of non-ionizing radiation using animals because "*the effects of whole-body exposure do not reflect the real-world situation of localized exposure to the ear and head from a handset as used by humans*." Here, intentionally or not, FDA misses the point. *Whole-body exposure* is exactly what the public is currently experiencing, resulting from the ubiquity and aggregate exposures of wireless devices in public spaces as well as private homes. FDA's negligence in failing to recognize and address this large and growing public exposure, and failing to advise the public about ways to reduce exposure, violates both the letter and spirit of this section of the law and puts public health at increased risk.

2. Planning, conducting, coordinating and supporting training and operational activities

The law requires FDA to engage in training and operational activities that result in minimizing the public's "unnecessary" exposure to non-ionizing radiation. Given the wide array of potential exposures, this requirement might be satisfied by coordinating or conducting professional training of medical, educational, and commercial providers in techniques through which public exposure might be minimized. It could include participation at continuing medical education conferences. Due to the recent deployment of wireless technology in school settings, it should include evaluations of methods to reduce exposures of children in classrooms and coordination with the Department of Education to promulgate recommendations and best practices. At the very least, FDA should be requiring commercial providers to participate in the development of exposure reduction techniques, such as one-button wireless disconnects, which could then be promulgated by FDA, or FDA could develop its own exposure reduction techniques.

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[16] See, *inter alia*, https://www.fda.gov/radiation-emitting-products/home-business-and-entertainment-products/cell-phones

None of these activities, or any others that might reasonably satisfy the requirements of the law are being undertaken by FDA.[17] While FDA does include some cursory language on its website about how individuals may voluntarily limit their own exposure by taking simple steps such as reducing the amount of time spent on phones or using the speaker setting, it only does so in the context of actions it portrays as entirely unnecessary,[18] and which only pertain to cell phones. FDA is doing nothing about singular or aggregate exposures from other electronic products or workplace environments where prolonged and sustained exposure is unavoidable. FDA's innocuous, incidental and half-hearted advisories do not in any way constitute "support" for such measures or reasonable compliance with the law.

3. Conclusion: Requested Action No. 1

For the foregoing reasons, Petitioners respectfully request the Commissioner to direct CDRH or such other division of FDA as may be capable of carrying out the requirements of this section to take such actions as may be required to bring FDA into full compliance with § 360 ii (a) (2), including regularly producing and making public information detailing the agency's actions that help consumers reduce their exposures and demonstrate compliance with the law. Such information should include details of specific actions taken by FDA including (1) research commissioned, organized, conducted and/or supported by FDA concerning methods or techniques for reducing exposures, (2) records of meetings, conferences or other events at which FDA solicited or presented scientific studies on exposure reduction, (3) publication of specific and dedicated web pages on FDA's website regarding this research and its conclusions,

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[17] FDA, through the Office of Medical Device and Radiological Health Operations (OMDRHO), a program office within the Office of Medical Products and Tobacco Operations (OMPTO), a part the Office of Regulatory Affairs (ORA), does conduct an annual conference and other activities designed to allow government agencies and medical professionals to share ideas and collaborate on methods to protect public health from some types of radiation exposure. However, the OMDRHO is focused exclusively on medical devices and radiological health products, and Congress did not limit the purview of FDA with regard to different types of radiation exposure. Accordingly, such efforts fail to extinguish the FDA's obligation to address **all** types of radiation exposure, including those identified in this Petition.

[18] See, *inter alia*, https://www.fda.gov/radiation-emitting-products/cell-phones/reducing-radio-frequency-exposure- cell-phones "There is no established health benefit from reducing an individual's exposure from cell phones."

and (4) notices of the publication of FDA's research specifically addressing non-ionizing radiation exposure reduction.

B. REQUESTED ACTION NO. 2

21 USC 360ii (a) (4) requires FDA to study and evaluate emissions of, and conditions of exposure to, electronic products that emit non-ionizing radiation.

1. Studying Emissions of Electronic Products

The number of electronic products that emit radiation has grown by orders of magnitude since passage of the original Radiation Control for Health and Safety Act of 1968. These products now include not only mobile phones, but routers, smart utility meters, cordless phones, GPS devices, wireless computer keyboards, tablets, virtual reality headsets, baby monitors, wearables and the myriad other radiation-emitting devices to which millions of Americans are exposed every day.

Petitioners are unable to find any evidence that FDA has engaged or participated in any publicly available research regarding the emissions of such devices, maintained any record of citizen complaints or adverse effects of exposure, participated in or directed any monitoring activities, or required manufacturers to do so. Available technologies that can accurately measure levels of non-ionizing radiation, especially aggregate levels from multiple devices which characterize the majority of public exposures today, remain unutilized by FDA. Instead, FDA seems to be relying on other federal agencies to do the research. The Federal Communications Commission (FCC) does require manufacturers to submit test results showing their individual devices comply with the agency's thermal-only emission standards, but the FCC does not have, by its own admission, either the authority or capacity to study, evaluate and promulgate techniques for reducing the risk to public health. That is the duty and legal obligation of FDA.

Miriam-Webster defines the word "study" as "*careful or extended consideration*" and "*careful examination of a phenomenon, development or question.*" and "*application of the*

mental faculties to the acquisition of knowledge."[19] Congress clearly intended FDA to devote time, attention, and resources to considering, examining and understanding ways in which people are exposed to non-ionizing radiation and how they might reduce that exposure, including all of the ways mentioned above. FDA has repeatedly failed to comply with these statutory requirements.

2. Studying and Evaluating Conditions of Exposure

The law also instructs FDA to engage in activities to study the conditions under which the public may be exposed to non-ionizing radiation, and to evaluate those exposures for the purpose of finding ways to reduce them. As the use of electronic products that emit non-ionizing radiation has grown exponentially, with virtually every man, woman and child now regularly exposed, often without their knowledge or consent, FDA is failing to monitor these exposures or evaluate the conditions under which they take place.

For example, the introduction of wireless technology into America's classrooms, where the exposure from multiple devices is nearly constant and affects the whole body of a uniquely vulnerable population, would, by any reasonable interpretation of the law, constitute a "condition of exposure" which demands investigation and evaluation by FDA. Yet Petitioners can find no publicly available evidence that FDA has studied, measured, or evaluated such exposures. There are no public reports of any FDA inspections of schools to measure cumulative or aggregate exposure levels in busy classrooms, or the effects of exposure on students, teachers, and staff. FDA maintains no records from schools of reported adverse reactions, and FDA's website contains no mention of any research the agency is supporting or conducting to evaluate the potential risk associated with exposures in schools, especially those experienced by very young children. FDA has issued no advisories or recommendations to schools, educational organizations, or teachers unions about reducing their exposures.

Another common radiation exposure for many people are the high bursts of radiation emitted by so-called "smart" utility meters. These bursts of radiation emanating from the meter

[19] https://www.merriam-webster.com/dictionary/study

have caused many individuals, including several of the Petitioners, to experience acute symptoms often associated with exposure to non-ionizing radiation which are alleviated when the source of radiation is removed. These symptoms include headaches, dizziness, nausea, insomnia, tinnitus, confusion, and other symptoms. The installation of a smart meter has also triggered heightened electromagnetic sensitivity among a small but growing community of individuals who find their lives completely disrupted by the condition, and who cannot easily escape. Petitioners can find no evidence that FDA has engaged in any analysis or evaluation of the emissions of wireless utility meters, conducted any research to understand how bursts of non-ionizing radiation may impact humans differently from constant low levels, established a mechanism by which consumers can report adverse health reactions to such devices, or determined why some individuals are more sensitive to bursts of non-ionizing radiation than others, and what they can do about it. Under the plain language of the law, FDA is legally obligated to act but is failing to act.

The world's largest insurance companies, which employ legions of experts to evaluate potential risks, have decided that exposure to non-ionizing radiation poses a potential health risk so high it must be excluded from their commercial liability policies. An evaluation of the available science by experts at Swiss Re advises investors, "*Existing concerns regarding potential negative health effects from electromagnetic fields (EMF) are only likely to increase. An uptick in liability claims could be a potential long-term consequence.*"[20] Lloyds of London warns its customers in its commercial liability policies that the company's insurance does not cover any claims "*directly or indirectly arising out of, resulting from or contributed to by electromagnetic fields, electromagnetic radiation, electromagnetism, radio waves or noise.*" Even the purveyors of wireless technologies acknowledge the risk involved and warn their investors in their SEC 10K filings that their future earnings may be adversely affected by liability claims due to exposures.[21] FDA is silent, issuing no advisories or warnings to the public, in spite of the law's clear requirement that it do so.

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[20] Swiss Re SONAR New emerging risk insights May 2019 Accessed March 21, 2023 at https://www.swissre.com/institute/research/sonar/sonar2019.html

[21] For example, this statement from Verizon's 2018 filing with the SEC: "Our wireless business also faces personal injury and wrongful death lawsuits relating to alleged health effects of wireless phones or radio frequency transmitters. We may incur significant expenses in defending these lawsuits. In addition, we may be required to pay

3. Conclusion: Requested Action No. 2

For the foregoing reasons, Petitioners respectfully request the Commissioner to direct CDRH or such other division of FDA as may be capable of carrying out the requirements of this section to take such actions as may be required to bring FDA into full compliance with the law, and specifically to study and evaluate the conditions of the public's many sources of exposure to non-ionizing radiation, including the impact of peak exposures and chronic exposures of children occurring in schools, and to produce and make public regularly updated information detailing the agency's actions to help the public reduce its exposures. Such information should include details of specific actions taken by FDA including (1) the design, execution and/or results of independent research designed, performed or commissioned by FDA regarding various types of public exposures, especially *involuntary* exposures emanating from wireless utility meters, high levels of radiation in workplace environments, and exposures of children in school classrooms, (2) summaries of reports or tests performed by other agencies and independent experts with whom FDA has consulted about reducing exposures, and (3) publication of this information on dedicated web pages of the FDA website.

C. REQUESTED ACTION NO. 3

21 USC 360ii (a) (5) requires FDA to develop, test and evaluate the effectiveness of procedures and techniques for minimizing exposure to electronic product radiation.

1. Developing Procedures and Techniques for Minimizing Exposure

In writing the law, Congress clearly intended for FDA to actively engage in developing plans, procedures, strategies, and techniques for minimizing the exposure of the public to radiation of all kinds. Such procedures might include working with wireless device manufacturers to provide a one-button disconnect that would immediately disable all wireless antennas. New cars could be outfitted with a switch to turn off all unnecessary wireless

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significant awards or settlements."
https://www.sec.gov/Archives/edgar/data/732712/000073271219000012/a2018q410-k.htm

circuits. Routers could be manufactured with circuits to automatically turn off when not in use or at night when users are asleep.

Public buildings could provide radiation-free zones for citizens. Colleges and universities could be encouraged to set aside spaces where non-ionizing radiation is minimized. Hotels could be encouraged to provide "Wi-Fi-free" rooms for individuals who suffer from electromagnetic sensitivity. All wireless devices, including cell phones, could be required to include more prominent consumer warnings about the hazards of exposure. FDA could engage with companies that provide shielding materials to reduce the transmission of radiation through walls and windows, and those that create equipment to test and monitor for radiation levels.

FDA's responsibility for developing techniques for minimizing exposure to electronic product radiation is not optional. FDA has been given the authority and responsibility by Congress, but has failed to engage in any of these, or other similar activities that meet even the minimum requirements of the law.

2. Testing the Techniques and Procedures for Minimizing Exposure

FDA is required by law to ***test*** the procedures it has developed for minimizing the public's exposure to all types of radiation, but obviously there can be no testing of procedures if no procedures have been developed. If FDA doesn't at present have sufficient staff to meet this requirement, the agency should request appropriations from Congress to fund such activity. Human lives are at stake. It is not a matter of administrative or corporate convenience. FDA's responsibility and failure are clear.

3. Evaluating the Effectiveness of Procedures and Techniques

Here again, FDA is unable to meet the requirements of the law because of its failure to carry out any of the activities specified earlier in this section. It's not up to FDA to decide which parts of the law it wants to comply with and which to disregard. If Congress wishes to change the law, it can. Barring such a change, FDA has no legal choice but to carry out the stipulated activities.

4. Conclusion: Requested Action No. 3

For the foregoing reasons, Petitioners respectfully request the Commissioner to direct CDRH or such other division of FDA as may be capable of carrying out the requirements of this section to take such actions as may be required to bring FDA into full compliance with the law, and specifically to develop or cause to be developed techniques for minimizing the public's exposure to non-ionizing radiation from the full array and aggregate emissions of electronic products to which people are exposed, and produce and make public regularly updated information detailing the agency's actions that demonstrate compliance with the law. The information should include details of specific actions taken by the agency including (1) specific techniques developed by or for FDA which result in minimizing human exposure to non-ionizing radiation, (2) meetings or conferences organized or attended by FDA where minimizing human exposure to non-ionizing radiation was discussed, (3) outreach efforts by FDA to acquire data about reducing exposure to non-ionizing radiation from third parties, (4) activities to educate the medical profession about techniques for reducing exposures, and (5) interim or final reports of FDA's related research or other relevant materials.

SECTION 4. PUBLICLY AVAILABLE INFORMATION IS REQUIRED

A. ACCURATE INFORMATION SERVES THE PUBLIC INTEREST

The public concern over the risk from non-ionizing radiation emitted from electronic products has been deepened recently by studies questioning the adequacy of current federal safety guidelines to protect public health,[22] and media reports suggesting that the federal government is not focused on protecting the health of the public but instead on protecting the wireless industry from scrutiny.[23] The plain language of the statute suggests that Congress expects FDA to promulgate information to help the public reduce its risk, at least in part to help assure the public that there are ways to use electronic products safely.

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[22] International Commission on the Biological Effects of Electromagnetic Fields (ICBE-EMF) "Scientific evidence invalidates health assumptions underlying the FCC and ICNIRP exposure limit determinations for radiofrequency radiation: implications for 5G" *Environ Health* **21**, 92 (2022). https://doi.org/10.1186/s12940-022-00900-9

[23] *Inter Alia*, Peter Elkind, "How the FCC Shields Cellphone Companies from Safety Concerns" ProPublica, November 10, 2022, https://www.propublica.org/article/fcc-5g-wireless-safety-cellphones-risk

Congress actually got it right in 1968. It foresaw that certain values, particularly protection of the public from the risks of radiation, are imperative and superior to manufacturer or shareholder interests. Production and promulgation of publicly available information detailing the efforts of FDA to fully engage in a rigorous program of investigation, research, monitoring, and testing of the myriad wireless electronic devices currently in use every day by consumers, and otherwise fulfilling the requirements of the law, would provide local, state and federal elected officials, medical practitioners, school administrators, parents and other members of the public with tools to help them reduce exposures to those electronic devices, as Congress intended.

B. INFORMATION WOULD AID OTHER BRANCHES OF GOVERNMENT

Federal agencies and other branches of the government, including the Federal Communications Commission, the Department of Commerce, Department of Transportation, Department of Labor, Occupational Safety and Health Administration, Centers for Disease Control, Department of Defense, Department of Education, Congressional Research Service and others which depend on scientific information from FDA to determine their own policies will benefit from knowing the results of efforts by FDA to evaluate and reduce the public's exposures to non-ionizing radiation in schools, factories, office buildings, electric vehicles, trains, airplanes and other environments.

Such information would also be consistent with FDA's legal obligation under § 360ii (6) which requires the Secretary of HHS to:

> *"[C]onsult and maintain liaison with the Secretary of Commerce, the Secretary of Defense, the Secretary of Labor, the Atomic Energy Commission, and other appropriate Federal departments and agencies on (A) techniques, equipment, and programs for testing and evaluating electronic product radiation, and (B) the development of performance standards pursuant to section 360kk of this title to control such radiation emissions."*

Publication of the information on the FDA website, with notice and opportunities

for public comment will help fulfill the agency's mission to protect public health and build public confidence that the agency is acting in *their* best interests, not the interests of the wireless industry.

SECTION 5. FDA'S FAILURE TO OBEY THE LAW IS PUTTING PUBLIC HEALTH AT RISK

Petitioners assert that FDA has a duty to act in good faith to convey accurate and truthful information to the public, and that the continued failure of FDA to abide by the clear and unambiguous language of the statute, combined with its unequivocal public stance that biological risks of exposure to non-thermal levels of non-ionizing radiation simply do not exist, is resulting in significant and growing harm to public health. This is manifested in numerous instances of irreversible but completely avoidable illness, mental anguish and stress among tens or hundreds of thousands of Americans who, because of FDA's negligence, may fail to attribute their own health conditions to over-exposure to non-ionizing radiation or worse, may develop a life-threatening illness.

A. MEDICAL PRACTITIONERS ARE NOT RECEIVING FULL DISCLOSURE OF RELEVANT MEDICAL INFORMATION FROM FDA

Petitioners acknowledge that scientific debate exists regarding the various mechanisms by which acute or long-term exposure to non-ionizing radiation triggers biological changes, although many studies exist to strongly suggest possible culprits, including, most notably, oxidative stress.[24] However, the lack of scientific consensus regarding the root cause and mechanism of biological changes is not proof that such changes are not occurring, or that the science is settled on the subject, or that the public should bear the burden of proof of harm, especially when Congress has already recognized that a significant risk exists.

FDA's failure to advise the public on ways to reduce exposure, combined with its public stance on the issue of non-ionizing radiation from wireless devices is misleading and confusing to physicians and clinicians who – when faced with patients exhibiting a variety of

[24] See, *inter alia*, The effect of radiofrequency electromagnetic fields (RF-EMF)) on biomarkers of oxidative stress in vivo and in vitro: A protocol for a systematic review, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8668870/

symptoms often associated with non-ionizing chronic radiation exposure – discount the possibility of a link to such exposure because they have been led to believe that this exposure is not a clinically relevant concern. As a result, physicians are misdiagnosing these conditions, making medical decisions, and prescribing medications for patients, all based on the false belief that FDA is actively carrying out its obligations under the law and has developed its official policy and position that the health risks associated with exposure to non-thermal levels of non-ionizing radiation are *de minimis*.

The development of any official FDA policy is subject to the Administrative Procedure Act (APA) (5 U.S.C. Chapter 5), the Congressional Review Act, the Paperwork Reduction Act, the Regulatory Flexibility Act and various Executive Orders. Petitioners can find no substantial evidence that FDA has engaged in any of the necessary steps to develop an official policy regarding human exposure to non-ionizing radiation from electronic devices, or any documentation from FDA about the basis for its claim of safety or acknowledgement of the vigorous scientific debate over this issue.

Nevertheless, FDA has articulated a *de facto* policy, whether official or not. FDA's failure to research, analyze and promote techniques for reducing exposures is steering medical professionals away from information that may help them diagnose and treat medical conditions, which may in turn be caused by unnecessary exposures. This is a serious breach of the agency's most fundamental duty of care.

B. FDA IS FAILING TO ADVISE SCHOOL OFFICIALS ABOUT REDUCING EXPOSURES IN CLASSROOMS

Today's school classrooms are filled with wireless technology. In elementary schools, most students are provided with their own personal wireless device for use in class, and the classroom itself is outfitted with wireless routers, smart boards, and projectors among other wireless educational products; in secondary schools, personal wireless computers are required. In addition, many students have their own personal cell phones, making school classrooms

potentially "hot" environments for non-ionizing radiation with dozens of devices operating simultaneously in a confined area.

The implementation of wireless technology in classrooms is taking place in a regulatory vacuum caused by FDA's failure to implement the measures prescribed by Congress to avoid just such a situation. No other federal agency has been empowered, indeed *directed*, to identify situations such as school classrooms in which large numbers of people - in this case, children - are being regularly exposed to non-ionizing radiation from wireless devices, and to undertake efforts to reduce that exposure. FDA alone currently has this oversight authority and responsibility.

In the absence of FDA action, school administrators, parents and teachers are going along with the wireless industry's relentless push to transform education into a digital service based on the assumption that FDA has fulfilled its legal obligation to develop, test, evaluate and promulgate procedures and techniques for minimizing exposures, and that schools are complying with those recommendations. That is not the case.

Teachers, many of whom are of child-bearing age, are being exposed throughout the day to the cumulative non-ionizing radiation emanating from all wireless devices in the classroom. Some studies have shown that exposure during pregnancy can disrupt normal brain development;[25] nevertheless, the FDA is mute, neither alerting young teachers to the potential for harm from constant exposure nor carrying out the activities prescribed by law that could provide teachers and administrators with information to help them reduce exposures in classrooms.

Parents of children suffering from acute symptoms of over-exposure to non-ionizing radiation in schools are facing an impossible choice: watch their children continue to suffer, day after day, or pull them out of school and provide some form of home schooling, which for working families may be impossible. Their concerns about their children are often summarily

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[25] Aldad, et al, Fetal Radiofrequency Radiation Exposure From 800-1900 Mhz-Rated Cellular Telephones Affects Neurodevelopment and Behavior in Mice, Sci Rep. 2012; 2: 312.

dismissed by uninformed school nurses or school administrators, who trust FDA's unfounded claims that there are no non-thermal effects from exposure to non-ionizing radiation. School officials also cite claims by manufacturers that each of their devices meets FCC guidelines - guidelines which, in turn, rely completely on the endorsement of FDA. In the absence of any advisories or warnings from FDA, school administrators lack any information on which to base decisions about the deployment of wireless devices and products – the very opposite of what Congress intended.

C. FDA IS FAILING TO ADVISE PARENTS ABOUT HOW TO REDUCE EXPOSURES FOR SMALL CHILDREN

Today's consumer marketplace is flooded with wireless devices of all kinds, from smart diapers to the Smart Elderly Tracker. According to researchers, the average American household now has 16 internet-connected devices,[26] many of them wireless. Parents of pre-teens are besieged to provide their children with smart phones, game consoles, drone controllers, and other wireless devices. Peer pressure to have access to messaging apps on electronic devices is intense. Researchers at Stanford University found that about 25% of children received phones by age 10, and 75% by age 12. Nearly all children had phones by age 15 years.[27]

Instead of providing any information about the large and robust body of developing science regarding potential biological harm from exposure or carrying out its own evaluations as required by law, the FDA's website conveys a false and inaccurate sense of security and safety to anxious parents who may have concerns about the health and safety of their children. It boldly proclaims:

> *"Current scientific evidence does not show a danger to any users of cell phones from radio frequency [non-ionizing] energy, including children and teenagers."*[28]

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[26] https://www.parksassociates.com/blog/article/04272022

[27] https://med.stanford.edu/news/all-news/2022/11/children-mobile-phone-age.html

[28] https://www.fda.gov/radiation-emitting-products/cell-phones/children-and-teens-and-cell-phones

This is a blatantly false statement. There ***is*** current scientific evidence showing a danger to users of cell phones. FDA may not like the results or choose not to assign the benefit of the doubt to studies showing harm, but the agency does not serve the interest of public health by ignoring or discounting important scientific studies – including its own study – that show an elevated risk of harm. Moreover, FDA has failed to engage in the legally required activities that that would result in alerting the public to possible harm and advising them on ways to lower their risk of harm.

It is well established that children are not just little adults; their rapidly developing physiology, behavioral patterns and immature detoxification systems make them more prone to environmental insults than adults. Among other things, their thinner skulls allow for the deeper penetration of non-ionizing radiation into the brain. Despite solid scientific evidence of this phenomenon, FDA has not conducted or supported any publicly available research into the typical patterns of electronic product use by children and teenagers or developed any procedures to reduce their exposures, both of which are required by law.

Any inquisitive parent, visiting FDA's website for information on the possible health risks of exposure to radiation from electronic devices would be misled and falsely comforted by the statements and pictures found there and assume that FDA's statement is based on rigorous scientific inquiry and compliance with the law. They would be tragically wrong.

D. FDA IS FAILING TO ADVISE UTILITY CUSTOMERS ABOUT REDUCING EXPOSURES FROM SMART METERS

According to the U.S. Energy Information Administration, there are now more than 111 million Advanced Metering Infrastructure (AMI) or "smart" utility meters installed in the United States, and as of 2018, more than 80% of them had been installed on residential buildings.[29] These meters provide the utility with detailed information about the customer's use of electricity (similar types of meters are used for monitoring and reporting gas and water),

[29] https://www.eia.gov/tools/faqs/faq.php

including the exact time of usage. Some meters also allow the utility to restrict or cut off the customer's service. AMI meters use pulsed non-ionizing radiation to transmit large amounts of data at various intervals throughout the day.

There is increasing evidence that pulsed, polarized radiation has a greater effect on human biology than non-pulsed signals. In 2011, personnel at the U.S. Army Medical Research Detachment of the Walter Reed Army Institute of Research and the Air Force Research Laboratory at Brooks Air Force Base conducted a review of the extensive scientific literature regarding the biological effects of pulsed radiation that had been developed by Russian scientists. The authors noted:

> *"Unfortunately, most of this research was published in Russian; these publications are scarcely available in the West and have not ever been reviewed in English. Even some key findings, which may affect the conceptual understanding of interaction mechanisms and approaches to [non-ionizing radiation] safety, seem to be not known in the West, and their replication in Western laboratories has never been attempted."*[30]

Petitioners can find no evidence that FDA has evaluated these kinds of exposures, or worked with manufacturers to reduce exposures, even though more than 90% of residential households now have at least one pulsing electronic meter attached to their home which they can neither turn off nor move. The failure of FDA to investigate this widespread public exposure violates Congress' explicit instruction to study and evaluate the emissions of, and conditions of exposure to, electronic product radiation as well as its directive to develop, test and evaluate the effectiveness of procedures and techniques for minimizing exposure to such devices.

Petitioners note here that hundreds of individuals have previously submitted comments to FDA regarding serious health problems which developed shortly after the installation of a "smart" utility meter on their home or apartment. While correlation is not causation, hundreds of field reports of adverse health conditions would normally trigger an immediate response from

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[30] Pakhomov and Murphy, " A Comprehensive Review of the Research on Biological Effects of Pulsed Radiofrequency Radiation in Russia and the Former Soviet Union" Advances in Electromagnetic Fields in Living Systems (pp.265-290) (2011)

FDA and an investigation of potential causes. In this case, there was no response, no investigation, and no compliance with the clear letter of the law. The burden has been placed entirely - and unfairly- on the consumer, as FDA continues to ignore its legal responsibility.

E. FDA IS FAILING TO ADVISE EMPLOYERS ABOUT HOW TO REDUCE WORKPLACE EXPOSURES

Today's modern workplaces, from factory floors to executive suites, are filled with wireless technology, connecting workers to their superiors and each other. Local area networks pervade virtually every business environment, connecting wireless computers, printers, scanners and myriad other wireless devices.

Wearable wireless devices, first popular as a trendy fashion accessory, are now taking their place as required equipment in a growing number of manufacturing, warehousing and distribution situations, with estimates of wearable devices now exceeding one billion worldwide.[31] Workplace wearables are promoted as important elements to improve worker safety and comfort but can also be used to monitor employee behavior and precise locations during the workday. Some workplace environments are now using "smart helmets" that continuously monitor employees' location, physical symptoms or chemical exposures and wirelessly transmit data to central servers.

This type of near-constant, close proximity use of wireless technology is entirely unmonitored and unprecedented, and is taking place in a regulatory vacuum, with no pre-market safety testing, and subject only to long-outdated non-ionizing radiation exposure guidelines developed by engineers in the 1980s based on very limited studies of monkeys and rats.

FDA has again failed to evaluate these kinds of exposures, or promulgated any recommendations to employers or employees on how to they can reduce them. Employers, questioned about the relative safety of such exposures or faced with employees complaining of headaches, nausea, dizziness, tinnitus or other symptoms commonly associated with exposure to non-ionizing radiation, are relying completely on manufacturer's claims of compliance with FCC

[31] https://www.statista.com/statistics/487291/global-connected-wearable-devices/

standards, which themselves rely on the unsubstantiated and conclusory assertions by the FDA that there are no risks associated with exposure to non-thermal levels of non-ionizing radiation. This chain of reliance by employees, employers, manufacturers and the FCC is built entirely on the premise that FDA is, and has always been, in full compliance with the law. It is not.

SECTION 6. CONCLUSION

FDA's website boasts that the agency relies on "*one of the world's most comprehensive and effective networks of public health and consumer protections*"[24] as it regulates food and food ingredients, ensures the safety and effectiveness of drugs and medical devices, and takes steps to make sure cosmetics, medical products and consumer products that emit radiation do no harm.

To accomplish its mission, the agency relies on the consumer protection laws enacted by Congress which give the agency this authority.

But the same laws that give the agency its authority to regulate also confer certain enumerated legal obligations on the agency to perform specified activities. In this instance, FDA has chosen to use the law when it wants to enforce its rules and regulations, but completely and blatantly ignore the law when it applies to its own conduct. The freedom to pick and choose which parts of the law it is obligated to obey was never granted to the FDA by Congress.

For the reasons above, Petitioners ask the Commissioner to grant this Petition and order such actions as may be required to bring the agency into full compliance with the law.

SECTION 7. ENVIRONMENTAL IMPACT

Petitioners claim a categorical exclusion under one or more provisions of 21 C.F.R. §§ 25.30- 25.34.

SECTION 8. CERTIFICATION

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition and its attachments includes all information and views on which the petition relies.

Douglas A. Wood
Founder and National Director

SECTION 9. STATEMENTS OF PETITIONERS

All petitioners have granted permission for their statements to be made part of the public record.

Statement of Grassroots Environmental Education
Statement of Consumers for Safe Cell Phones
Statement of the California Brain Tumor Association
Statement of Manhattan Neighbors for Safer Telecommunications
Statement of Michelle Lewis
Statement of Zen Honeycutt
Statement of Michele Hertz
Statement of Laurie Brown

GRASSROOTS
Environmental Education
184 Main Street • Port Washington • New York • 11050 • (516) 883-0887 • www.GrassrootsInfo.org

Statement of Grassroots Environmental Education

This document is submitted under penalty of perjury in support of the Citizens Petition filed by Americans for Responsible Technology regarding the failure of the FDA to abide by the clear and unambiguous requirements of the law regarding public exposure to radiofrequency (RF) radiation from all types of wireless devices.

Grassroots Environmental Education (Grassroots) is a science-based non-profit organization with a mission to inform the public about the links between common environmental exposures and human health, and to empower individuals to act as catalysts for change in their own communities.

Our work in the area of RF radiation and human health began in 2012, when we were introduced to the work of Dr. Hugh Taylor at Yale University and his team of researchers who had just published a study demonstrating that the offspring of mice exposed to radiation from a cell phone had abnormal brain development and behavioral characteristics. The study was the basis for our development, in partnership with Dr. Devra Davis of Environmental Health Trust, of the BabySafe Project (www.BabySafeProject.org). This project warns pregnant women not to keep their cell phones in a pocket over their developing babies or use their pregnant belly as a platform for their wireless laptop or tablet.

That project, and all of our ensuing work to inform the public about the potential risks of exposure to RF radiation was necessitated because of the failure of the FDA to carry out its most basic function: to make the public aware of potential health risks and provide information on reducing those risks.

It was only recently that we learned that this mandate to keep the public informed about the potential dangers associated with exposure to RF radiation is actually part of a 1968 law issued by Congress because of what Congress understood even back then to be a serious public health hazard. We were shocked to realize that **all of our work to warn the public about exposure is work that the FDA was supposed to have been doing for more than half a century.**

Grassroots has created websites, pamphlets, flyers and tip cards with accurate, science-based information about the potential harm from RF radiation exposure, and simple steps that can be taken to reduce that risk. We have attended conferences and trade shows, sent staff to testify at hearings and events across the country, engaged professional lobbyists to help carry our message to legislators in states from Connecticut to California. We have made hundreds of presentations to local groups throughout the Northeast, and handled phone and email inquiries

from thousands of individuals whose lives have been turned upside down by health problems associated with exposure to RF radiation.

We are particularly concerned about potentially elevated RF radiation exposures experienced by children in school classrooms utilizing wireless technology. We have developed and promoted an entire program (TechSafeSchools.org) to warn school administrators of the potential risk of chronic RF radiation exposure for students. The program is based in part on the legal concept of "Duty of Care" which all administrators have to ensure the safety of learning environments. This is exactly the same ethical and moral obligation that FDA has to the American people.

Our tireless work to try and protect people from RF radiation is **not** our job. This large expenditure of time, money, and resources was only made necessary because of FDA's refusal to abide by the law, and its flagrant disregard for the safety and health of the American people. We urge the FDA to re-think its cavalier attitude toward this growing public health threat and fully engage in the activities Congress has mandated.

Sincerely,

Patricia J. Wood
Executive Director

DECLARATION OF CYNTHIA FRANKLIN
ON BEHALF OF
CONSUMERS FOR SAFE CELL PHONES

April 23, 2023 - I, Cynthia Franklin, hereby state, under penalty of perjury, that the following information is true to my knowledge, information, and belief:

I am the President of Consumers for Safe Cell Phones ("CSCP"), a 501(c)(3) non-profit organization. As the group's name suggests, CSCP educates consumers as to ways to reduce microwave radio frequency radiation (RFR) exposure from cell phones, tablets, WIFI routers and other wireless devices.

This statement is submitted in support of the Citizens Petition filed by Americans for Responsible Technology and other petitioners pursuant to FDA's failure to abide by the language of 21 USC 360ii.

CSCP has approximately 5,800 social media followers who regularly receive information and advice from CSCP. The group also communicates with the public through webinars and online informational articles. CSCP provides updated information to its followers on, among other matters, the science and research being conducted on RFR and potential biological impacts. In offering these services, CSCP does not have the resources to conduct its own scientific studies, but instead reviews information from publicly available sources, including the FDA.

Congress intended that the FDA, as the nation's premiere public health agency, should be the source of such studies; but, the FDA has failed to follow the law, causing CSCP to expend significant time, effort and resources researching and disseminating other sources of reliable scientific information.

One issue CSCP is focused on is the federal regulatory RFR exposure compliance testing procedures for approving the marketing and sale of cell phones. Cell phone manufacturers are not required to test their products directly against the body even though it is well known that consumers regularly wear and use their cell phones in shirt and pants pockets and bras.

In 2012, the U.S. Government Accountability Office (GAO) published the report, **GAO-12-771** "Telecommunications: Exposure and Testing Requirements for Mobile Phones

Should Be Reassessed" in which it was concluded that:

> *"By not formally reassessing its current limit, FCC cannot ensure it is using a limit that reflects the latest research on RF energy exposure. FCC has also not reassessed its testing requirements to ensure that they identify the maximum RF energy exposure a user could experience.* ***Some consumers may use mobile phones against the body, which FCC does not currently test, and could result in RF energy exposure higher than the FCC limit."***

While the FCC may possess legal authority to set exposure standards for products it regulates, it is the FDA which has the authority, capacity, and legal responsibility to provide the scientific foundation for such standards. It is the FDA, not the FCC, which is supposed to "*plan, conduct, coordinate, and support research, development, training, and operational activities to minimize the emissions of and the exposure of people to, unnecessary electronic product radiation.*" It is the FDA, not the FCC, which is supposed to evaluate the kinds of exposures people are experiencing as they use electronic devices that emit RFR. And it is the responsibility of the FDA, not the FCC, to develop ways in which cell phones can be made safer.

Cell phone manufacturers are substantially underestimating actual RFR exposure levels when demonstrating compliance with the FCC's RFR exposure limits. The 2012 GAO report states that federal testing procedures for wireless devices allow consumers to be exposed to RFR levels "higher than the FCC limit."

The FDA claims on its website that it provides guidance to "federal agencies on techniques and programs for testing and evaluating electronic product radiation:"

> *"Under the law, the FDA is responsible for, among other things: Consulting with other federal agencies on techniques and programs for testing and evaluating electronic product radiation. For example, the FDA provides scientific input and expertise to the Federal Communications Commission (FCC). The FCC sets limits on the emissions of radio frequency energy by cell phones and similar wireless products."*

This statement implies that FDA is in full compliance with the law and has carried out all of the activities required by the law. Yet there is no publicly available evidence that this is true. There are no FDA studies (other than its own incriminating study curiously disavowed by the agency), and no record of FDA conducting any other research or investigation to support its conclusion that the exposure being experienced every day by millions of Americans is safe.

On August 13, 2021, the DC Circuit Court of Appeals in its ruling in Environmental

Health Trust v The Federal Communications Commission (EHT v FCC) found:

> *"...the Commission's [December 4th, 2019] order arbitrary and capricious in its failure to respond to record evidence that exposure to RF radiation at levels below the Commission's current [thermal] limits may cause negative health effects unrelated to cancer.* ***That failure undermines the Commission's conclusions regarding the adequacy of its testing procedures, particularly as they relate to children."***

An even more alarming statement from the EHT v FCC ruling is that "***the factual premise - the non-existence of non-thermal biological effects — underlying the current RF guidelines may no longer be accurate.***"

Thousands of studies – including FDA's own multi-million dollar RFR study documenting "clear evidence" of cancer from cell phone exposure[1] - have documented serious biological harm from exposure to levels of RFR far below those that could possibly be powerful enough to cause heating of tissue. This means that the current FCC testing guidelines, based solely upon protection from heating, are thousands, possibly even hundreds of thousands of times more lenient than limits that would be necessary to protect the public from non-thermal exposures.

As the Court found in EHT v FCC, the FCC's 27 year old exposure limits are based upon an outdated assumption that the only harm from RFR is that of heating – and the implications of this regulatory failure are a major public health threat, "***particularly as they relate for children.***"

It is unclear why the FDA believes that the current RFR limits, which were adopted 27 years ago, still protect us even though patterns of use and the newer, more biologically harmful pulsed RFR exposures have changed significantly since 1996, with the amount of radiation we are exposed to on a daily basis increasing substantially.

The FDA has left all of us in the dark on how and why it decided that current research on biological risks from "non thermal" levels of RFR exposure does not warrant a change in federal RFR standards or cellphone testing procedures. The FDA has ignored all the scientific research documenting biological harm at low exposure levels far below those "heating-only" exposure limits currently being used by FCC in their testing protocols.

With seemingly little concern for the health and safety of the public, the FDA presents

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[1] https://ntp.niehs.nih.gov/whatwestudy/topics/cellphones/index.html

confusing and conflicting advice on its website[2] and in public statements, assuring everyone that cell phones are safe even if used directly against the body while receiving RFR levels in excess of the FCC's limits....***even with unlimited use by children and pregnant women.***

This absolute regulatory failure by the FDA means that CSCP now has to divert resources toward efforts to counter the disinformation being disseminated by the FDA website, as well as from biased and unfounded opinion reports and misleading public statements issued by Jeffrey Shuren, director of FDA's Center for Devices and Radiological Health.

This means CSCP is not able to supplement the information that it provides to its followers with what should be the most comprehensive assessment of RFR scientific research to date by the FDA, the agency charged with protecting the public from RFR exposures.

Cynthia Franklin

Cynthia Franklin, President
Consumers for Safe Cell Phones
829 Briar Rd
Bellingham, WA 98225

[2] https://www.fda.gov/radiation-emitting-products/cell-phones/scientific-evidence-cell-phone-safety

Statement of the California Brain Tumor Association

My name is Ellen Marks. I am the founder of the California Brain Tumor Association (CBTA) and I am submitting this declaration in support of the Citizens Petition by Americans for Responsible Technology and other petitioners regarding FDA's failure to follow the law and develop a Program of Control to protect consumers who are unaware of the potential danger posed by cell phones and other wireless devices.

In May of 2008, my seemingly healthy 56 year-old husband Alan had a grand mal seizure and subsequent diagnosis of a brain tumor. He was in real estate development and sales and always held his cell phone to his right ear, exactly where the tumor developed. He used the cell phone virtually all day, every day, holding the device against his head as he talked, unaware that such behavior could result in the development of brain cancer. FDA's failure to study these kinds of exposures, evaluate their potential health risks, develop techniques for reducing exposures and alert the public to the potential danger was directly responsible for my husband's condition.

In September of 2008, I testified at a Congressional hearing on Cell Phones and Health. A representative from the FCC was also there, and when asked why they had not changed their outdated obsolete guidelines since 1996, he responded that Congress had not instructed them to do so. He also stated they have no scientific expertise in this area; they defer to other government agencies like the FDA. I later learned that because the FDA had failed to follow the law, it was unable to provide the FCC with any scientific foundation on which to base its guidelines.

In 2012 I went to Washington again and met with officials of the General Accounting Office (GAO) at their request. They had been asked by several legislators to investigate this issue. The GEO released its report a short while later, instructing the FCC to reassess their guidelines for human exposure to cell phones. The FCC eventually opened a formal Notice of Inquiry and received thousands of comments from experts and individuals harmed by their exposure to wireless radiation. The FCC ignored the comments in their entirety and in 2019 decided - arbitrarily and capriciously –to keep the outdated guidelines in place.

The FDA, the nation's premiere public health agency, and the one charged with the responsibility for developing a Program of Control, provided a letter to the FCC saying the agency thought the current guidelines were just fine. This flimsy and unsupported document earned the FDA a sharp rebuke from the federal court in EHT et al v. FCC. (2019), which called the letter "conclusory" and rejected it as an adequate basis for the FCC's decision.

The FDA's action, or inaction, impacted my husband and millions of others. My husband had his first craniotomy in June of 2008. He was fortunate, as his glioma was a grade 2. However, it affected his cognitive abilities and behavior greatly. As his neuropsychiatrist stated: "This tumor set off a nuclear bomb in your living room." This tumor, caused by exposure to his cell phone and a lack of science-based information from the FDA, robbed me of my real husband and our 3 children of their real father. In 2020 his tumor returned and this time the doctors informed us it is terminal. He recently underwent another craniotomy and is not doing well.

My husband had no other exposures to radiation or other risk factors which are likely to be the primary cause of his brain tumors. There is excellent science proving the link to cell phone radiation, yet the FDA is ignoring its legal responsibility to conduct research, evaluate the different kinds of exposures which people are receiving, and develop ways to minimize exposures to devices like cell phones. It is pretending it has done the research to support its conclusions, but like Han Christian Anderson's fable about the Emperor's New Clothes, there is nothing there. The FDA hasn't done the work, but instead, continues to spread misleading and unsupported information that is putting the public at risk.

In 2019 Dr. Jeffrey Shuren, director of the Center for Devices and Radiological Health at the FDA, responding to questions posed by Representative Anna Eshoo concerning radiofrequency radiation and health, furnished an unsigned, so-called "scientific review" which was neither scientific nor peer reviewed. The report read as though it was written by the cell phone industry. This bogus document, filled with only industry funded studies, appeared to appease Rep. Eshoo and other members of Congress, and the inquiry died. What FDA failed to acknowledge is that they never performed the activities required by the law, and thus were misleading Congress about their role.

Because of FDA's failure to follow the law and provide science-based information to the public, I have spent many hours of my life working to help cities and states adopt cell phone laws that do what the FDA is supposed to do - require retailers to post advisories about the dangers of exposure at the point of sale. The public wants this, but the industry has used the courts to block any such laws. In Berkeley, CA the law prevailed all the way to the Supreme Court of the United States. At the last moment the FCC joined in the case, stating they already have FDA-approved guidelines in place and therefore Berkeley's law was pre-empted. The Court agreed with the FCC, and once again, our government agencies kept the truth from the public, under the guise of already having provided "science-based" information. The plain fact is, the FDA/FCC guidelines are obsolete. They do not protect human health and are a disgrace and disservice to the American people.

My husband's cancer from his cell phone has destroyed our lives. Another victim commented to me that "the only thing worse than dying from a brain tumor is living with one." I agree. It is a horrific disease which affects the entire family. I am not foolish enough to advocate against the use of cell phone use. This technology is here to stay. But we do need safer equipment (which I understand the telecom industry has already patented but not yet released), clear use instructions at the point of sale, and most importantly federal guidelines that truly protect human health. It's time for the FDA to follow the law and do its job.

Under penalty of perjury I submit this declaration.

/s/Ellen Marks
Ellen Marks

Camilla R. G. Rees
Manhattan Neighbors for Safer Telecommunications
www.manhattanneighbors.org
crgr@aol.com - 415-992-5093

April 18, 2023

Division of Dockets Management
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

This letter is in support of the Citizen Petition and Request for Legal Compliance with the Legal Obligations of the FDA Regarding Public Exposure to Non-Ionizing Radiation from Electronic Products submitted by Americans for Responsible Technology and other Petitioners.

My name is Camilla Rees. I was seriously injured by Radiofrequency Radiation (RF) exposures on several occasions dating back over 15 years. Initially, by using a cell phone against my head, then severely impacted by a neighbor's wireless router that was on the other side of a wall from my pillow for several months, as well as in two office environments. As a result, I have dedicated much of my time to educating about cell phone and wireless risks through Manhattan Neighbors for Safer Telecommunications, ElectromagneticHealth.org and through policy work via the National Institute for Science, Law and Public Policy in Washington, D.C. By strictly limiting RF exposures I function well today, but this required me to retreat from city life, take time off to restore my health, and to live in an area without commercial activity, to a great degree, relatively speaking, very isolated. The quality of my daily life and career potential have been significantly impacted.

Like millions of Americans, when I first started using a cell phone I assumed the FDA had thoroughly evaluated cell phones for safety. I assumed the same about other electronic devices and equipment emitting Radiofrequency Radiation, such as computers, wireless routers, tablets, smart meters, etc. When cell towers increasingly appeared in cities, on highways, and when antennas appeared in residential neighborhoods on utility poles, near 2nd floor bedroom windows, I assumed the same--that this technology would not have been allowed on the market were it known to be dangerous for human or environment health.

I never imagined that volumes of science showing risk from this radiation would be suppressed in this country, with politicians and regulators turning a blind eye to very serious risks, as happened decades ago with tobacco risks, but this is what I found. I trusted that when it came to public health a genuine commitment to integrity existed in the United States at the FDA.

- *I assumed, incorrectly, that the FDA had reviewed the safety of radiation emitting telecommunications technologies, as it does new drugs or medical devices (including Radiofrequency Radiation-emitting medical devices).*
- *I was aghast to learn the FDA officially does not review the safety of radiation emitting telecommunications technologies before they are allowed on the market, while the FCC claims it relies on the safety expertise of the FDA and that it considers opinions of the FDA in setting its safety guidelines for Radiofrequency Radiation.*
- *I later learned thousands of scientific studies dating back 80+ years document risks from Radiofrequency Radiation, and that this large (and ever growing) body of research includes many detailed scientific reports about risks prepared by the U.S. government itself, such as by the Naval Medical Research Institute (1971), NASA (1972, 1981), Defense Intelligence Agency (1976), EPA (review draft 1990, suppressed), U.S. Air Force (1994), Department of the Army (1998, declassified 2006), the National Institute on Drug Abuse /NIH with the Department of Energy (2011), Department of Interior (2014) and the National Institute of Environmental Health Sciences/NIH National Toxicology Program (NTP) (2018).*

If the FDA had been doing its job, thoroughly researching the risks of these technologies, and informed the FCC as to what would be acceptable exposure limits for cell phones and wireless technologies from a biological perspective, we would be living in a different world today.

All of us would not be blanketed in harmful radiation, indoors and out, impacting our immune systems, DNA, neurological function, cognitive function, and much, much more. Fiber optic cables to the premises would be the technology of choice to access the Internet, affording advanced, far faster and more energy efficient Internet communication without any of the health risks (As described in the 2018 policy paper, "Re-Inventing Wires: The Future of Landlines and Networks").

If the FDA had done its job, I would have been informed of the risks from cell phones and wireless devices and been able to make informed choices about exposures to these technologies. I would likely not have purchased a cell phone, or at least never used it against my head, or used it frequently, or for long durations.

If the FDA had done its job, over a hundred million radiating utility meters would not have been installed across our country, severely damaging peoples' health right in their own homes. State and local governments would not have been deceived about the radiation risks to residents from these meters, nor about the alleged benefits (that they would support expansion of renewable energy technologies), nor deceived about alleged customer benefits (97% of which have never materialized).

Stimulus funding using taxpayer dollars would not have been wasted on 'smart' meters, that harm people while only serving the economic benefits of the utilities, which are incentivized to spend on capital investments to collect guaranteed rates of return from ratepayers on capital spending.

If the FDA had done its job, the media the world over would have been able to warn the public about cell phone and wireless risks, instead of parroting the 'no risk' narrative.

Because of the misperception that a thorough FDA evaluation had informed the FCC's exposure guidelines for Radiofrequency Radiation, the media has largely turned a blind eye to the cellphone and wireless risks, for decades, while exposures have impaired peoples' quality of life, job performance, ability to learn in educational settings, and driven up illnesses of many, many kinds, with most people in the dark not connecting the dots between their health challenges and the cellphone and wireless exposures.

If the FDA had done its job, health practitioners and patients would have been informed about the potential for Radiofrequency Radiation to impact drug actions, suppressing or amplifying the effects, in the over 4 billion U.S. retail prescriptions filled (2021).

If the FDA had done its job, industry representatives and their consultants would not have been able to mislead about Radiofrequency Radiation risk, as in this case, in a Verizon's consultant's report to a Manhattan Co-Op Board of Directors I advised. This is what was erroneously claimed:

"Note that both the FCC and the Food and Drug Administration (FDA) have certified that continuous human exposure at RF levels up to and including the FCC MPE [Maximum Permitted] limit is considered to present no RF health risk. Moreover, the FCC MPE limit has been designed to provide appropriate protection for humans of either sex, all ages, all sizes, and under all conditions."

Misleading about risks using the FDA's name is being done all across the country, leading local officials to make decisions that are dangerous for public health.

If the FDA had done its job, society would also not live with non-stop online communications to the degree it does today, and the health and mental health risks from online time and social media algorithms that damage brains, including children's brains, would never be occurring.

I refer you to the Harvard University report by Norm Alster at the Edmond J. Safra Center for Ethics, "How the Federal Communications Commission is Dominated by the Industries it Presumably Regulates" (2015). This report suggests the telecommunications industry is using the same playbook the tobacco industry did to downplay the risks of Radiofrequency Radiation, including:

- Obtuse refusal to examine the health evidence
- Hyper-aggressive legal action and bullying
- Stonewalling PR
- Undermining credibility of the scientists
- Cutting scientist funding
- Publishing contradictory science
- Trivializing highly credible dissenters

- Misleading about scientific consensus
- Light regulation
- Industry control of Congressional committees
- Revolving door between industry & regulator
- Enormous sums on direct lobbying & via associations
- Hard $ and soft $ contributions

Clearly, if the FDA had been doing its job, and had thoroughly evaluated the biological and health risks from the Radiofrequency Radiation emitted by cell phones and wireless equipment, most of the above would never have been able to occur, or would have been called out.

An important question the Harvard analysis probed, by way of a poll, was:

"Would consumers embrace cell phones and WiFi so enthusiastically if the wireless industry, enabled by FCC and 'Congressional errand boys', had not so consistently stonewalled on evidence and substituted legal intimidation for honest inquiry?"

This poll showed that if certain health claims about cell phone radiation were known to be true, the public's behavior would change. Informed citizens, the poll showed, would:

- Reduce wireless use
- Restore landlines
- Protect their children

It is high time for the FDA to come into integrity and conduct a thorough analysis of risks from Radiofrequency Radiation so that proper protection of human, animal and environmental health interests can take place.

- Protective, biologically-based exposure guidelines for RFR must be set.
- The pros and cons of different telecommunications technologies (fiber, wireless, cable, advanced copper, etc.) must be known so that the public, government officials and businesses can make fully informed choices;
- The FDA must conduct pre-market safety testing of wireless devices and wireless infrastructure prior to release of new equipment onto the market;
- The FDA must conduct short- and long-term post-market health monitoring of individuals living in dense wireless environments, and require towers be moved to protect public health, if necessary;
- The FDA and others must educate about health risks and how, through lifestyle changes, exposures might be reduced.
- The FDA must do everything possible to assure the American people that regulators' top priority is public health and safety and demonstrate it is not a captured agency.

Additional steps that can restore the trust that has been lost due to lack of clarity on responsibility between the FCC and FDA and failure of government to protect public health can be found in "33 Recommendations for the FCC, FDA and Congress".

Respectfully submitted in support of *the Citizen Petition and Request for Legal Compliance with the Legal Obligations of the FDA Regarding Public Exposure to Non-Ionizing Radiation from Electronic Products submitted by Americans for Responsible Technology and other Petitioners*

Camilla R. G. Rees

Statement of Michelle Lewis

My name is Michelle Lewis. I am an attorney and a brain cancer survivor, and I am writing this statement in support of a Citizens Petition from Americans for Responsible Technology concerning the responsibility of the Department of Health and Human Services and its FDA division to comply with 21 USC Section 360 ii.

Having worked in law for a quarter century, I continually used two cell phones to balance my work life with my private life as a wife and mother. On calls, when I felt a slight burning sensation in my right ear, I simply switched the phones to my left and continued on with my calls. I had no idea that there could be any problem with cell phones, and was completely unaware that many independent scientific studies had demonstrated the potential for cell phone radiation to cause biological harm, at levels below government safety standards.

After many years of holding a cell phone against my head, doctors discovered a tumor the size of a grapefruit on the right side of my brain. I was devastated. I had no family history of brain cancer, and no other risk factors.

When I subsequently learned that the FDA has, since 1968, had a statutory responsibility to conduct research on this type of radiation, to evaluate the kinds of exposures that Americans are experiencing, and to develop techniques for reducing exposures, I was shocked. I wish I had been aware of the possible risk so I could have avoided a traumatic surgery that could have resulted in paralysis. Had I known, a simple change (not holding the phone to my ear) in my behavior would have saved my family many sleepless nights and the healthcare system significant expense.

I implore the FDA to embrace its legal responsibility to fully assess and disclose hazardous levels of radiation that result from improper cell phone usage.

Since my diagnosis and surgery, I have met countless other people who had experiences similar to mine, rarely with such positive outcomes. I am aware of others who have died from their cancer, never knowing that the FDA was supposed to be protecting public health by informing citizens of the potential danger from cell phones and other wireless devices.

I will always be grateful for a wonderful surgeon and a positive medical outcome, but my family and I now live with a chance of recurrence – all which I believe could have been prevented if the FDA had studied the risks, and made public the scientific debate

regarding those risks. To ignore this legal and ethical responsibility and place citizens in harm's way is unconscionable.

/s/
Michelle Lewis

Statement of Zen Honeycutt

My name is Zen Honeycutt. I am the Founding Executive Director of the non-profit organization Moms Across America. I am submitting this statement in support of the Petition to the Food and Drug Administration (FDA) by Americans for Responsible Technology and other petitioners.

My family has suffered prolonged emotional stress, and my son has experienced debilitating physical symptoms related to exposure to radio-frequency radiation in his school. The failure of the FDA to follow the clear instructions of Congress to conduct research, evaluate current exposures and develop techniques for reducing or eliminating exposures is inexcusable, and has had had a direct, profound and life-altering negative impact on my son and our family.

After a move, and after COVID shutdowns, our son entered a new high school in Buncombe County, NC. Within a few months, he was coming home with nosebleeds, headaches, fatigue, sadness, and a lack of focus. His normally straight A's in honors and AP classes dropped to D's and F's. At that time I had seen articles and news about teenagers being exposed to wireless routers (wireless access points, or WAPS) at school, linking the technology to depression and suicide, and I asked him where he was sitting in relation to the WAPs. He realized he was sitting directly below them in almost all of his classrooms, and when he moved away from them, he felt somewhat better. We brought him to a psychologist MD and he was diagnosed with depression and side effects from electromagnetic sensitivity.[1]

Our son finished his Junior year at high school, feeling depressed and enduring headaches, but could not attend his entire senior year at the public school because they refused to accommodate him by hardwiring even one classroom for him. He stayed home and homeschooled himself online, isolated, which contributed to a socialization depression. He is now likely permanently damaged from the close proximity and prolonged exposure to high levels of wireless radiation from the school. He can feel when a cell phone is on next to him and gets headaches when we travel due to the ubiquitous use of WiFi and Bluetooth technology in society. He is unable attend college and sleep in dormitories or enjoy a social life with his peers. This is a young man who had the intelligence and drive to attend a college such as MIT and make huge contributions to society in technology. He can no longer do so. His life has been forever altered.

Because the school looks to the FCC and its guidelines, which in turn depend on rigorous scientific analysis by the FDA, administrators continue to maintain that the exposure levels the children are experiencing are safe and they have no responsibility to make changes. They are unaware that FDA has shirked its legal responsibility and failed to do what was mandated by Congress. My son reported that he knew several children in each class that were depressed and

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[1] Note: According to Allan Brennan, award-winning WIFI installer, a WAP should never be placed directly in a classroom. Instead, they should be placed in the hallways, shielded and the power reduced by 99%. At these low levels, up to 1500 devices per school can be efficiently serviced. He states that the reason why service providers recommend one WAP per classroom is not for functionality but for the monthly service fees. The more devices they sell the more profit they make, regardless of the prolonged, close proximity exposure to our children.

reported headaches and nosebleeds as well, they just didn't know or want to believe it was the exposure to the WAPS that was causing the effects. At least one of those students that he knows of committed suicide that year.

Because the FDA has failed to follow the law, the FCC is refusing to acknowledge that prolonged exposure to wireless technology, in the forms of WAPs incorrectly placed in the classrooms (instead of in the hallways), and children across the nation are being harmed. This is unacceptable. Our children, our future workforce, and our leadership are being compromised. Therefore the future of our country is being compromised. The FDA must publicly admit its failure and advise the FCC to put out guidelines that account for the safety of the children.

Respectfully submitted,

/s/
Zen Honeycutt

STATMENT OF MICHELE L. HERTZ

My name is Michele L. Hertz. I am 64, an artist, wife, mother and the President of the New York Safe Utility Meter Association (NYSUMA). I am submitting this statement in support of the Citizens Petition being filed by Americans for Responsible Technology and other Petitioners.

The facts I present below demonstrate that I have suffered an injury traceable to the radiofrequency (RF) radiation emissions from digital utility meters,[1] a situation created by the failure by the U.S. Food and Drug Administration (FDA) to fulfill its legal duty to oversee such emissions by non-medical RF radiation emitting devices.

Since 2010, I have researched and documented the health and fire problems associated with digital utility meters. I have filed comments, sent letters, emails and phoned New York State and Federal government agencies, including the FDA, the Federal Communications Commission (FCC) and the U.S. Department of Energy (DOE), regarding the injuries that I (and others) have suffered due to the pulsed transmitted and conducted electrical and RF radiation from digital utility meters, sometimes known as "smart meters".

Before I was injured by the RF radiation emissions from digital utility meters, my family and I led a normal life. My husband and I both worked. We took many family trips with our sons. We were happy in our community. At home we used Wi-Fi and both my husband and I used cell phones.

The biggest mistake I have ever made was to allow utility workers to install "smart" AMR utility meters on my properties. With no available information from the FDA, I had no idea that a utility meter could be a health hazard. I relied on utility employees who told me that digital meters were safe. I infer they were only repeating what they were told by their superiors.

In 2008, I began to experience heart palpitations and insomnia. Then came agitation, memory loss, inability to concentrate on my work and hormone disruption. Then came the nightmares and waking with frightening heart palpitations, pains in my head, buzzing in my ears and headaches. I developed constant diarrhea that lasted for months. I lost 25 pounds. Then I developed Grave's disease, a health condition that can be caused by exposure to radiation. During this time, there were nights I would wake up thinking there was an earthquake, but it was my own body quaking and shaking. Other members of my family also began having health problems too, however my health was the most affected.

Because the FDA has failed to follow the mandate of Congress to develop a Program of Control, there was very little available information on what was happening to me. After a great deal of research and speaking with experts in electricity, I learned that my health problems – which started after the installation of digital utility meters – were unequivocally caused by

[1] Digital Utility Meters include AMI, PLC, AMR, ERT, non-transmitting digital, Smart, etc. meters. Digital utility meters contain electronic components including antenna, switch-mode power supply, batteries, clocks and more. Analog utility meters are purely electro mechanical utility meters that contain no electronic components at all.

those meters. Finally, in 2010, I convinced the utilities to remove the offending meters and replace them with analog meters, and the worst of my health problems diminished substantially.

At this point I understood that there was something wrong with the new meters. I watched as other people in Hastings got sick and died. The meters were obviously dangerous. I tried to alert the utilities, elected officials, and state and federal government agencies, including the FCC, FDA, DOE, etc., thinking that the meters might be recalled. The evasive, irresponsible, dismissive, discourteous and lame responses I received from all of the above stunned me.

While I felt better after I convinced the utilities to remove the digital meters and replace them with analog meters, I continue, to this day, to experience RF sickness when I am exposed to some electronic and wireless devices and infrastructure.

In 2011, I had to relocate for periods of time from my home in Hastings, family, community and the art studio where I had worked for 15 years to a rural area in upstate, New York. I simply could no longer tolerate a congested RF environment flooded with radiation from numerous sources including cell towers, digital electric, water and gas utility meters and Wi-Fi routers.

In 2013, I got together with neighbors and commissioned an RF study of transmitting digital utility meters in our Hastings neighborhood, once we learned that digital meters were approved but never tested for health dangers by any government bodies. We hired an industry RF engineer, who discovered and documented that not only were the meters transmitting RF spikes constantly every 30 seconds, they were also causing RF to conduct onto home electrical wiring.[2]

This conducted and transmitted RF and electrical radiation remains, to this day, an unprecedented whole-body radiation exposure that surrounds us in buildings and the environment. Utility companies continue to claim, with no proof or factual basis, that digital meters are safe and only transmit once a day or for a few seconds a day. The FDA, with legal responsibility for evaluating these kinds of emissions, has failed to do its job.

FCC testing failed to detect health risks caused by the meters, but the FCC is not a health protection agency. It was and remains the FDA that is a health agency and which should have required testing for digital meters before they were unleashed on an unknowing public. Had the FDA tested the meters, as it was obligated to do, they would not have been approved. Injuries would have been avoided and lives would have been saved.

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[2] The engineer explains in his report that the FCC tested and approved electronic meters based on FCC Part 15 testing - not a test for health and safety but only to detect interference. The test was set up for wireless devices that employ power cords. This test was improper for digital utility meters because these meters do not employ power cords. Instead of developing testing for digital utility meters, the FCC-accredited lab workers altered the wireless meter by fastening a power cord to it. They altered the meter to fit a test modality that was not designed for utility meters. This laboratory set- up, in isolated conditions, failed to include utility-side wiring, consumers' circuit breaker panels, consumers' electrical circuitry and real-life electrical events like voltage surges.

Based on the FCC's defective and inadequate testing and approval process, and in the absence of any effort by the FDA to evaluate the potential effect of exposures from these meters on people, state regulators across the US approved digital utility meters and then only tested the new meters for accuracy. Together this colossal system failure and negligence has resulted in suffering and loss of life and property.

We had spent over two decades carefully restoring our historic 1910 home in Hastings, getting involved in community and school affairs. Finally, in 2019, after 22 years, my husband and I left Hastings for good and moved to a quieter RF area where we now reside.

I felt well for one year. Then in 2020 "smart" digital meters were installed on other homes in my neighborhood along with the wireless equipment necessary for their operation, and two huge 4/5G cell towers were built within 1.5 miles of our home. More recently, fiber optic equipment has gone up in our neighborhood. For me, having an analog utility meter is lifesaving but with all of the other equipment that has been deployed once again I am suffering. I am waking up at night alarmed with heart palpitations and am often unable to fall asleep again. I am again concerned that I am going to have a heart attack. Again, I am facing dangerous disruptions in my life and injuries due to the fact that there is no oversight for the safety of any of this technology.

While the FCC, with no health expertise or authority, clings to its dangerously outdated RF guidelines and the FDA completely ignores its own obligations regarding RF radiation, people, like me, get sick. Through the years I have tried to help as many RF injured people as I can, but I can never really help because the impact of these devices is not in my control. This predicament is the result of incompetence, avoidance and, ultimately, the abdication by state and federal government agencies of their legal duties, including the FDA.

Respectfully submitted,

Michele L. Hertz

Statement of Laurie Brown

My name is Laurie Brown. I am submitting this declaration in support of the petition by Americans for Responsible Technology and other petitioners regarding FDA's failure to follow the law concerning the public's exposure to pulsating wireless devices emitting biologically disruptive radiation. The failure of FDA to provide truthful and complete information to the public has had a significant detrimental effect on my life and the lives of countless other Americans.

Despite the proliferation of wireless antennas, wireless devices, and the installation of cell towers and access points for Wi-Fi and wireless connectivity, the FDA is failing to ensure the public's safety as required by the law. The current safety guidelines promulgated by the FCC, which are allegedly based on information from the FDA, are outdated and are only thermal based. The FDA needs to conduct the necessary studies, evaluate the kinds of exposures that are happening in the real world, acknowledge, and address the biological harm caused by the increasing and limitless saturation of wireless radiation in our environment. The public deserves to know the truth and to be protected from increasing exposures that cause biological harm, symptoms, and diseases, preventing individuals from working, attending school, and living a healthy and fulfilling life.

I taught middle school for the Los Angeles Unified School District (LAUSD) for approximately 26 years. I rarely was ill and accumulated approximately 800 hours of sick time during my career, the equivalent of nearly 7-8 months of work. I enjoyed a normal, healthy life and never had to concern myself with routers, Wi-Fi or electro-magnetic radiation. Unfortunately, my career, health, and life as I knew it changed in April 2015, when my school "upgraded" our Wi-Fi system and added 190 access points, two in every classroom, and brought in wireless devices, increasing the total wireless radiation on campus. My District did little to protect me from the peaks or spikes of radiation emitted from all the wireless devices on campus.

Our system was activated in April 2015. After a few hours on campus, I would begin to feel ill and experience symptoms such as headaches, heart palpitations, skin burning, earaches, nausea, foggy headedness, inability to concentrate, and many other debilitating symptoms – all symptoms of microwave sickness. I was becoming electro sensitive and was diagnosed with Chronic Inflammatory Response Syndrome caused by exposure to RF radiation. After a few consecutive days of work and increased exposure on campus, I started using my illness days. Some other staff members experienced physical and debilitating symptoms from the increased radiofrequencies on campus, too.

My principal contacted LAUSD's Office of Environmental Health and Safety (OEHS) and wrote to the Inspector General of LAUSD sharing his concern as well as staff members' concerns. The District's OEHS Initially waited approximately 6 weeks, until Common Core Testing was over, when fewer students would be operating devices and on campus with cell phones, to measure the RF frequencies in specific classrooms. On June 22, 2015, during the

summer break, my principal wrote to LAUSD's Inspector General stating, "After the system was turned on, several employees complained of illness (headaches, light headedness, etc.)."

After the installation of the new commercial Wi-Fi system at my school and becoming ill from my exposure to EMF/EMR, I learned LAUSD had been warned by doctors and scientists, prior to installation, that the commercial grade Wi-Fi being considered was untested and potentially dangerous in school environments.

Meanwhile, the FDA is silent. It is not conducting studies, as the law requires. It is not evaluating workplace exposures like mine. And it is certainly not engaging in efforts to reduce or minimize those exposures, which is also required by the law.

When doctors prescribe medications, they do so with specific instructions to minimize side effects and over-dosing. The same safety precautions and concerns apply to overdosing on wireless radiation. More is not better and controls and guidelines are necessary. The FCC's old guidelines and school districts' RF protocols are not actually based on science, and are insufficient to protect children and the public. The FDA must address this immediate public health crisis. Protocols and protective measures must be developed and applied in real time, before it is too late.

Today, I no longer teach, something that was not only a career, but a great passion in my life. I loved teaching, found it stimulating, rewarding, and incredibly fulfilling. Because I enjoyed it so much, I intended to work for a lot longer, until a ripe old age, but I found it difficult to return to work without being reasonably accommodated. Unfortunately, I am unable to fill all my free time with meaningful activities and work due to the proliferation and installation of wireless antennas and devices everywhere. Therefore, I limit my time and exposure to RF radiation. Fortunately, my friends are willing to turn off their cell phones when they are out with me and in my home. My husband and I removed our Wi-Fi and cordless phones, turned off our wireless emitting devices, and use hardwired connections. I have a cell phone, but do not turn it on often and my husband mostly keeps his off around me. I know longer have the same freedom or luxury to enjoy limitless time out, travel, staying in a hotel, visiting family, and grocery shopping as I once did.

Living with Chronic Inflammatory Response Syndrome caused by EMFs (microwave sickness) is challenging and limiting. My quality of life has been severely reduced and none of it occurred by my choice: it was the direct result of FDA's failure to abide by the clear and unambiguous mandate from Congress. My health, lifestyle, quality of life, and freedom to come and go as I please have been drastically and negatively affected. In addition, my income and retirement have been significantly reduced. I am very fortunate to have a supportive and loving husband and family. Still, though, my condition and losses have impacted us.

As the nation's premiere public health agency, the FDA needs to be actively monitoring public exposure to wireless radiation. No longer should law-abiding, tax-paying citizens be

expected to sit by idly while our world is increasingly filled with dangerous radiation. Although it may be an inconvenient truth, more is dangerous and is very unhealthy. Too many people are already sick and more people will become seriously ill if we stand by and do nothing to address our chronic and limitless exposure to wireless radiation. I do not want others to suffer the same fate as me.

/s/Laurie Brown

Laurie Brown
4221 Noble Ave
Sherman Oaks, CA 91403

EMFscientist.org

International EMF Scientist Appeal calls for greater health protection

In May 2015, 190 scientists submitted the International EMF Scientist Appeal addressed to the top leaders at the **United Nations, the World Health Organization, and the UN Environment Program.** The Appeal **urgently calls for greater health protection** in the midst of what has become an historic, global phenomenon -- the rapid expansion and proliferation of wireless communications and electrical technologies. The possible impact of deployment of these technologies on human health has not yet been thoroughly studied. **As of September 1, 2018, 244 scientists have signed the Appeal.**

These scientists have published over 2,000 research papers on electromagnetic fields (EMF) on biology or health. Their concern is based on the vast number of studies that reported biological and adverse health effects of non-ionizing EMF far below the current exposure guidelines set by the FCC and other international EMF-exposure guideline setting organizations. Their concerns mainly include **radiofrequency radiation (RFR)** emitting devices, such as cellular and cordless phones, cell towers, Wi-Fi, radio and TV broadcast antennas, smart meters, and baby monitors, as well as **extremely-low frequency electromagnetic fields (ELF EMF)** emitted by electric devices and infrastructures used in the delivery of electricity.

The **scientific basis for their collective concern is** "numerous recent scientific publications have shown that EMF affects living organisms at levels well below most international and national guidelines. Effects include increased cancer risk. cellular stress, increase in harmful free radicals, genetic damages, structural and functional changes of the reproductive system, learning and memory deficits, neurological disorders, and negative impacts on general well-being in humans."

These scientists make the following recommendations: protection of children and pregnant women; strengthened guidelines and regulatory standards; development of safer technology; utilities maintain adequate power quality and ensure proper electrical wiring; public health information and harm reduction strategies; medical education and training, establishment of independent, sustained government research programs; media disclosure of EMF expert's financial ties to industry; and designation of white zones (radiation-free areas).

The Advisors to the Appeal recommend that 5th Generation Wireless (i.e. 5G) should be investigated before it is deployed.

Ronald Melnick, Ph.D., Senior Toxicologist (retired) and former leader of the NTP's health effects studies of cell phone radio frequency radiation, National Toxicology Program. National Institute of Environmental Health Sciences, USA), and an advisor to the Appeal, states:

> *"I) find it appalling that mobile phone emission standards do not adjust for children when it is well established that the absorption of radiofrequency radiation by the brain is greater in children than in adults, the developing brain is highly susceptible to tissue damaging agents, and the use of wireless devices is being actively marketed to children. At a minimum, regulatory agencies need to make strong recommendations for consumers to take precautionary measures and avoid close contact with their mobile phones."*

For the complete Appeal, go to https://emfscientist.org/. For more information, contact: Joel Moskowitz, Ph.D., (jmm@berkeley.edu) or Elizabeth Kelley, MA, (info@emfscientist.org).

EMFscientist.org

Selected quotations from scientists who signed the International EMF Scientist Appeal

(Alphabetical, by country)

Note: Some of the signatories to this appeal are below as individuals, giving their professional affiliations, but this does not necessarily mean that this represents the views of their employers or the professional organizations they are affiliated with

Don Maisch, Australia

"We are now entering the era of the '**Internet of Things** (IoT)' where all our appliances will be Wi-Fi enabled, endlessly communicating with each other and us through so-called smart devices. This "brave new world" dictates that human exposure to radiofrequency radiation must greatly increase in order to accommodate the technology. This is a planned world being created by technocrats totally ignorant of the reality of our biology, an ignorance fostered by the existing thermal-effects only standards/guidelines. Now, more than ever, we need new, biologically relevant standards to meet the challenge of the future."

Don Maisch, Ph.D., Australia.
Tel: +61 3 62430195 Email: dmaisch@emfacts.com

Mary Redmayne, Australia

"There is much high-quality research showing bio-physiological effects from permitted electromagnetic exposures; these findings are not nullified by research which fails to find effects. To claim that the 'weight of evidence' does not support these effects (even if it were true) is misleading. To infer that this means no precautions are needed is illogical and non-scientific."

"It would help parents and policy makers if consensus among advisory organisations and scientists could be reached acknowledging that assurance of safety of chronic low-dose radiofrequency exposure cannot be guaranteed and is related to ill-health in some people. Therefore, **minimising exposure, especially children's**, is sensible. This should be treated like other daily health precautions and warnings such as those about diet."

Prof. Mary Redmayne, Ph.D., Department of Epidemiology & Preventive Medicine, Monash University, Australia
Email: mary.redmayne@gmail.com

Marie-Claire Cammaerts, Belgium

"Man-made electromagnetic fields impact all living organisms, acting first on the unit membrane. We must reduce our dependence on 'wireless' technologies, reduce the numbers of masts (i.e., cell towers), of Wi-Fi apparatus, of cordless phones and so on, and clearly indicate, in public spaces, the intensity of the ambient electromagnetic field."

Prof. Marie-Claire Cammaerts, Ph.D., Free University of Brussels, Faculty of Science, Belgium.
Email: mtricot@ulb.ac.be

Alvaro Augusto de Salles, Brazil

"Non-ionizing radiation (NIR) absorption by the population increased many times in the last few decades. The health effects of this will show a dramatic impact in the near future. Therefore effective precautionary procedures should urgently be adopted aiming to reduce NIR exposure and to reduce its health risks, in line with the IARC 2002 and 2011 recommendations that NIR is a possible human carcinogen."

Alvaro Augusto de Salles, Ph.D., Professor, Federal University of Rio Grande do Sul – UFRGS, Porto Alegre, RS, Brazil.
Email: aasalles@ufrgs.br

Magda Havas, Canada

"One of the most serious environmental pollutants affecting the health of human populations and resulting in chronic illness is **electrosmog**. A combination of low frequency electromagnetic fields, poor power quality, ground current and especially radio frequency and microwave radiation is making people sick. We have enough peer-reviewed scientific studies documenting the adverse effects, which include cancers, reproductive problems and symptoms of electrohypersensitivity, for governing bodies to promote practices, devices and legislation that reduce our exposure to these frequencies.

Putting **Wi-Fi** in schools; allowing **cordless phones** that radiate constantly to be manufactured; placing **wireless baby monitors** near an infant; using a **wireless tablet, smart phone or computer** while pregnant; holding a **cell phone** next to the head and keeping a cell phone in a bra or hip pocket or under a pillow; placing **cell phone antennas** near homes, schools and on hospitals; metering electricity, water and gas with **wireless smart meters** and designing **smart appliances** for the home will be viewed by future generations as **dumb technology** generated by **greed** for a population that is largely **ignorant** of the consequences. We need to protect the health and wellbeing of future generations, because without them there is no future! If we don't do it . . . who will?"

Magda Havas, Ph.D., Environmental and Resource Studies, Centre for Health Studies, Trent University, Canada

Email: DrMagdaHavas@gmail.com

Paul Héroux, Canada

"Electromagnetic fields from power and telecommunications systems, as they are present in our everyday environment, have biological and human health impacts that have not been officially acknowledged. The effects of these fields have simply not been taken seriously enough."

Paul Héroux, Ph.D., Department of Epidemiology, Biostatistics and Occupational Health
McGill University Medicine, Montreal Canada,
Tel. (514) 398-6988 Cell (514) 222-2197
InVitroPlus Laboratory, Department of Surgery Royal Victoria Hospital
Tel. (514) 934-1934 ext 35270
Email: paul.heroux@mcgill.ca
http://www.invitroplus.mcgill.ca/

Wenjun Sun, China

"我们的研究表明，强度低于 ICNIRP 暴露限值的电磁场依然可以产生生物效应。因此，在作用机制阐明之前，对无处不在并日益增强的环境电磁场暴露限值的制订应该慎重。"

"Our studies show that exposure to electromagnetic fields with intensity lower than the ICNIRP exposure guidelines can produce biological effects. Thus, on a precautionary basis, before we understand the detailed mechanisms, we should adopt protective standards that limit the ubiquitous and increasing electromagnetic fields in occupational and public environments."

Dr. Wenjun Sun, Director of Institute of Environmental Medicine, Bioelectromagnetics Key Laboratory, Zhejiang University School of Medicine, Hangzhou, China. Tel: +86-571-88208166, Email: sunwj@zju.edu.cn

Dariusz Leszczynski, Finland

"Evidence of health hazard is here since IARC 2011. It surely was enough time to introduce new safety standards and Precautionary Principle."

Dariusz Leszczynski, Ph.D., Adjunct Professor of Biochemistry, University of Helsinki, Finland;
Member of the IARC Working Group that classified cell phone radiation as possible carcinogen.
Email: blogbrhp@gmail.com. Blog: http://betweenrockandhardplace.wordpress.com/

Dominique Belpomme, France

"Les effets nocifs des champs électromagnétiques, quelle que soit leur fréquence, sont maintenant scientifiquement établis. Les femmes enceintes (le fœtus) et les enfants et adolescents sont particulièrement vulnérables. L'OMS a reconnu les effets possiblement cancérigènes des champs électromagnétiques; cette action doit être prolongée par la reconnaissance de l'électrohypersensibilité comme affection à part entière entrant dans le cadre nosologique de l'intolérance environnementale

idiopathique qu'elle a individualisé. C'est ce que propose le colloque international organisé le 18 mai à l'Académie Royale de Médecine de Belgique."

"The harmful effects of electromagnetic fields, regardless of their frequencies, are now scientifically settled. Pregnant women (the fetus) and **children and adolescents** are particularly vulnerable. WHO has recognized the possibly carcinogenic effects of electromagnetic fields; its policy program should now recognize **electrohypersensitivity** as a disorder entering the nosologic framework of Idiopathic Environmental Intolerance. This is what the International Congress held on the 18th of May, 2015 at the Royal Belgian Academy of Medicine proposes."

Dominique Belpomme, M.D., MPH, Professor in Oncology, Paris V Descartes University, European Cancer & Environment Research institute, Executive Director.
Tel: 0033(0)1 45 78 53 53, E-mail : contact.belpomme@gmail.com

Lebrecht von Klitzing, Germany

"Our research finds that periodic, pulsed electromagnetic fields used for wireless communication reduce vegetative bioregulation activity. Continued exposure to **WiFi in Germany has deleterious effects on the cardiovascular system**. We must reduce the spread and utilization of these systems."

Lebrecht von Klitzing, Ph.D. Medical Physicist, Institute of Environmental Physics,
DE 36466 Wiesenthal, Germany
Medizinphysiker (DGMP),
Medizinphysik - Umweltphysik, DE-36466 Wiesenthal, Schwimmbadweg 21
Tel: 036964 863446 + 831203, Email: vonklitzing@umweltphysik.com, www.umweltphysik.com

Lukas Margaritis, Greece

"Σχεδόν όλα τα σύγχρονα προϊόντα υψηλής τεχνολογίας της καθημερινής μας ζωής χρησιμοποιούν ασύρματη τεχνολογία. Παρόλη αυτή την πληθώρα εφαρμογών δεν έχουν γίνει σοβαρές και αντικειμενικές προσπάθειες από τον Παγκόσμιο Οργανισμό Υγείας να δει τις πιθανές επιπτώσεις στην υγεία, ειδικά σε καθημερινούς χρήστες, σε παιδιά και εγκύους. Η έρευνά μας οδηγεί στο συμπέρασμα ότι πρέπει να εφαρμοστεί η Αρχή της Πρόληψης και να μειωθούν τα «όρια ασφαλείας» με δεδομένη την πολυπλοκότητα των ακτινοβολιών αυτών (με διαμόρφωση και παλμούς) σε αντίθεση με όλες τις άλλες ακτινοβολίες στη γη."

ΛΟΥΚΑΣ Χ. ΜΑΡΓΑΡΙΤΗΣ
Ομότιμος Καθηγητής Κυτταρικής Βιολογίας και Ραδιοβιολογίας
Συντονιστής ερευνητικού προγράμματος ακτινοβολιών ΘΑΛΗΣ
Τομέας Βιολογίας Κυττάρου και Βιοφυσικής, Τμήμα Βιολογίας,
ΕΘΝΙΚΟ & ΚΑΠΟΔΙΣΤΡΙΑΚΟ ΠΑΝΕΠΙΣΤΗΜΙΟ ΑΘΗΝΩΝ
Tel: +30-2107274542, +30-6972051345

"Wireless technology has driven most new high-tech products and has been a key factor in everyday domestic and commercial life. Still no serious efforts have been made by authorities to look seriously

without bias at the health effects especially for **heavy users, children, and pregnant women**. Our research points out the necessity for precautionary measures and new safety limits given the complexity of the signals (with modulation and pulses) unlike any other radiation on earth."

Lukas H. Margaritis
Professor emeritus of Cell Biology and Radiobiology
Coordinator, Radiation Research Program THALIS
Dept of Cell Biology and Biophysics, Faculty of Biology
NATIONAL AND KAPODISTRIAN UNIVERSITY OF ATHENS, Greece
Tel: +30-2107274542, +30-6972051345 Email: lmargar@biol.uoa.gr

Kavindra Kumar Kesari, India

"The debate about the effect of electromagnetic fields (EMFs) on human health is a growing concern of the 21st century. On the basis of scientific evidence, there is no question that EMF emissions from devices like cell phones, cellular antennas, and microwave ovens, have a causative effect on the brain and reproductive organs. But no action has been taken despite our awareness of the harmful impact of electro-pollution due to **political interference**. It is therefore imperative that the implications of **electro-pollution** must be fully explored by government bodies after consulting with concerned experts, and safety criteria be re-examined."

Dr. Kavindra Kesari, MBA, Ph.D., Resident scientist, School of Environmental Science, University of Eastern Finland, Kuopio Finland; Assistant Professor, Professor, Jaipur National University, India
E-mail: kavindra_biotech@yahoo.co.in, kavindra.kesari@uef.fi

SMJ Mortazavi, Iran

"Limiting the exposure to electromagnetic fields is indeed among the basic steps to ensure a better life for mankind!"

SMJ Mortazavi, Ph.D., Professor of Medical Physics
Ionizing and Non-ionizing Radiation Protection Research Center (INIRPRC), Dean, Medical Physics & Medical Engineering Department, Dean, Shiraz University of Medical Sciences, Iran
E-mail: mmortazavi@sums.ac.ir
Tel: +98-711-2349332 Fax1: +98-711-2349332 Fax2: +98-711-2289113
http://home.sums.ac.ir/~mmortazavi; http://crrs.sums.ac.ir

Yury Grigoryev, Russian Federation

"It is **immoral** that the regulatory standards for electromagnetic fields (EMF) used in cellular communication are inadequate and pose a serious health risk. The amount of harm from radio frequency EMF exposure to the brain is inestimable. **Children** are at higher risk than professional workers."

Professor Yury Grigoryev, MD, Chairman of Russian National Committee on Non-Ionizing Radiation Protection; Member, International Advisory Committee for the WHO "EMF and Health" Program. Moscow, Russia. (presently not available for media inquiries)

Alonso Balmori, Spain

"Los árboles y los animales nos están mostrando cosas que las personas no estamos comprendiendo. Sabemos con certeza que las radiaciones electromagnéticas producidas por el hombre están debilitando lentamente la salud de los seres vivos: animales, plantas y hombres. Es urgente una toma de conciencia de la sociedad en su conjunto para afrontar este grave problema ambiental y sanitario."

"**Trees and animals** are showing important signs that mankind does not comprehend. We know with certainty that anthropogenic electromagnetic radiation is slowly eroding the health of living organisms: animals, plants and people. It is urgent that society as a whole address this serious environmental and health problem."

Alfonso Balmori, Biologist. Independent researcher on wildlife and EMF, Spain
Alfonso Balmori, Biólogo. Investigador independiente sobre los efectos de las radiaciones electromagnéticas en los seres vivos, Espana; Email: abalmorimartinez@gmail.com

Claudio Gomez-Perretta, Spain

"Technological applications using non-ionizing radiation are advancing rapidly, increasing at every step the gap with the assessment of their possible side effects. The REFLEX project and other scientific reports like the BioInitiative Report have unfortunately been ignored by authorities worldwide. Perhaps the coming generations will curse these leaders for their ineffectiveness at the right moment."

Claudio Gomez- Perretta, M.D., Ph.D. Researcher, University La Fe of Valencia, Spain
Email: gomez_cla@gva.es

Yoon-Won Kim, South Korea (Republic of Korea)

"International exposure guidelines for electromagnetic fields (EMF) must be revisited due to the existence of their adverse effects on our bodies, particularly on the **male reproductive system**. It is time to re-establish the safety level of EMF for the general public to reduce our exposure to protect us from EMF."

Dr. Yoon-Won Kim, MD. PhD. Professor, Hallym University and member of the Bioelectromagnetics Society, Korea. Tel: +82-33-248-2663, Email: ywkim@hallym.ac.kr

Lennart Hardell, Sweden

"Based upon epidemiological studies there is consistent evidence of increased risk for brain tumors (glioma and acoustic neuroma) associated with use of wireless phones. Urgent revision of current guidelines for exposure to radiofrequency emissions is needed."

Lennart Hardell, MD, PhD, Department of Oncology, University Hospital, Orebro, Sweden
Email: Lennart.hardell@regionorbrolan.se

Daniel Favre, Switzerland

"Active mobile phone handsets have a dramatic **impact on the behavior of honeybees** by inducing the worker piping signal, triggering the swarming process, the sign of a disturbed bee colony. Signals from mobile phones and masts (i.e., cell towers) could also be contributing to the decline of honeybees around the world. I am calling on the international scientific community for more research in this field and for protection of this crucial pollinator."

Dr. phil. nat. Daniel Favre, Biologist and apiary adviser, Switzerland (www.ephiscience.net).
Email: daniel_favre@yahoo.com

Suleyman Dasdag, Turkey

"Sağlıklı ve mutlu bir dünya için daha az ve kontrollü radyasyon."

"We need shorter and more controlled radiation exposure for a happy and healthy world."

Prof. Dr. Suleyman Dasdag, PhD., Dept. of Biophysics, Medical School of Dicle University, Turkey
Email: sdasdag@gmail.com

Nesrin Seyhan, Turkey

"Radyofrekans alanlara maruziyet sınır degerlerinin hiç biri hamile anne karnındaki bebek,ve yaşlıları dikkate alarak hazırlanmamıştır. Genel Halkın Radyofrekans maruziyet **sınırlar** bu alanlara daha hassas olan hamile, anne karnındaki bebek, çocuk ve yaşlılar gözönüne alınarak aşa ğ ı çekilmelidir."

"None of the radiofrequency radiation exposure guidelines take **pregnant women, fetuses, and the elderly** into consideration! RF exposure limits for the general public should be lowered to protect all those more vulnerable to electromagnetic fields."

Prof. Dr. Nesrin Seyhan, Founding Chair, Biophysics Dept ; Founding Director, GNRK Center Medical Faculty of Gazi University, Ankara, Turkey. (Presently not available for media inquiries)

Martin Blank, USA

"International exposure guidelines for electromagnetic fields must be strengthened to reflect the reality of their impact on our bodies, especially on our **DNA**. The time to deal with the harmful biological and health effects is long overdue. We must reduce exposure by establishing more protective guidelines."

Martin Blank, Ph.D., Special Lecturer, Columbia University, New York USA
Email: mbphd32@gmail.com

Elizabeth Kelley, USA

"Solutions must be found that place the highest priority on protecting people and the planet over the powerful economic forces driving new technologies without thought for biology. We *can* have both innovation and public safety if there is political will. This transcends national boundaries. The UN, the World Health Organization, and the UN Environmental Programme are the best organizations on earth to make these recommendations."

Elizabeth Kelley, MA, is the Director of EMFScientist.org, and formerly was Managing Secretariat for the International Commission on Electromagnetic Safety (icems.eu), Italy
Email: info@EMFscientist.org

Albert Manville, USA

"While we like our electronic gadgets, the worldwide demand for these technologies of convenience only grows, as do the gargantuan profits that come from selling the devices and their services. While human health and safety continue to be dismissed by many, growing scientific evidence is showing a dark side to cell phone, WiFi, smart meter and point-to-point technologies. **Migratory birds** – incredibly important to the global economy and for the ecological services they provide – now appear to be negatively affected by non-ionizing radiation. This alarm sounds a call to action acknowledging that electromagnetic radiation is indeed a problem that needs to be addressed."

Dr. Albert Manville, Adjunct Professor, Johns Hopkins University; Senior Wildlife Biologist, U.S. Fish & Wildlife Service (FWS), Emeritus/Retired; and Wildlife Consultant, WHCS LLC.,USA
Email: albertsandy@verizon.net, whcslls006@verizon.net

Joel Moskowitz, USA

"U.S. regulatory standards and international guidelines only control for short-term heating of tissue. The standards do not protect us from the low-intensity, chronic exposures to electromagnetic fields (EMF) that are common today. The scientists who signed the Appeal request that the UN and member nations protect the global human population, animals and plants from EMF exposures.

There has been strong support from the international scientific community for the Appeal, even among those who believe that scientists should not take public policy positions. Some have taken personal risks to sign the Appeal because this is a public health issue that affects everyone now, as well as future generations.

The scientists who have signed the Appeal have **published more than 2,000 peer-reviewed research papers** on electromagnetic fields."

Joel Moskowitz, Ph.D., Director, Center for Family and Community Health, School of Public Health, University of California, Berkeley, USA
Tel: 1-510-643-7314. Email: jmm@berkeley.edu. Electromagnetic Radiation Safety website: saferemr.com

June 15, 2023

Virginia Department of Health
9960 Mayland drive
Richmond VA

Re: Quarterly Meeting

To : Board Members of VDH

The following paragraph has been copied from the VDH website:

The Virginia Department of Health (VDH) is dedicated to protecting and promoting the health of Virginians. The VDH is made up of a statewide Central Office in Richmond and 35 local health districts. These entities work together to promote healthy lifestyle choices that can combat chronic disease, educate the public about emergency preparedness and threats to their health, and track disease outbreaks in Virginia.

However, I feel that for the past three years VDH has fallen short on their duties. I quote From "Cause Unknown" The epidemic of Sudden Deaths in 2021 and 2022 by Edward Dowd, Copyright 2022. Published by Skyhorse Publishing.

On Page 1 of the Foreword which is written by Robert F. Kennedy Jr. , Dowd is quoted: "From February 2021 to March 2022, millennials experienced he equivalent of a Vietnam war with more than 60,000 excess deaths. The Vietnam war took 12 years to kill the same number of healthy young people we have seen die in 12 months."

Also from the same book in the Afterword page 121:

"Imagine that thousands of healthy young Americans died suddenly, unexpectedly, mysteriously and then kept dying at an alarming and escalating rate. (Once upon a time) that would trigger an urgent CDC inquiry to determine the cause of the deaths. Imagine attentive and curious public health officials discover the decedents had all repeatedly ingested a new and little understood drug. Next, the officials determine to certainty that the drug these kids took has a clear mechanism of action for causing inflammation of the heart and other cardiac injuries in some people. They learn that public health officials in other countries have seen the same thing and stopped recommending this same drug to young people. Next, some of the most senior and revered scientific advisors to the U.S. Government publicly recommend the drug be stopped for young people. Finally thousands of doctors around the world sign petitions and write op-eds opposing the drug. Nothing changed."

There are 1000 scientific papers on COVID vaccine injury. Surely the VA Health Department is aware of this because it is part of their job. But nothing has been done except the continuing government narrative of "get the shot" Anthony Fauci, aka Dr. Mengele, is now facing criminal charges along with his co conspirators. In addition, the family of a deceased college student who died from myocarditis as a result of the Covid shot has filed suit against theBiden administration and the Department of Defense. Operation "Warp Speed" was managed by the military and the shot produced by military contractors I am hoping that VDH cares about the damage that is being perpetrated and will do their job as public health officials.and stop these shots that are causing the death of young people, children, and the rest of us in between. Otherwise, I do not know how you sleep at night.

Carol Campbell Sargeant RN BSN MPH
Henrico County, VA

VAMFA speech 150623 for VA Board of Health Meeting
Lori D. Leonard

Over the past three years, we have known family members and friends who have "died suddenly". People have "turbo cancers", athletes and pilots are dying, and young people having life-threatening heart pathologies.

Stop normalizing the abnormal. Stop gaslighting truth tellers. Let's call this for what it is: murder. And it needs to stop. NOW.

Pfizer's documents admit that their mRNA injections do NOT prevent infection. (Kingston) Why are they still being given, and promoted in Virginia?

The jabs were patented by DoD and DARPA as bioweapons (Kingston, Martin, Malone, others), to kill as many people as quickly as possible worldwide. This is not subject to debate. WHO, WEF, UN, DoD, patents, Big Pharma, UNC Chapel Hill and others are all on record about this. Why do Virginia health care officials stand by, watching this complete destruction of society, and pretend like everything is okay?

Pfizer knew that their injections caused infertility, miscarriages, and even killed nursing babies. (Wolf) How can anyone still encourage everyone to get these jabs?

Doctors and hospitals are paid massive sums of money to use the covid cocktail which is KNOWN to kill patients. This needs to be open public knowledge.

The world's children are being subjected to sacrifice, murder, and experimentation. Did you know that aborted children's body parts have been used for years in manufacturing injections?

All bioweapon injections must be removed from Virginia immediately. Giving them amounts to crimes against humanity. Why do we still have doctors, nurses, and the media pushing us to get our next jab? How many more people will die or become permanently disabled before the Virginia health system acts on our behalf and stops this tyrannical genocide?

My name is Ann Parker, I'm a Mother, Grandmother and School Board Member with grave concerns of EMF Radiation levels everywhere in Virginia.

Over 200 Scientist have been Appealing to the UN and WHO with Urgent Pleas for Greater Health Protection from EMF Radiation since 2015.

Their main concerns are RadioFrequency Radiation levels from cell and cordless phones, cell towers, wifi, radio/tv antennas, smart meters and baby monitors.

Numerous Scientific Studies prove Radiation levels Not flagged as harmful by current international guidelines, do in fact cause harms such as cancers, neurological disorders, changes in the reproductive system and worse.

These Scientists find dangerous radiation effects in all living organisms, and have identified children and pregnant women at highest risk of injury.

Ronald Melnick, PhD with the National Toxicology Program said "the absorption of radiation is greater in children" and "the developing brain is highly susceptible to tissue damage".

We implore all of you to further educate yourselves on these dangers, and we ask the Dept of Health to demand safer technology by reducing the acceptable Radiation thresholds in Virginia, require hard-wiring infrastructures in public buildings, high occupancy residential and commercial spaces and provide education for all Virginians regarding the risks of non-ionizing Electromagnetic and RadioFrequency Radiation.

The Virginia Department of Health has informed doctors to recommend the Covid-19 injection, to include babies at 6 months of age. The doctors I have spoken to did not know about the release of the Pfizer documents with the potential adverse events known by February 28, 2021.

They also didn't know about the CDC's V-Safe data. Of course, the CDC had to be sued twice to release ~~these documents~~ their data.

My guess is that the doctors don't know that Moderna had to be sued for their data. Hopefully it will be released in July 2023

Recent data from Israel showed that zero healthy individuals under the age of 50 died of COVID.

My daughter is vaccine injured. It started with her menstrual cycle getting farther and farther apart. We now know that she also has vascular and autoimmune issues. Two of my friend's daughters stopped having their menstrual cycles. These girls were not given informed consent when the colleges were mandating the jab. There are 36, 209 Menstrual disorders reported in VAERS. My daughter and my friends' daughters were not reported to VAERS. Evidently doctors don't want to report them to VAERS because they are afraid to lose their job or their license. In a systematic review of over 78K women over 52% had menstrual issues post jab.

My niece recently had a beautiful healthy son. She is unvaccinated. Two of her friends just had miscarriages. They were vaccinated. They were also not reported to VAERS.

My uncle that died 2 days after the booster was also not reported to VAERS.

I met a mom the other night whose daughter started having seizures after the jab. She said that she knows of 5 children that started having seizures. They were also not reported to VAERS. What else is going to happen to children when they are given the Covid jab?

If you are telling doctors to recommend this jab, then you need to give the doctors the information so they can give their patients informed consent. In general, people trust their doctors. Will they still trust their doctors when they find out that they weren't given informed consent?

The Virginia Department of Health has informed doctors to recommend the Covid-19 injection, to include babies at 6 months of age. https://www.vdh.virginia.gov/clinicians/covid-19-updates-for-virginia/ The doctors I have spoken to did not know about the release of the Pfizer documents with the potential adverse events known by February 28, 2021.

Do the doctors know that the FDA had to be sued for this information and wanted to withhold it for 75 years? https://www.fdanews.com/articles/206113-federal-judge-tells-fda-it-must-make-public-55000-pages-a-month-of-pfizer-vaccine-data

To find this in the full document, go to www.phmpt.org click on documents, type in the search bar 5.3.6 - for the adverse reactions go to pages 30 – 38. Please note that these are only the side effects known as of February 28, 2021.

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Recent data from Israel showed that zero healthy individuals under the age of 50 died of COVID.

https://www.theepochtimes.com/zero-young-healthy-individuals-died-of-covid-19-israeli-data-show_5293587.html?utm_source=partner&utm_campaign=TheChiefNerd&src_src=partner&src_cmp=TheChiefNerd – "Zero healthy individuals under the age of 50 have died of COVID-19 in Israel, according to newly released data."

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Menstrual Cycles: Consider adding your story there. https://mycyclestory.com/ This systematic review of over ***78K women reveals results that over 52% of women reported menstrual abnormalities*** post jab. https://doi.org/10.1016/j.vacun.2022.07.001

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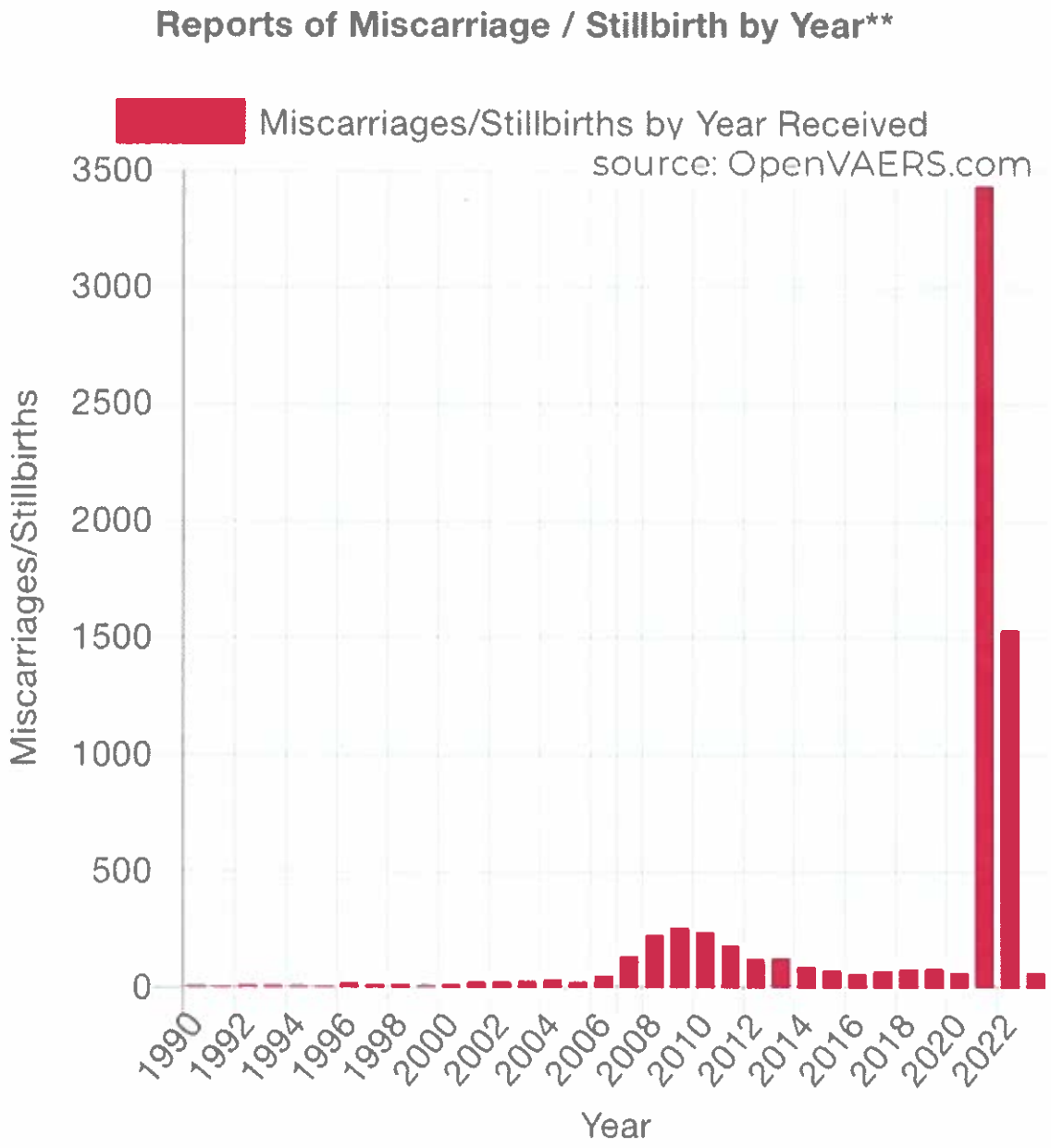

36,209 Menstrual Disorders Reports - VAERS

- Miscarriage/Stillbirth **4,930**
- Menstrual Disorders **36,209**
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- Caesarean / Preterm Labour / Birth Difficulties / Premature Birth **1,410**
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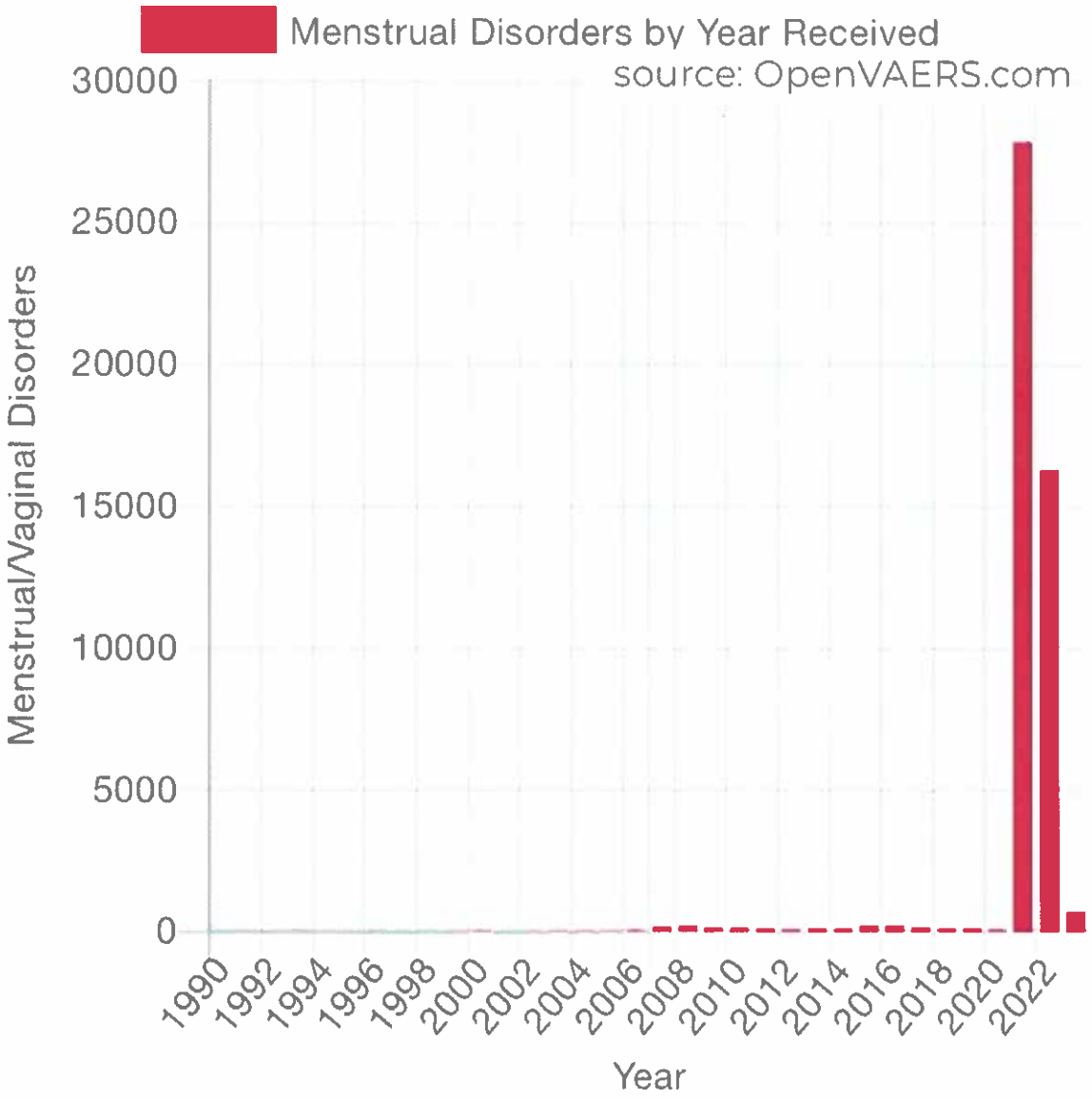
https://www.openvaers.com/covid-data/reproductive-health

Reports of Menstrual / Haemorrhages by Year



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Hello, my name is Jennifer,

It is my understanding that the Virginia Department of Health has informed doctors to recommend the Covid-19 injection, to include babies at 6 months of age. The doctors I have spoken to did not know about the Pfizer documents and the adverse events that were known by February 28, 2021. Do the doctors know that the FDA had to be sued for this information and wanted to withhold it for 75 years? Do they know about the CDC's V-Safe data that shows that out of 10 million v-safe users over 7.7% had a health event requiring medical attention and 25%, 1.2 million were unable to perform normal activities? Do they know that the CDC had to be sued twice for this information?

Do the doctors know that Moderna also had to be sued for their data and that hopefully it will be released in July 2023? How are people getting informed consent if the doctors haven't been given this information?

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To find this in the full document, go to www.phmpt.org click on documents, type in the search bar 5.3.6 - for the adverse reactions go to pages 30 – 38. Please note that these are only the side effects known as of February 28, 2021.

Do the doctors know that the FDA had to be sued for this information and wanted to withhold it for 75 years? https://www.fdanews.com/articles/206113-federal-judge-tells-fda-it-must-make-public-55000-pages-a-month-of-pfizer-vaccine-data

Do they know about the CDC's V-Safe data that shows that out of 10 million v-safe users over 7.7% had a health event requiring medical attention and 25%, 1.2 million were unable to perform normal activities? Do they know that the CDC had to be sued twice for this information? https://icandecide.org/article/v-safe/ https://icandecide.org/v-safe-data/

Do the doctors know that Moderna also had to be sued for their data and that hopefully it will be released in July 2023? https://icandecide.org/press-release/breaking-icans-attorneys-score-another-major-win-against-fda-with-pfizer-and-moderna-covid-19-vaccine-documents/ How are people getting informed consent if the doctors haven't been given this information?

My daughter is vaccine injured. It started with her menstrual cycle getting farther and farther apart. We now know that she also has vascular and autoimmune issues. Two of my friend's daughters stopped having their menstrual cycles.

These girls were not given informed consent when the colleges were mandating the jab. In fact, I don't know of anyone that was giving informed consent prior to getting the jab. Menstrual Cycles: Consider adding your story there. https://mycyclestory.com/ This systematic review of over ***78K women reveals results that over 52% of women reported menstrual abnormalities*** post jab. https://doi.org/10.1016/j.vacun.2022.07.001 I could easily write a paper about my family and friends that are vaccine injured to include menstrual issues, blood clots, shingles, neurological issues, heart attacks and death 2 days after the booster. If these aren't caused by the jab, then there are an awful lot of coincidences. I do not believe that they could all be coincidences.

If you are telling doctors to recommend this jab, then you need to give the doctors the information so they can give their patients informed consent. In general, people trust their doctors. Will they still trust their doctors when they find out that they weren't given informed consent?

https://www.theepochtimes.com/zero-young-healthy-individuals-died-of-covid-19-israeli-data-show_5293587.html?utm_source=partner&utm_campaign=TheChiefNerd&src_src=partner&src_cmp=TheChiefNerd – "Zero healthy individuals under the age of 50 have died of COVID-19 in Israel, according to newly released data."

My personal experience

Hello, my name is Jennifer, and I'm just a mom and a grandma. I would like to tell you about my observations over the past 3 years. Unfortunately, my observations are all too normal. So many people I have spoken to have had similar or worse experiences. I call them observances because they are written off as stress or just unfortunate.

Long story short, 3 of 4 of my kids were in college. One dropped out when the college went online. 2 were vaccinated. One came to me and told me that her menstrual cycles were getting farther and farther apart. I was in denial, but still doing my research listening to the silenced doctors and researching our history and the history of Africa and India where girls of childbearing age had been experimented on with vaccines and had become infertile or were having more and more miscarriages. I feel blessed that my eyes were opened and I could at least try to help my daughter. Two friends told me that their daughters had stopped having their menstrual cycle. I took the Pfizer documents and DMED data to 3 doctors and they said that they would put her on the pill. Fortunately, my research led me to 2 health professionals that knew what was going on and did the tests that led us to vascular issues or autoimmune issues that were also causing her to get sick every other week. I am thankful for the healthcare professionals that have cared for my daughter. How many girls are having this problem, or worse, and have been ignored? A systematic review of over ***78K women reveals results that over 52% of women reported menstrual abnormalities*** post jab.

One of my best friends called me when her 20-year-old daughter was in the hospital with shingles (herpes zoster) then another in her twenties with shingles, then 2 more in their forties. They were all told that it was just stress.

I presented the Pfizer documents and DMED data to another friend. Her husband said that this may be why her thyroid issue had been so much worse. She had already told me about her father having mini strokes, a co-worker getting breast cancer, and another needing to see a neurologist.

Another friend's husband started having tremors and shakes. Her mother had a mini stroke and had to have a clot removed from her neck.

My husband's uncle passed away suddenly from a heart attack 2 days after the booster on his way to the hardware store to get materials for another one of his amazing backyard projects. He got the shots to protect his mom.

My cousin just had open heart surgery and his father (my uncle) just had a stroke.

It would take quite a while to tell you all my stories. Are these all coincidences? I don't think so. I am more than thankful to all the doctors that are speaking up. I am thankful for them, and that God woke me up.

NOTES:

Menstrual Cycles: Consider adding your story there. https://mycyclestory.com/

This systematic review of over ***78K women reveals results that over 52% of women reported menstrual abnormalities*** post jab.
https://doi.org/10.1016/j.vacun.2022.07.001

www.phmpt.org
click on "documents"
Search 5.3.6
pgs. 30-38 - Adverse Event Reports

5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021

Report Prepared by:

Worldwide Safety

Pfizer

APPENDIX 1. LIST OF ADVERSE EVENTS OF SPECIAL INTEREST

1p36 deletion syndrome;2-Hydroxyglutaric aciduria;5'nucleotidase increased;Acoustic neuritis;Acquired C1 inhibitor deficiency;Acquired epidermolysis bullosa;Acquired epileptic aphasia;Acute cutaneous lupus erythematosus;Acute disseminated encephalomyelitis;Acute encephalitis with refractory, repetitive partial seizures;Acute febrile neutrophilic dermatosis;Acute flaccid myelitis;Acute haemorrhagic leukoencephalitis;Acute haemorrhagic oedema of infancy;Acute kidney injury;Acute macular outer retinopathy;Acute motor axonal neuropathy;Acute motor-sensory axonal neuropathy;Acute myocardial infarction;Acute respiratory distress syndrome;Acute respiratory failure;Addison's disease;Administration site thrombosis;Administration site vasculitis;Adrenal thrombosis;Adverse event following immunisation;Ageusia;Agranulocytosis;Air embolism;Alanine aminotransferase abnormal;Alanine aminotransferase increased;Alcoholic seizure;Allergic bronchopulmonary mycosis;Allergic oedema;Alloimmune hepatitis;Alopecia areata;Alpers disease;Alveolar proteinosis;Ammonia abnormal;Ammonia increased;Amniotic cavity infection;Amygdalohippocampectomy;Amyloid arthropathy;Amyloidosis;Amyloidosis senile;Anaphylactic reaction;Anaphylactic shock;Anaphylactic transfusion reaction;Anaphylactoid reaction;Anaphylactoid shock;Anaphylactoid syndrome of pregnancy;Angioedema;Angiopathic neuropathy;Ankylosing spondylitis;Anosmia;Antiacetylcholine receptor antibody positive;Anti-actin antibody positive;Anti-aquaporin-4 antibody positive;Anti-basal ganglia antibody positive;Anti-cyclic citrullinated peptide antibody positive;Anti-epithelial antibody positive;Anti-erythrocyte antibody positive;Anti-exosome complex antibody positive;Anti-GAD antibody negative;Anti-GAD antibody positive;Anti-ganglioside antibody positive;Antigliadin antibody positive;Anti-glomerular basement membrane antibody positive;Anti-glomerular basement membrane disease;Anti-glycyl-tRNA synthetase antibody positive;Anti-HLA antibody test positive;Anti-IA2 antibody positive;Anti-insulin antibody increased;Anti-insulin antibody positive;Anti-insulin receptor antibody increased;Anti-insulin receptor antibody positive;Anti-interferon antibody negative;Anti-interferon antibody positive;Anti-islet cell antibody positive;Antimitochondrial antibody positive;Anti-muscle specific kinase antibody positive;Anti-myelin-associated glycoprotein antibodies positive;Anti-myelin-associated glycoprotein associated polyneuropathy;Antimyocardial antibody positive;Anti-neuronal antibody positive;Antineutrophil cytoplasmic antibody increased;Antineutrophil cytoplasmic antibody positive;Anti-neutrophil cytoplasmic antibody positive vasculitis;Anti-NMDA antibody positive;Antinuclear antibody increased;Antinuclear antibody positive;Antiphospholipid antibodies positive;Antiphospholipid syndrome;Anti-platelet antibody positive;Anti-prothrombin antibody positive;Antiribosomal P antibody positive;Anti-RNA polymerase III antibody positive;Anti-saccharomyces cerevisiae antibody test positive;Anti-sperm antibody positive;Anti-SRP antibody positive;Antisynthetase syndrome;Anti-thyroid antibody positive;Anti-transglutaminase antibody increased;Anti-VGCC antibody positive;Anti-VGKC antibody positive;Anti-vimentin antibody positive;Antiviral prophylaxis;Antiviral treatment;Anti-zinc transporter 8 antibody positive;Aortic embolus;Aortic thrombosis;Aortitis;Aplasia pure red cell;Aplastic anaemia;Application site thrombosis;Application site vasculitis;Arrhythmia;Arterial bypass occlusion;Arterial bypass thrombosis;Arterial thrombosis;Arteriovenous fistula thrombosis;Arteriovenous graft site stenosis;Arteriovenous graft thrombosis;Arteritis;Arteritis

coronary:Arthralgia:Arthritis:Arthritis enteropathic:Ascites:Aseptic cavernous sinus thrombosis:Aspartate aminotransferase abnormal:Aspartate aminotransferase increased:Aspartate-glutamate-transporter deficiency:AST to platelet ratio index increased:AST/ALT ratio abnormal:Asthma:Asymptomatic COVID-19:Ataxia:Atheroembolism:Atonic seizures:Atrial thrombosis:Atrophic thyroiditis:Atypical benign partial epilepsy:Atypical pneumonia:Aura:Autoantibody positive:Autoimmune anaemia:Autoimmune aplastic anaemia:Autoimmune arthritis:Autoimmune blistering disease:Autoimmune cholangitis:Autoimmune colitis:Autoimmune demyelinating disease:Autoimmune dermatitis:Autoimmune disorder:Autoimmune encephalopathy:Autoimmune endocrine disorder:Autoimmune enteropathy:Autoimmune eye disorder:Autoimmune haemolytic anaemia:Autoimmune heparin-induced thrombocytopenia:Autoimmune hepatitis:Autoimmune hyperlipidaemia:Autoimmune hypothyroidism:Autoimmune inner ear disease:Autoimmune lung disease:Autoimmune lymphoproliferative syndrome:Autoimmune myocarditis:Autoimmune myositis:Autoimmune nephritis:Autoimmune neuropathy:Autoimmune neutropenia:Autoimmune pancreatitis:Autoimmune pancytopenia:Autoimmune pericarditis:Autoimmune retinopathy:Autoimmune thyroid disorder:Autoimmune thyroiditis:Autoimmune uveitis:Autoinflammation with infantile enterocolitis:Autoinflammatory disease:Automatism epileptic:Autonomic nervous system imbalance:Autonomic seizure:Axial spondyloarthritis:Axillary vein thrombosis:Axonal and demyelinating polyneuropathy:Axonal neuropathy:Bacterascites:Baltic myoclonic epilepsy:Band sensation:Basedow's disease:Basilar artery thrombosis:Basophilopenia:B-cell aplasia:Behcet's syndrome:Benign ethnic neutropenia:Benign familial neonatal convulsions:Benign familial pemphigus:Benign rolandic epilepsy:Beta-2 glycoprotein antibody positive:Bickerstaff's encephalitis:Bile output abnormal:Bile output decreased:Biliary ascites:Bilirubin conjugated abnormal:Bilirubin conjugated increased:Bilirubin urine present:Biopsy liver abnormal:Biotinidase deficiency:Birdshot chorioretinopathy:Blood alkaline phosphatase abnormal:Blood alkaline phosphatase increased:Blood bilirubin abnormal:Blood bilirubin increased:Blood bilirubin unconjugated increased:Blood cholinesterase abnormal:Blood cholinesterase decreased:Blood pressure decreased:Blood pressure diastolic decreased:Blood pressure systolic decreased:Blue toe syndrome:Brachiocephalic vein thrombosis:Brain stem embolism:Brain stem thrombosis:Bromosulphthalein test abnormal:Bronchial oedema:Bronchitis:Bronchitis mycoplasmal:Bronchitis viral:Bronchopulmonary aspergillosis allergic:Bronchospasm:Budd-Chiari syndrome:Bulbar palsy:Butterfly rash:C1q nephropathy:Caesarean section:Calcium embolism:Capillaritis:Caplan's syndrome:Cardiac amyloidosis:Cardiac arrest:Cardiac failure:Cardiac failure acute:Cardiac sarcoidosis:Cardiac ventricular thrombosis:Cardiogenic shock:Cardiolipin antibody positive:Cardiopulmonary failure:Cardio-respiratory arrest:Cardio-respiratory distress:Cardiovascular insufficiency:Carotid arterial embolus:Carotid artery thrombosis:Cataplexy:Catheter site thrombosis:Catheter site vasculitis:Cavernous sinus thrombosis:CDKL5 deficiency disorder:CEC syndrome:Cement embolism:Central nervous system lupus:Central nervous system vasculitis:Cerebellar artery thrombosis:Cerebellar embolism:Cerebral amyloid angiopathy:Cerebral arteritis:Cerebral artery embolism:Cerebral artery thrombosis:Cerebral gas embolism:Cerebral microembolism:Cerebral septic infarct:Cerebral thrombosis:Cerebral venous sinus thrombosis:Cerebral venous thrombosis:Cerebrospinal thrombotic

tamponade;Cerebrovascular accident;Change in seizure presentation;Chest discomfort;Child-Pugh-Turcotte score abnormal;Child-Pugh-Turcotte score increased;Chilblains;Choking;Choking sensation;Cholangitis sclerosing;Chronic autoimmune glomerulonephritis;Chronic cutaneous lupus erythematosus;Chronic fatigue syndrome;Chronic gastritis;Chronic inflammatory demyelinating polyradiculoneuropathy;Chronic lymphocytic inflammation with pontine perivascular enhancement responsive to steroids;Chronic recurrent multifocal osteomyelitis;Chronic respiratory failure;Chronic spontaneous urticaria;Circulatory collapse;Circumoral oedema;Circumoral swelling;Clinically isolated syndrome;Clonic convulsion;Coeliac disease;Cogan's syndrome;Cold agglutinins positive;Cold type haemolytic anaemia;Colitis;Colitis erosive;Colitis herpes;Colitis microscopic;Colitis ulcerative;Collagen disorder;Collagen-vascular disease;Complement factor abnormal;Complement factor C1 decreased;Complement factor C2 decreased;Complement factor C3 decreased;Complement factor C4 decreased;Complement factor decreased;Computerised tomogram liver abnormal;Concentric sclerosis;Congenital anomaly;Congenital bilateral perisylvian syndrome;Congenital herpes simplex infection;Congenital myasthenic syndrome;Congenital varicella infection;Congestive hepatopathy;Convulsion in childhood;Convulsions local;Convulsive threshold lowered;Coombs positive haemolytic anaemia;Coronary artery disease;Coronary artery embolism;Coronary artery thrombosis;Coronary bypass thrombosis;Coronavirus infection;Coronavirus test;Coronavirus test negative;Coronavirus test positive;Corpus callosotomy;Cough;Cough variant asthma;COVID-19;COVID-19 immunisation;COVID-19 pneumonia;COVID-19 prophylaxis;COVID-19 treatment;Cranial nerve disorder;Cranial nerve palsies multiple;Cranial nerve paralysis;CREST syndrome;Crohn's disease;Cryofibrinogenaemia;Cryoglobulinaemia;CSF oligoclonal band present;CSWS syndrome;Cutaneous amyloidosis;Cutaneous lupus erythematosus;Cutaneous sarcoidosis;Cutaneous vasculitis;Cyanosis;Cyclic neutropenia;Cystitis interstitial;Cytokine release syndrome;Cytokine storm;De novo purine synthesis inhibitors associated acute inflammatory syndrome;Death neonatal;Deep vein thrombosis;Deep vein thrombosis postoperative;Deficiency of bile secretion;Deja vu;Demyelinating polyneuropathy;Demyelination;Dermatitis;Dermatitis bullous;Dermatitis herpetiformis;Dermatomyositis;Device embolisation;Device related thrombosis;Diabetes mellitus;Diabetic ketoacidosis;Diabetic mastopathy;Dialysis amyloidosis;Dialysis membrane reaction;Diastolic hypotension;Diffuse vasculitis;Digital pitting scar;Disseminated intravascular coagulation;Disseminated intravascular coagulation in newborn;Disseminated neonatal herpes simplex;Disseminated varicella;Disseminated varicella zoster vaccine virus infection;Disseminated varicella zoster virus infection;DNA antibody positive;Double cortex syndrome;Double stranded DNA antibody positive;Dreamy state;Dressler's syndrome;Drop attacks;Drug withdrawal convulsions;Dyspnoea;Early infantile epileptic encephalopathy with burst-suppression;Eclampsia;Eczema herpeticum;Embolia cutis medicamentosa;Embolic cerebellar infarction;Embolic cerebral infarction;Embolic pneumonia;Embolic stroke;Embolism;Embolism arterial;Embolism venous;Encephalitis;Encephalitis allergic;Encephalitis autoimmune;Encephalitis brain stem;Encephalitis haemorrhagic;Encephalitis periaxialis diffusa;Encephalitis post immunisation;Encephalomyelitis;Encephalopathy;Endocrine disorder;Endocrine ophthalmopathy;Endotracheal intubation;Enteritis;Enteritis leukopenic;Enterobacter pneumonia;Enterocolitis;Enteropathic spondylitis;Eosinopenia;Eosinophilic

fasciitis;Eosinophilic granulomatosis with polyangiitis;Eosinophilic oesophagitis;Epidermolysis;Epilepsy;Epilepsy surgery;Epilepsy with myoclonic-atonic seizures;Epileptic aura;Epileptic psychosis;Erythema;Erythema induratum;Erythema multiforme;Erythema nodosum;Evans syndrome;Exanthema subitum;Expanded disability status scale score decreased;Expanded disability status scale score increased;Exposure to communicable disease;Exposure to SARS-CoV-2;Eye oedema;Eye pruritus;Eye swelling;Eyelid oedema;Face oedema;Facial paralysis;Facial paresis;Faciobrachial dystonic seizure;Fat embolism;Febrile convulsion;Febrile infection-related epilepsy syndrome;Febrile neutropenia;Felty's syndrome;Femoral artery embolism;Fibrillary glomerulonephritis;Fibromyalgia;Flushing;Foaming at mouth;Focal cortical resection;Focal dyscognitive seizures;Foetal distress syndrome;Foetal placental thrombosis;Foetor hepaticus;Foreign body embolism;Frontal lobe epilepsy;Fulminant type 1 diabetes mellitus;Galactose elimination capacity test abnormal;Galactose elimination capacity test decreased;Gamma-glutamyltransferase abnormal;Gamma-glutamyltransferase increased;Gastritis herpes;Gastrointestinal amyloidosis;Gelastic seizure;Generalised onset non-motor seizure;Generalised tonic-clonic seizure;Genital herpes;Genital herpes simplex;Genital herpes zoster;Giant cell arteritis;Glomerulonephritis;Glomerulonephritis membranoproliferative;Glomerulonephritis membranous;Glomerulonephritis rapidly progressive;Glossopharyngeal nerve paralysis;Glucose transporter type 1 deficiency syndrome;Glutamate dehydrogenase increased;Glycocholic acid increased;GM2 gangliosidosis;Goodpasture's syndrome;Graft thrombosis;Granulocytopenia;Granulocytopenia neonatal;Granulomatosis with polyangiitis;Granulomatous dermatitis;Grey matter heterotopia;Guanase increased;Guillain-Barre syndrome;Haemolytic anaemia;Haemophagocytic lymphohistiocytosis;Haemorrhage;Haemorrhagic ascites;Haemorrhagic disorder;Haemorrhagic pneumonia;Haemorrhagic varicella syndrome;Haemorrhagic vasculitis;Hantavirus pulmonary infection;Hashimoto's encephalopathy;Hashitoxicosis;Hemimegalencephaly;Henoch-Schonlein purpura;Henoch-Schonlein purpura nephritis;Hepaplastin abnormal;Hepaplastin decreased;Heparin-induced thrombocytopenia;Hepatic amyloidosis;Hepatic artery embolism;Hepatic artery flow decreased;Hepatic artery thrombosis;Hepatic enzyme abnormal;Hepatic enzyme decreased;Hepatic enzyme increased;Hepatic fibrosis marker abnormal;Hepatic fibrosis marker increased;Hepatic function abnormal;Hepatic hydrothorax;Hepatic hypertrophy;Hepatic hypoperfusion;Hepatic lymphocytic infiltration;Hepatic mass;Hepatic pain;Hepatic sequestration;Hepatic vascular resistance increased;Hepatic vascular thrombosis;Hepatic vein embolism;Hepatic vein thrombosis;Hepatic venous pressure gradient abnormal;Hepatic venous pressure gradient increased;Hepatitis;Hepatobiliary scan abnormal;Hepatomegaly;Hepatosplenomegaly;Hereditary angioedema with C1 esterase inhibitor deficiency;Herpes dermatitis;Herpes gestationis;Herpes oesophagitis;Herpes ophthalmic;Herpes pharyngitis;Herpes sepsis;Herpes simplex;Herpes simplex cervicitis;Herpes simplex colitis;Herpes simplex encephalitis;Herpes simplex gastritis;Herpes simplex hepatitis;Herpes simplex meningitis;Herpes simplex meningoencephalitis;Herpes simplex meningomyelitis;Herpes simplex necrotising retinopathy;Herpes simplex oesophagitis;Herpes simplex otitis externa;Herpes simplex pharyngitis;Herpes simplex pneumonia;Herpes simplex reactivation;Herpes simplex sepsis;Herpes simplex viraemia;Herpes simplex virus conjunctivitis neonatal;Herpes simplex visceral;Herpes virus

infection;Herpes zoster;Herpes zoster cutaneous disseminated;Herpes zoster infection neurological;Herpes zoster meningitis;Herpes zoster meningoencephalitis;Herpes zoster meningomyelitis;Herpes zoster meningoradiculitis;Herpes zoster necrotising retinopathy;Herpes zoster oticus;Herpes zoster pharyngitis;Herpes zoster reactivation;Herpetic radiculopathy;Histone antibody positive;Hoigne's syndrome;Human herpesvirus 6 encephalitis;Human herpesvirus 6 infection;Human herpesvirus 6 infection reactivation;Human herpesvirus 7 infection;Human herpesvirus 8 infection;Hyperammonaemia;Hyperbilirubinaemia;Hypercholia;Hypergammaglobulinaemia benign monoclonal;Hyperglycaemic seizure;Hypersensitivity;Hypersensitivity vasculitis;Hyperthyroidism;Hypertransaminasaemia;Hyperventilation;Hypoalbuminaemia;Hypocalcaemic seizure;Hypogammaglobulinaemia;Hypoglossal nerve paralysis;Hypoglossal nerve paresis;Hypoglycaemic seizure;Hyponatraemic seizure;Hypotension;Hypotensive crisis;Hypothenar hammer syndrome;Hypothyroidism;Hypoxia;Idiopathic CD4 lymphocytopenia;Idiopathic generalised epilepsy;Idiopathic interstitial pneumonia;Idiopathic neutropenia;Idiopathic pulmonary fibrosis;IgA nephropathy;IgM nephropathy;IIrd nerve paralysis;IIrd nerve paresis;Iliac artery embolism;Immune thrombocytopenia;Immune-mediated adverse reaction;Immune-mediated cholangitis;Immune-mediated cholestasis;Immune-mediated cytopenia;Immune-mediated encephalitis;Immune-mediated encephalopathy;Immune-mediated endocrinopathy;Immune-mediated enterocolitis;Immune-mediated gastritis;Immune-mediated hepatic disorder;Immune-mediated hepatitis;Immune-mediated hyperthyroidism;Immune-mediated hypothyroidism;Immune-mediated myocarditis;Immune-mediated myositis;Immune-mediated nephritis;Immune-mediated neuropathy;Immune-mediated pancreatitis;Immune-mediated pneumonitis;Immune-mediated renal disorder;Immune-mediated thyroiditis;Immune-mediated uveitis;Immunoglobulin G4 related disease;Immunoglobulins abnormal;Implant site thrombosis;Inclusion body myositis;Infantile genetic agranulocytosis;Infantile spasms;Infected vasculitis;Infective thrombosis;Inflammation;Inflammatory bowel disease;Infusion site thrombosis;Infusion site vasculitis;Injection site thrombosis;Injection site urticaria;Injection site vasculitis;Instillation site thrombosis;Insulin autoimmune syndrome;Interstitial granulomatous dermatitis;Interstitial lung disease;Intracardiac mass;Intracardiac thrombus;Intracranial pressure increased;Intrapericardial thrombosis;Intrinsic factor antibody abnormal;Intrinsic factor antibody positive;IPEX syndrome;Irregular breathing;IRVAN syndrome;IVth nerve paralysis;IVth nerve paresis;JC polyomavirus test positive;JC virus CSF test positive;Jeavons syndrome;Jugular vein embolism;Jugular vein thrombosis;Juvenile idiopathic arthritis;Juvenile myoclonic epilepsy;Juvenile polymyositis;Juvenile psoriatic arthritis;Juvenile spondyloarthritis;Kaposi sarcoma inflammatory cytokine syndrome;Kawasaki's disease;Kayser-Fleischer ring;Keratoderma blenorrhagica;Ketosis-prone diabetes mellitus;Kounis syndrome;Lafora's myoclonic epilepsy;Lambl's excrescences;Laryngeal dyspnoea;Laryngeal oedema;Laryngeal rheumatoid arthritis;Laryngospasm;Laryngotracheal oedema;Latent autoimmune diabetes in adults;LE cells present;Lemierre syndrome;Lennox-Gastaut syndrome;Leucine aminopeptidase increased;Leukoencephalomyelitis;Leukoencephalopathy;Leukopenia;Leukopenia neonatal;Lewis-Sumner syndrome;Lhermitte's sign;Lichen planopilaris;Lichen planus;Lichen sclerosus;Limbic encephalitis;Linear IgA disease;Lip oedema;Lip swelling;Liver function test abnormal;Liver function test decreased;Liver function test increased;Liver induration;Liver injury;Liver iron concentration abnormal;Liver iron concentration

increased;Liver opacity;Liver palpable;Liver sarcoidosis;Liver scan abnormal;Liver tenderness;Low birth weight baby;Lower respiratory tract herpes infection;Lower respiratory tract infection;Lower respiratory tract infection viral;Lung abscess;Lupoid hepatic cirrhosis;Lupus cystitis;Lupus encephalitis;Lupus endocarditis;Lupus enteritis;Lupus hepatitis;Lupus myocarditis;Lupus myositis;Lupus nephritis;Lupus pancreatitis;Lupus pleurisy;Lupus pneumonitis;Lupus vasculitis;Lupus-like syndrome;Lymphocytic hypophysitis;Lymphocytopenia neonatal;Lymphopenia;MAGIC syndrome;Magnetic resonance imaging liver abnormal;Magnetic resonance proton density fat fraction measurement;Mahler sign;Manufacturing laboratory analytical testing issue;Manufacturing materials issue;Manufacturing production issue;Marburg's variant multiple sclerosis;Marchiafava-Bignami disease;Marine Lenhart syndrome;Mastocytic enterocolitis;Maternal exposure during pregnancy;Medical device site thrombosis;Medical device site vasculitis;MELAS syndrome;Meningitis;Meningitis aseptic;Meningitis herpes;Meningoencephalitis herpes simplex neonatal;Meningoencephalitis herpetic;Meningomyelitis herpes;MERS-CoV test;MERS-CoV test negative;MERS-CoV test positive;Mesangioproliferative glomerulonephritis;Mesenteric artery embolism;Mesenteric artery thrombosis;Mesenteric vein thrombosis;Metapneumovirus infection;Metastatic cutaneous Crohn's disease;Metastatic pulmonary embolism;Microangiopathy;Microembolism;Microscopic polyangiitis;Middle East respiratory syndrome;Migraine-triggered seizure;Miliary pneumonia;Miller Fisher syndrome;Mitochondrial aspartate aminotransferase increased;Mixed connective tissue disease;Model for end stage liver disease score abnormal;Model for end stage liver disease score increased;Molar ratio of total branched-chain amino acid to tyrosine;Molybdenum cofactor deficiency;Monocytopenia;Mononeuritis;Mononeuropathy multiplex;Morphoea;Morvan syndrome;Mouth swelling;Moyamoya disease;Multifocal motor neuropathy;Multiple organ dysfunction syndrome;Multiple sclerosis;Multiple sclerosis relapse;Multiple sclerosis relapse prophylaxis;Multiple subpial transection;Multisystem inflammatory syndrome in children;Muscular sarcoidosis;Myasthenia gravis;Myasthenia gravis crisis;Myasthenia gravis neonatal;Myasthenic syndrome;Myelitis;Myelitis transverse;Myocardial infarction;Myocarditis;Myocarditis post infection;Myoclonic epilepsy;Myoclonic epilepsy and ragged-red fibres;Myokymia;Myositis;Narcolepsy;Nasal herpes;Nasal obstruction;Necrotising herpetic retinopathy;Neonatal Crohn's disease;Neonatal epileptic seizure;Neonatal lupus erythematosus;Neonatal mucocutaneous herpes simplex;Neonatal pneumonia;Neonatal seizure;Nephritis;Nephrogenic systemic fibrosis;Neuralgic amyotrophy;Neuritis;Neuritis cranial;Neuromyelitis optica pseudo relapse;Neuromyelitis optica spectrum disorder;Neuromyotonia;Neuronal neuropathy;Neuropathy peripheral;Neuropathy, ataxia, retinitis pigmentosa syndrome;Neuropsychiatric lupus;Neurosarcoidosis;Neutropenia;Neutropenia neonatal;Neutropenic colitis;Neutropenic infection;Neutropenic sepsis;Nodular rash;Nodular vasculitis;Noninfectious myelitis;Noninfective encephalitis;Noninfective encephalomyelitis;Noninfective oophoritis;Obstetrical pulmonary embolism;Occupational exposure to communicable disease;Occupational exposure to SARS-CoV-2;Ocular hyperaemia;Ocular myasthenia;Ocular pemphigoid;Ocular sarcoidosis;Ocular vasculitis;Oculofacial paralysis;Oedema;Oedema blister;Oedema due to hepatic disease;Oedema mouth;Oesophageal achalasia;Ophthalmic artery thrombosis;Ophthalmic herpes simplex;Ophthalmic herpes zoster;Ophthalmic vein thrombosis;Optic neuritis;Optic

neuropathy;Optic perineuritis;Oral herpes;Oral lichen planus;Oropharyngeal oedema;Oropharyngeal spasm;Oropharyngeal swelling;Osmotic demyelination syndrome;Ovarian vein thrombosis;Overlap syndrome;Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection;Paget-Schroetter syndrome;Palindromic rheumatism;Palisaded neutrophilic granulomatous dermatitis;Palmoplantar keratoderma;Palpable purpura;Pancreatitis;Panencephalitis;Papillophlebitis;Paracancerous pneumonia;Paradoxical embolism;Parainfluenzae viral laryngotracheobronchitis;Paraneoplastic dermatomyositis;Paraneoplastic pemphigus;Paraneoplastic thrombosis;Paresis cranial nerve;Parietal cell antibody positive;Paroxysmal nocturnal haemoglobinuria;Partial seizures;Partial seizures with secondary generalisation;Patient isolation;Pelvic venous thrombosis;Pemphigoid;Pemphigus;Penile vein thrombosis;Pericarditis;Pericarditis lupus;Perihepatic discomfort;Periorbital oedema;Periorbital swelling;Peripheral artery thrombosis;Peripheral embolism;Peripheral ischaemia;Peripheral vein thrombus extension;Periportal oedema;Peritoneal fluid protein abnormal;Peritoneal fluid protein decreased;Peritoneal fluid protein increased;Peritonitis lupus;Pernicious anaemia;Petit mal epilepsy;Pharyngeal oedema;Pharyngeal swelling;Pityriasis lichenoides et varioliformis acuta;Placenta praevia;Pleuroparenchymal fibroelastosis;Pneumobilia;Pneumonia;Pneumonia adenoviral;Pneumonia cytomegaloviral;Pneumonia herpes viral;Pneumonia influenzal;Pneumonia measles;Pneumonia mycoplasmal;Pneumonia necrotising;Pneumonia parainfluenzae viral;Pneumonia respiratory syncytial viral;Pneumonia viral;POEMS syndrome;Polyarteritis nodosa;Polyarthritis;Polychondritis;Polyglandular autoimmune syndrome type I;Polyglandular autoimmune syndrome type II;Polyglandular autoimmune syndrome type III;Polyglandular disorder;Polymicrogyria;Polymyalgia rheumatica;Polymyositis;Polyneuropathy;Polyneuropathy idiopathic progressive;Portal pyaemia;Portal vein embolism;Portal vein flow decreased;Portal vein pressure increased;Portal vein thrombosis;Portosplenomesenteric venous thrombosis;Post procedural hypotension;Post procedural pneumonia;Post procedural pulmonary embolism;Post stroke epilepsy;Post stroke seizure;Post thrombotic retinopathy;Post thrombotic syndrome;Post viral fatigue syndrome;Postictal headache;Postictal paralysis;Postictal psychosis;Postictal state;Postoperative respiratory distress;Postoperative respiratory failure;Postoperative thrombosis;Postpartum thrombosis;Postpartum venous thrombosis;Postpericardiotomy syndrome;Post-traumatic epilepsy;Postural orthostatic tachycardia syndrome;Precerebral artery thrombosis;Pre-eclampsia;Preictal state;Premature labour;Premature menopause;Primary amyloidosis;Primary biliary cholangitis;Primary progressive multiple sclerosis;Procedural shock;Proctitis herpes;Proctitis ulcerative;Product availability issue;Product distribution issue;Product supply issue;Progressive facial hemiatrophy;Progressive multifocal leukoencephalopathy;Progressive multiple sclerosis;Progressive relapsing multiple sclerosis;Prosthetic cardiac valve thrombosis;Pruritus;Pruritus allergic;Pseudovasculitis;Psoriasis;Psoriatic arthropathy;Pulmonary amyloidosis;Pulmonary artery thrombosis;Pulmonary embolism;Pulmonary fibrosis;Pulmonary haemorrhage;Pulmonary microemboli;Pulmonary oil microembolism;Pulmonary renal syndrome;Pulmonary sarcoidosis;Pulmonary sepsis;Pulmonary thrombosis;Pulmonary tumour thrombotic microangiopathy;Pulmonary vasculitis;Pulmonary veno-occlusive disease;Pulmonary venous thrombosis;Pyoderma gangrenosum;Pyostomatitis vegetans;Pyrexia;Quarantine;Radiation leukopenia;Radiculitis

brachial;Radiologically isolated syndrome;Rash;Rash erythematous;Rash pruritic;Rasmussen encephalitis;Raynaud's phenomenon;Reactive capillary endothelial proliferation;Relapsing multiple sclerosis;Relapsing-remitting multiple sclerosis;Renal amyloidosis;Renal arteritis;Renal artery thrombosis;Renal embolism;Renal failure;Renal vascular thrombosis;Renal vasculitis;Renal vein embolism;Renal vein thrombosis;Respiratory arrest;Respiratory disorder;Respiratory distress;Respiratory failure;Respiratory paralysis;Respiratory syncytial virus bronchiolitis;Respiratory syncytial virus bronchitis;Retinal artery embolism;Retinal artery occlusion;Retinal artery thrombosis;Retinal vascular thrombosis;Retinal vasculitis;Retinal vein occlusion;Retinal vein thrombosis;Retinol binding protein decreased;Retinopathy;Retrograde portal vein flow;Retroperitoneal fibrosis;Reversible airways obstruction;Reynold's syndrome;Rheumatic brain disease;Rheumatic disorder;Rheumatoid arthritis;Rheumatoid factor increased;Rheumatoid factor positive;Rheumatoid factor quantitative increased;Rheumatoid lung;Rheumatoid neutrophilic dermatosis;Rheumatoid nodule;Rheumatoid nodule removal;Rheumatoid scleritis;Rheumatoid vasculitis;Saccadic eye movement;SAPHO syndrome;Sarcoidosis;SARS-CoV-1 test;SARS-CoV-1 test negative;SARS-CoV-1 test positive;SARS-CoV-2 antibody test;SARS-CoV-2 antibody test negative;SARS-CoV-2 antibody test positive;SARS-CoV-2 carrier;SARS-CoV-2 sepsis;SARS-CoV-2 test;SARS-CoV-2 test false negative;SARS-CoV-2 test false positive;SARS-CoV-2 test negative;SARS-CoV-2 test positive;SARS-CoV-2 viraemia;Satoyoshi syndrome;Schizencephaly;Scleritis;Sclerodactylia;Scleroderma;Scleroderma associated digital ulcer;Scleroderma renal crisis;Scleroderma-like reaction;Secondary amyloidosis;Secondary cerebellar degeneration;Secondary progressive multiple sclerosis;Segmented hyalinising vasculitis;Seizure;Seizure anoxic;Seizure cluster;Seizure like phenomena;Seizure prophylaxis;Sensation of foreign body;Septic embolus;Septic pulmonary embolism;Severe acute respiratory syndrome;Severe myoclonic epilepsy of infancy;Shock;Shock symptom;Shrinking lung syndrome;Shunt thrombosis;Silent thyroiditis;Simple partial seizures;Sjogren's syndrome;Skin swelling;SLE arthritis;Smooth muscle antibody positive;Sneezing;Spinal artery embolism;Spinal artery thrombosis;Splenic artery thrombosis;Splenic embolism;Splenic thrombosis;Splenic vein thrombosis;Spondylitis;Spondyloarthropathy;Spontaneous heparin-induced thrombocytopenia syndrome;Status epilepticus;Stevens-Johnson syndrome;Stiff leg syndrome;Stiff person syndrome;Stillbirth;Still's disease;Stoma site thrombosis;Stoma site vasculitis;Stress cardiomyopathy;Stridor;Subacute cutaneous lupus erythematosus;Subacute endocarditis;Subacute inflammatory demyelinating polyneuropathy;Subclavian artery embolism;Subclavian artery thrombosis;Subclavian vein thrombosis;Sudden unexplained death in epilepsy;Superior sagittal sinus thrombosis;Susac's syndrome;Suspected COVID-19;Swelling;Swelling face;Swelling of eyelid;Swollen tongue;Sympathetic ophthalmia;Systemic lupus erythematosus;Systemic lupus erythematosus disease activity index abnormal;Systemic lupus erythematosus disease activity index decreased;Systemic lupus erythematosus disease activity index increased;Systemic lupus erythematosus rash;Systemic scleroderma;Systemic sclerosis pulmonary;Tachycardia;Tachypnoea;Takayasu's arteritis;Temporal lobe epilepsy;Terminal ileitis;Testicular autoimmunity;Throat tightness;Thromboangiitis obliterans;Thrombocytopenia;Thrombocytopenic purpura;Thrombophlebitis;Thrombophlebitis migrans;Thrombophlebitis

neonatal;Thrombophlebitis septic;Thrombophlebitis superficial;Thromboplastin antibody positive;Thrombosis;Thrombosis corpora cavernosa;Thrombosis in device;Thrombosis mesenteric vessel;Thrombotic cerebral infarction;Thrombotic microangiopathy;Thrombotic stroke;Thrombotic thrombocytopenic purpura;Thyroid disorder;Thyroid stimulating immunoglobulin increased;Thyroiditis;Tongue amyloidosis;Tongue biting;Tongue oedema;Tonic clonic movements;Tonic convulsion;Tonic posturing;Topectomy;Total bile acids increased;Toxic epidermal necrolysis;Toxic leukoencephalopathy;Toxic oil syndrome;Tracheal obstruction;Tracheal oedema;Tracheobronchitis;Tracheobronchitis mycoplasmal;Tracheobronchitis viral;Transaminases abnormal;Transaminases increased;Transfusion-related alloimmune neutropenia;Transient epileptic amnesia;Transverse sinus thrombosis;Trigeminal nerve paresis;Trigeminal neuralgia;Trigeminal palsy;Truncus coeliacus thrombosis;Tuberous sclerosis complex;Tubulointerstitial nephritis and uveitis syndrome;Tumefactive multiple sclerosis;Tumour embolism;Tumour thrombosis;Type 1 diabetes mellitus;Type I hypersensitivity;Type III immune complex mediated reaction;Uhthoff's phenomenon;Ulcerative keratitis;Ultrasound liver abnormal;Umbilical cord thrombosis;Uncinate fits;Undifferentiated connective tissue disease;Upper airway obstruction;Urine bilirubin increased;Urobilinogen urine decreased;Urobilinogen urine increased;Urticaria;Urticaria papular;Urticarial vasculitis;Uterine rupture;Uveitis;Vaccination site thrombosis;Vaccination site vasculitis;Vagus nerve paralysis;Varicella;Varicella keratitis;Varicella post vaccine;Varicella zoster gastritis;Varicella zoster oesophagitis;Varicella zoster pneumonia;Varicella zoster sepsis;Varicella zoster virus infection;Vasa praevia;Vascular graft thrombosis;Vascular pseudoaneurysm thrombosis;Vascular purpura;Vascular stent thrombosis;Vasculitic rash;Vasculitic ulcer;Vasculitis;Vasculitis gastrointestinal;Vasculitis necrotising;Vena cava embolism;Vena cava thrombosis;Venous intravasation;Venous recanalisation;Venous thrombosis;Venous thrombosis in pregnancy;Venous thrombosis limb;Venous thrombosis neonatal;Vertebral artery thrombosis;Vessel puncture site thrombosis;Visceral venous thrombosis;VIth nerve paralysis;VIth nerve paresis;Vitiligo;Vocal cord paralysis;Vocal cord paresis;Vogt-Koyanagi-Harada disease;Warm type haemolytic anaemia;Wheezing;White nipple sign;XIth nerve paralysis;X-ray hepatobiliary abnormal;Young's syndrome;Zika virus associated Guillain Barre syndrome.

DMED DATA % increase in partial year of 2021 (Oct 19) compared to years 2016-2020 you can find the full graph on www.renz-law.com https://renz-law.com/attorney-tom-renz-whistleblowers-dmed-defense-medical-epidemiology-database-reveals-incredibly-disturbing-spikes-in-diseases-infertility-injuries-across-the-board-after-the-military-was-forced-to/ Scroll to the bottom and click on "NEXT DMED DATA" – but you really need to read this page before you click for the data.

	2016	2017	2018	2019	2020	2021 (partial year)	% increase
Diseases and Injuries (Ambulatory)	2,059,630	2,058,379	2,022,663	2,110,383	1,976,724	21,512,583	988.30%
Diseases and injuries (Hospitalization)	43,786	43,338	42,024	43,493	40,052	54,776	36.80%
Diseases of the Nervous System	82,435	81,998	81,382	85,012	80,786	863,013	968.30%
Malignant Neuroendocrine Tumor	167	135	98	113	117	440	276.10%
Acute Myocardial Infarct	324	370	376	366	372	1,650	343.50%
Acute Myocarditis	84	92	116	159	108	307	184.30%
Acute Pericarditis	535	538	522	531	499	850	70.30%
Pulmonary Embolism	678	701	668	716	968	3,489	260.40%
Congenital Malformations	11,710	11,131	10,456	11,081	10,153	18,951	86.70%
Nontraumatic Subarachnoid Hemorrage	219	139	134	170	196	640	226.50%
Anxiety	37,011	36,667	36,145	37,762	37,870	931,791	2360.50%
Suicide	359	496	530	570	550	1798	226.90%
Neoplasms for All Cancers	41,557	39,139	37,756	38,889	36,050	114,645	218%
Cancer (Digestion)	660	654	633	602	704	4,060	476.70%
Cancer (Breast)	934	810	766	792	766	4,357	468.80%
Cancer (Testicular)	1,156	1,008	866	880	889	3,537	297.90%
Infertility (female)	2,261	2,262	2,243	2,340	2,262	11,748	419.40%
Dismenorrhea	3,104	3,403	3,481	3,943	3,900	12,539	221.50%
Ovarian Dysfunction	862	936	908	945	1,022	4,086	299.80%
Infertility (male)	2,187	2,287	2,037	2,152	1,990	8,365	320.40%
Guillian-Bare Syndrome	66	79	71	85	65	403	520%

friend's coworker, another [illegible] friend's wife

friend's co-worker, my mom, my best friend's husband, a friend

local school nurse

friend's old employer died, Cancer, a friend's father died, friend's cousin died, friend's sister [illegible], friend['s] co-worker

3 women at church

niece's friends

my daughter, my friend's daughter x2

over

Acute Transverse Myelitis	46	57	48	35	34	202	494.10%
Seizures	196	148	130	150	123	489	297.60%
Narcolepsy Cataplexy	995	898	864	830	766	2,097	351.70%
Rhabdomyolysis	706	696	740	755	669	5,162	671.60%
Multiple Sclerosis	479	391	367	400	385	2750	614.30%
Migraine	15,734	15,714	16,462	17,116	16,311	73,490	351.70%
Blood Disorders	11,533	11,122	10,851	11,773	11,429	34,486	204.10%
Hypertension	2,308	2,323	2,363	2,392	2,415	53,846	2129.60%
Cerebral Infarct	887	848	858	888	887	3,438	293.70%

← coronary artery aneurysm (open heart surgery)

stroke → friend's mom
friend's dad
my uncle

miscarriage - 2 of neice's friends

heartattack → 2 of brother-in-law's coworkers
accountant's father (died)
family friend
husband's uncle - died

infertility → several of neice's friends unable to conceive

neonatal death (in Pfizer documents)
friend's neice - twin babies died

There are way too many "coincidences"

Stop the Shots!!!

Commissioner's Report

Karen Shelton, MD
State Health Commissioner
Virginia Department of Health

Outline

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

Agency Stars

Mary Kate Bowser, DNP, MS, RN

Seth Levine, MPH

Suicide Prevention – Zero Suicide Website Launch

- VA Code § 32.1-73.7 designates VDH as the lead agency for youth suicide prevention

- VDH Suicide Prevention Program
  - Identify and assist persons at risk
  - Increase help seeking
  - Facilitate access to mental health treatment
  - Support linkages to treatment

- ARPA: Substance Misuse and Suicide Prevention
  - Zero Suicide Framework is a way to improve suicide care within health and behavioral health systems.

Image from Virginia's Zero Suicide Landing Page

Suicide Prevention – Zero Suicide Website Launch

Zero Suicide Website

- Launched July 2023
- Planning, implementation, and evaluation tools and training videos
- Technical Assistance Hub (2024 launch)
  - VDH staff provides technical assistance to implementors
  - Repository of policies, practices & procedures
  - Quarterly collaborative meetings among implementors to share lessons learned and build out additional resources
- Initial TA Hub implementors: VCU Health (Richmond, VA), Dominion HCA (Falls Church, VA), Augusta Health (Staunton, VA), Arlington CSB (Arlington, VA) and Encompass Community Supports (Culpeper, VA)
- Next Steps:
  - Expansion of participating health systems

Images from Virginia's Zero Suicide Landing Page

Substance Misuse

Right Help Right Now	VDH is involved in workstreams pertaining to supporting targeted programs for substance use prevention (naloxone distribution, CHR)
Senate Bill 1415	Naloxone Distribution Plan and Report to GA – under review Begin development of Opioid Impact Reduction Registry – under review
Executive Order 26	Develop a plan to utilize and fund wastewater surveillance for fentanyl Plan to address the fentanyl crisis with strategies including increased naloxone distribution and public awareness campaigns Develop plan to report data with VSP Fusion Center and participate in the Framework for Addiction Analysis and Community Transformation (FAACT) Assist localities in establishing overdose fatality review teams
VA Opioid Abatement Authority	One-time funding to expand naloxone distribution-$603,843 One-time funding to purchase naloxone-$1,000,000 Support and extend comprehensive harm reduction sites-$1,000,000 Salaries for 3 new local health district opioid use specialists-$300,000

Virginia Operations Plan Exercise (VOPEX)

- Held July 18, 2023; FEMA-evaluated exercise centered around a simulated radiological emergency at the Surry Power Station.
- **Goal:** to evaluate and assess offsite radiological emergency response plans developed by state and local governments to determine if they can be implemented during an emergency
- **By the numbers:**
  - 167 evaluated capability targets (planning standards)
  - 43 federal evaluators
  - 28 different locations
  - 10 Office of Radiological Health employees involved with the exercise
- **Outcome:** No performance issues identified
- FEMA's public statement on Surry VOPEX outcome:
  - *"The Commonwealth's Emergency Organizations have dedicated staff, plans and procedures, and equipment and demonstrated the capability to coordinate the response to a simulated radiological event within the 10-mile plume Emergency Planning Zone of the Surry Power Station"*

Health Director Meeting

First in-person meeting since prior to pandemic

Remarks from Dr. Shelton and Secretary Littel

Topics

- Non-Physician District Director Model
- Overdose Incident Management Team
- Strategic Planning
- Internal Audit
- Employee Engagement/Employee Relations
- Management of Number of Employee Positions
- Information Technology Projects and Procurements

"This internship has been absolutely amazing. I am so grateful to have been able to… experience what a public health career looks like."

- Cate Vaughn, Academy Intern

"This experience has majorly shifted my career goals, and I'm now seriously considering an MPH or MD program. I know that no matter what route I take, I want to continue to be involved with public health… in large part because of this internship."

- Connor Eickleman, Academy Intern

"...having an intern allows us to "nudge" projects not housed under a particular program into existence. [It] gives us energy."

- Maria Almond, MD, MPH, Director,
Piedmont Health District

"This internship has only strengthened my desire to work in public health. I have been able to work on some awesome projects and make great connections that I wouldn't have otherwise been able to do. I will stay connected with the Academy and I hope to be back at VDH soon!"

- Kira Funge, Academy Intern

VIRGINIA DEPARTMENT OF HEALTH

INTERNSHIP ACADEMY

402	Applications
42	Letters of Interest Screeners
26	Internship Participants
18	Local Health Districts
15	Colleges/Universities
5	Central Office Programs
1	Top 100 Virginia Employer for Interns Award (2023)

Workforce Engagement Director

This position is a Public Health Infrastructure Grant requirement. The Workforce Director must:

- be a full-time employee
- have sufficient authority and seniority to effectively manage the work under the grant
- report to the agency head or other senior level executive.
- represents the agency and actively participates in grant-related meetings, including CDC

Recruitment status:

- The Employee Work Profile has been completed.
- The position will report directly to the Health Commissioner.
- VDH expects to begin recruitment in early September.

Language Access

Federal Requirement to provide meaningful access to VDH services in languages other than English

VDH conducted a needs assessment coming out of the pandemic, and identified significant agency needs around language access

Two contractors were hired using federal grant funds: Language Access Coordinator and Translation & Interpretation Manager

CDC Public Health Infrastructure Grant Funds are being used to improve language access services

Language and Disability Access Plan under development

Stakeholder Workgroup on Local Health Department Structure and Financing

2022 Study – 11 Policy Options

Request from JCHC for VDH to Convene Stakeholder Workgroup for Follow-up and Prioritization of Policy Options

Workgroup Members

- Virginia Department of Health
- Virginia Association of Counties
- Virginia Municipal League
- Virginia Community Health Care Association
- Virginia Association of Free and Charitable Clinics
- Office of the Secretary of Health and Human Resources

Stakeholder Workgroup on Local Health Department Structure and Financing

First Workgroup Meeting – August 7 – focused on:

- Community Health Assessments/Community Health Improvement Plans;
- Accountability and Performance Management for Local Health Departments,
- State/Local Cooperative Health Budget

Next Steps

- Receive and incorporate feedback from workgroup members
- Schedule next workgroup meeting and develop agenda
- Continue review/analysis of financial, budgetary, staffing and community health assessment data
- Determine information to be shared with workgroup; determine additional meetings needed
- Begin work on draft report to General Assembly

Financial Management Transformation

Goals for the VDH Financial Management Transformation

1. Strengthen the **accountability framework** to achieve accurate, complete, and compliant financials
2. Implement an **organizational structure** that is right-sized, upskilled, and structured in an effective manner to achieve operational efficiencies
3. Institutionalize comprehensive **financial controls** through strengthened policies and processes
4. Implement **enterprise-wide reporting** to enable transparent near real-time analysis, timely financial reporting, and management dashboards

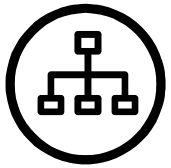
As planned, VDH is on track to make significant progress across the initiatives in FY24 and into FY25

Financial Management Transformation

There is progress underway across these six initiatives to address the highest priority areas

Budget

Improve the Budget Development and Execution process to enable more **timely and accurate budget management** and **reporting** throughout the year



Organization Improvement

Optimize where **financial management responsibilities** reside across the agency and **clarify roles**

Invoicing & Voucher Process

Improve the invoice review and approval processes to enable **prompt payments** for expenses

Travel Voucher Processing

Improve the travel voucher process to efficiently manage **requests, approvals**, and **reimbursements**

Accounting Processes & Controls

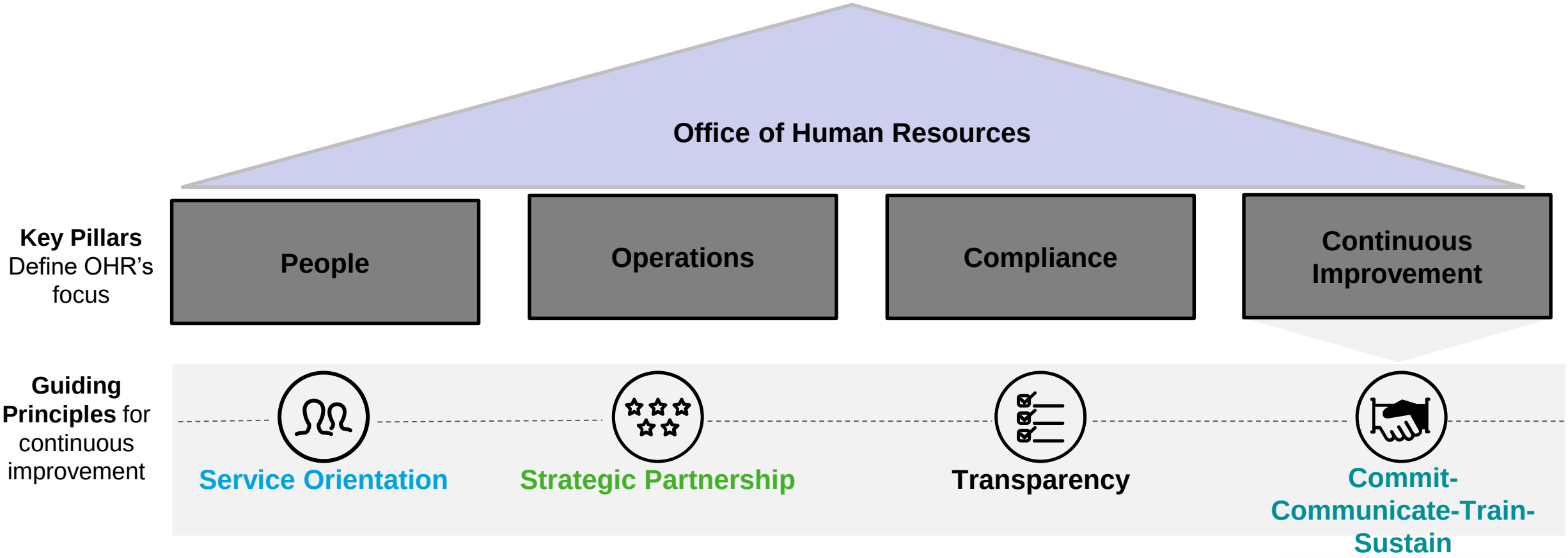
Improve Accounting processes and controls to **remediate audit findings** and **mitigate financial risks**

Grants

Improve the Grants Management process to **track, manage, report, and efficiently use grants**

HR Transformation

To be a trusted partner and deliver exceptional service and resources to all VDH employees.



HR Transformation

Guiding Principles

Service Orientation

Strategic Partnership

Transparency

Continuous Improvement

People

- Recruit and retain talent
- Proactive Employee Relations
- Effective Communication
- Training & Development
- Performance Management

Operations

- Streamline & standardize processes
- Effective Change Management
- Accurate HR Analytics

Compliance

- Mitigate risk to the organization by following all applicable employment laws and regulations
- Policy Update/Guidance

Continuous Improvement

- Analyze Root Cause
- Regularly evaluate systems and processes for effectiveness

Questions?

REGULATORY ACTION UPDATE

State Board of Health
Regulatory Action Update
September 14, 2023

Overview of Pending Regulatory Actions:

There are 47 pending actions under development:

- 9 NOIRAs
- 11 proposed actions
- 8 final actions
- 19 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 June 15, 2023 Board Meeting 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.*

Non-Regulatory Actions Taken by the Commissioner on Behalf of the Board since the June 15, 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 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 5-545[†]	Guidelines 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

[†]The Results of Periodic Review for 14 chapters are due to the Regulatory Coordinator before the December Board Meeting.
[††] The Result of Periodic Review has been submitted and is 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 June 15, 2023 Board Meeting:

The Office of the Attorney General certified:

- Final Regulations for the Regulations for Bedding and Upholstered Furniture Inspection Program (12VAC5-125)
- Fast Track Regulations Governing Eligibility Standards and Charges for Health Care Services to Individuals (12VAC5-200)
- Proposed Waterworks Operation Fee Regulations (12VAC5-600)
- Fast Track Regulations Governing Application Fees for Construction Permits for Onsite Sewage Disposal Systems and Private Wells (12VAC5-620)

The Department of Planning and Budget completed the review of:

- Final Regulations for the Regulations for Bedding and Upholstered Furniture Inspection Program (12VAC5-125)
- Fast Track Regulations for the Licensure of Nursing Facilities (12VAC5-371)
- Proposed Regulations for Home Care Organizations (12VAC5-381)
- Fast Track Regulations for the Licensure of Hospitals in Virginia (12VAC5-410)
- Proposed Waterworks Operation Fee Regulations (12VAC5-600)
- Fast Track Regulations Governing Application Fees for Construction Permits for Onsite Sewage Disposal Systems and Private Wells (12VAC5-620)

The Secretary of Health & Human Resources completed the review of:

- NOIRA for the Rules and Regulations Governing the Construction of Migrant Labor Camps (12VAC5-501)
- Proposed Rainwater Harvesting Systems Regulations (12VAC5-635)

SFY 2024 Unified Regulatory Plan

Pursuant to Executive Order 19 (2022) and the Office of Regulatory Management's (ORM) Procedures for Review of State Regulations, each agency is required to submit an annual Unified Regulatory Plan (URP) that details the anticipated regulatory actions and changes to the agency's guidance documents for a state fiscal year. The Board's SFY2024 URP was submitted to SHHR and ORM in June. The plan includes 40 anticipated regulatory stages and over 100 changes to the agency's guidance documents by June 30, 2024

Regulatory Reduction

ORM released a guide for agencies toward achieving the Administration's goal of reducing discretionary regulations by 25% by the end of the 2025. VDH submitted our "baseline" count of regulatory requirements to ORM on July 31. We are encouraging use of periodic reviews as major opportunities to consider options for regulatory reduction and will continue to coordinate efforts toward the 25% goal with VDH policy staff and leadership.

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….

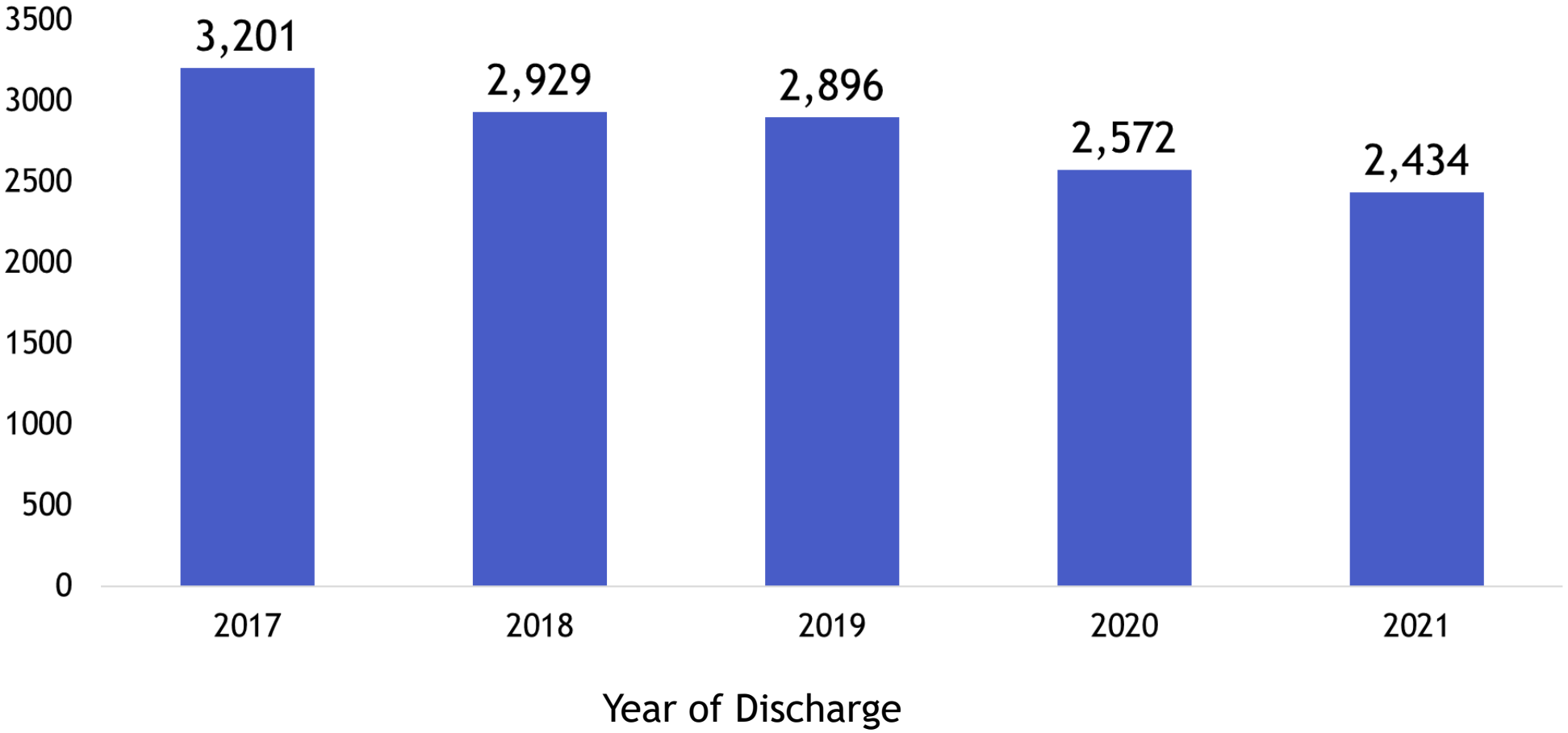
BREAK

LUNCH PRESENTATION

Injury and Violence Prevention Program Presentation on Suicide and Self-Harm

Tara Keen, MPH
Justin Wallace, MPH
Virginia Department Of Health
September 14th, 2023

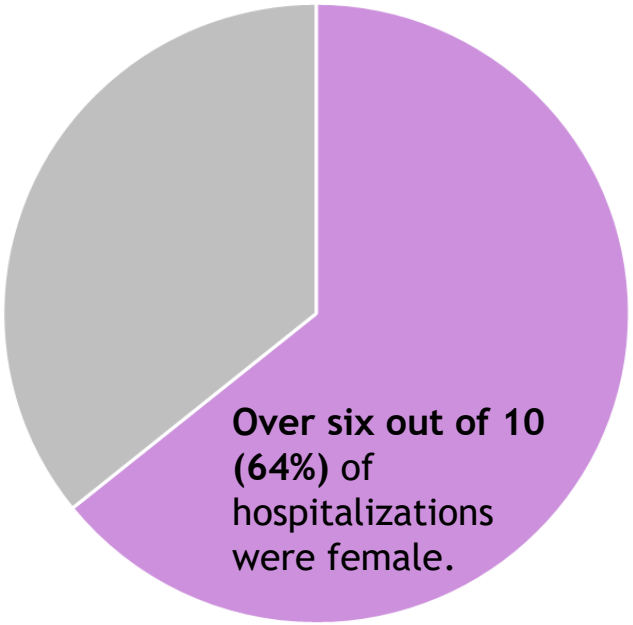
Non-fatal self-harm hospitalizations have declined by **24%** from 2017 to 2021.



*COVID-19 may have disrupted healthcare service delivery and healthcare seeking behaviors of people for self-harm in 2020 and 2021.

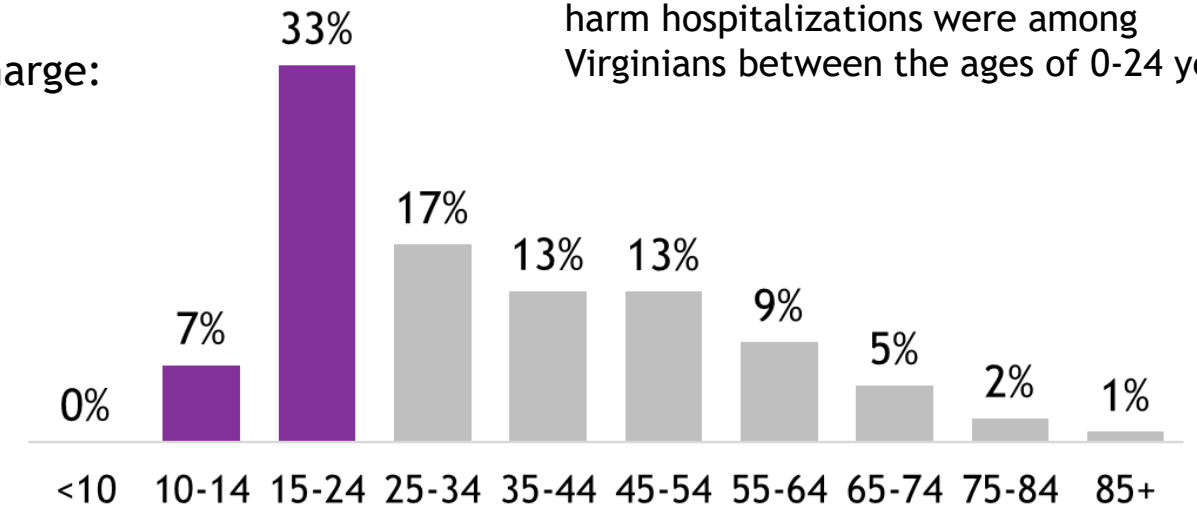
Non-fatal self-harm hospitalizations among Virginians in 2021 by demographics (n = 2,434)

By Sex:

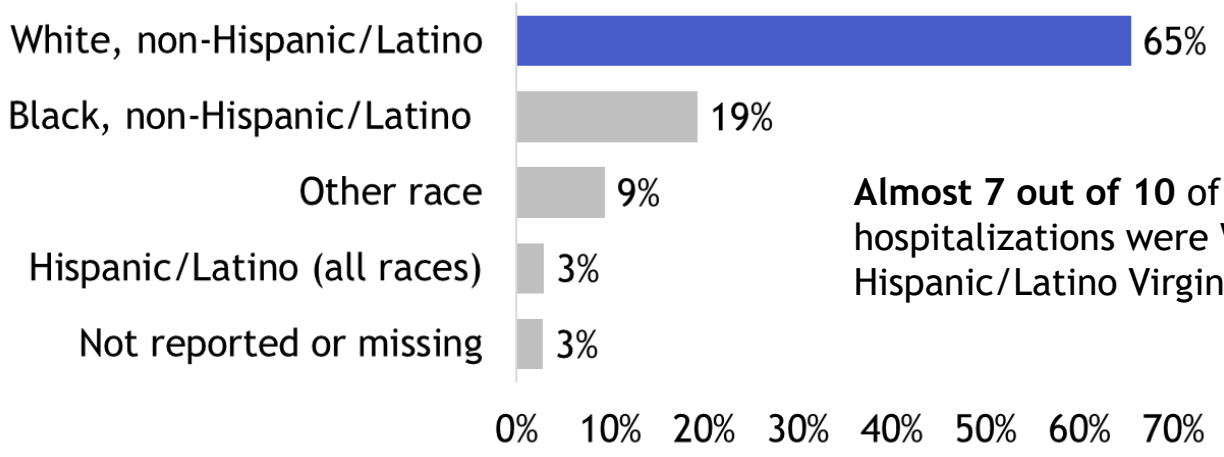


By Age at Discharge:

Four out of 10 (40%) of non-fatal self-harm hospitalizations were among Virginians between the ages of 0-24 years.

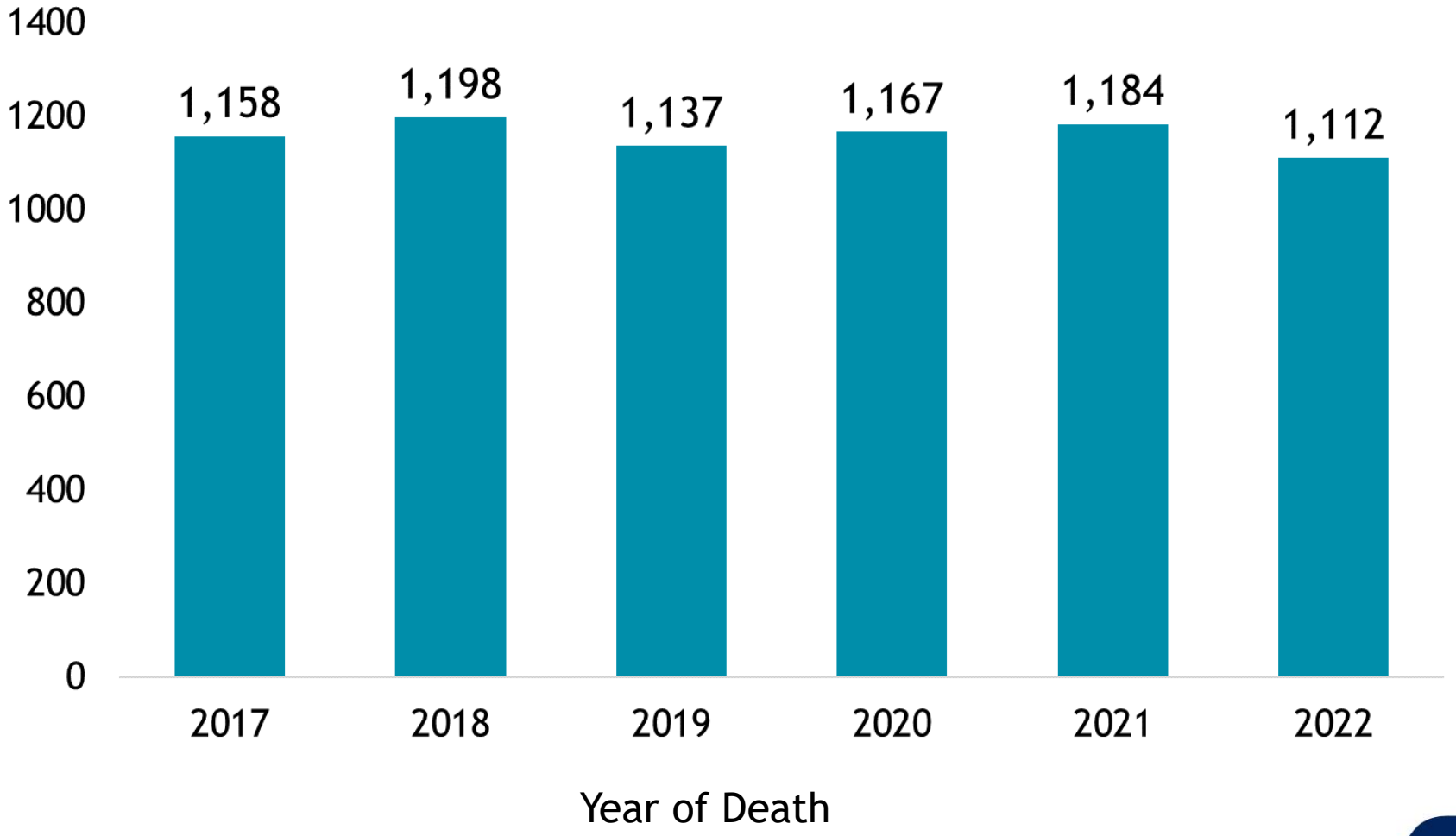


By Race / Ethnicity:



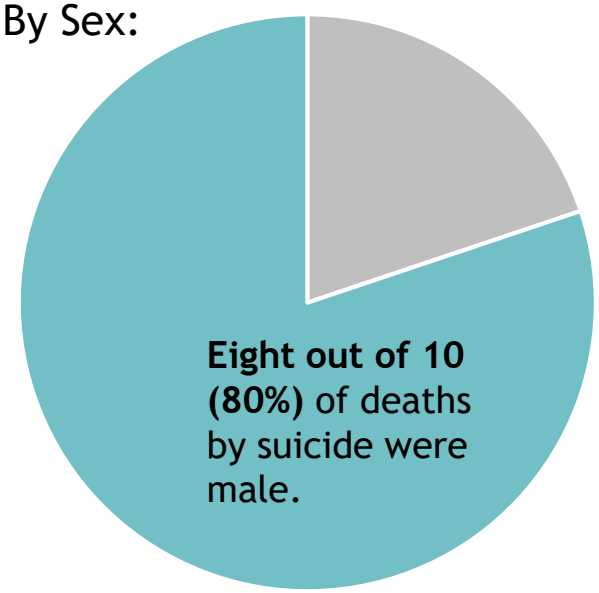
Almost 7 out of 10 of non-fatal self-harm hospitalizations were White, non-Hispanic/Latino Virginians.

Deaths by suicide among Virginians between 2017 and 2021 remained relatively stable.



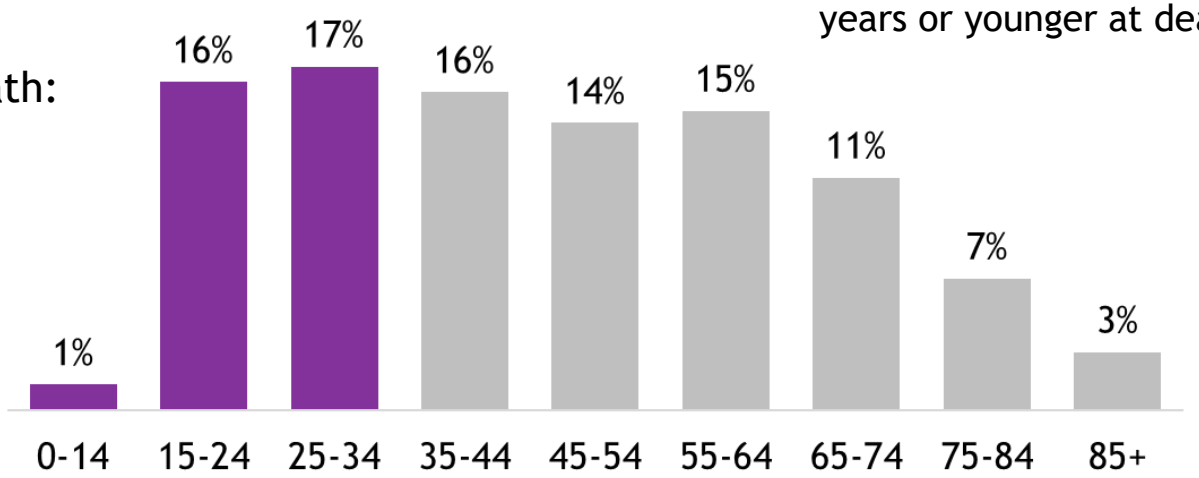
Deaths by suicide in 2021 among Virginians by demographics (n = 1,184)

By Sex:

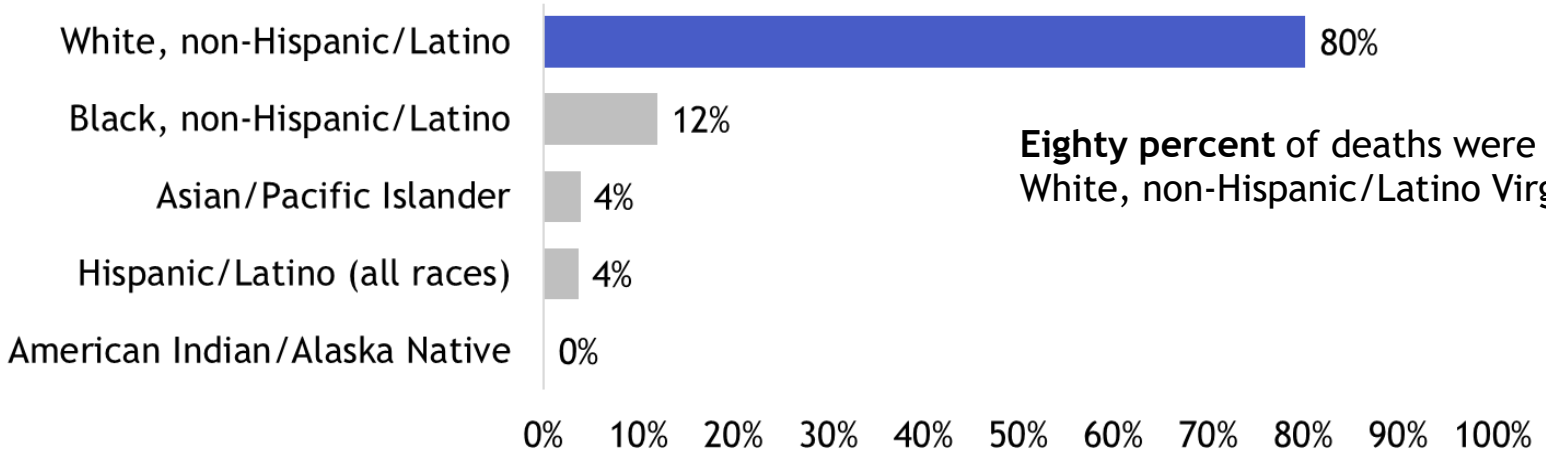


By Age at Death:

Over one-third (34%) were 34 years or younger at death.



By Race/Ethnicity:



Eighty percent of deaths were among White, non-Hispanic/Latino Virginians.

Overview: Trends in priority populations

Population	Trend
Non-Fatal Self-Harm	
Virginians aged 10-14 years	Non-fatal self-harm hospitalizations increased **36%** from 2017 to 2021 (120 in 2017 to 163 in 2021).
Suicide	
Virginians aged < 25 years	Deaths by suicide increased **24%** from 2017 to 2021 (167 in 2017 to 207 in 2021).
Black, non-Hispanic Virginians, all ages	Deaths by suicide increased **56%** from 2017 to 2021 (91 in 2017 to 142 in 2021).
Black, non-Hispanic Virginians aged <25 years	Deaths by suicide increased **65%** from 2017 to 2021 (26 in 2017 to 43 in 2021).
Southwest health region	The Southwest health region (18 per 100,000 population) had the highest suicide death rate in 2021 out of the five Virginia health regions.
All Virginians	Firearms were the leading mechanism (cause) of suicide death in 2017-2021 (**62%**). Suicide deaths by firearm increased **6%** from 2017 to 2021.

Collaborative Effort: Virginia Department of Health and the Department of Behavioral Health and Developmental Services

Virginia Department of Health	Department of Behavioral Health and Developmental Services
Non direct service project addressing prevention and postvention within suicide work	Direct service project addressing intervention within suicide work
§ 32.1-73.7. Department to be lead agency for ***youth suicide prevention***	§ 37.2-312.1. Department to be lead agency for suicide prevention ***across the lifespan***
Primary/Secondary Prevention – intervention prior to suicide, addressing shared risk and protective factors	Secondary/Tertiary Prevention – screening, assessment, hospitalization
Areas of Focus – policy, data collection, evaluation, coalition building, organizational practices, education, health promotion, SDoH	Areas of Focus - mobile crisis, public BH access points (CSBs), respite care, psychiatric hospitals
Supports – Campus Suicide Prevention Center of Virginia, LHD, Suicide Prevention Interagency Advisory Group	Supports – CSBs, Gatekeeper Training, Local Prevention Coalitions

Overview: Suicide Prevention
Injury and Violence Prevention Program (IVPP)

- Define and monitor the problem
  - Continued monitoring of existing data sources
  - Collaborative projects
  - Identify those at risk
- Promote “upstream” primary prevention, prevent suicide risk, and enhance protective factors
  - Provide technical assistance to state agencies and community organizations on comprehensive suicide prevention approaches
  - Expand and develop public/private partnerships
  - Assure widespread adoption through capacity building, technical assistance, state action planning, and policy development
- Overarching Goals
  - To foster leadership, collaboration and partnerships among public, private, non-profit and community entities, including the integration and coordination of suicide prevention efforts across multiple sectors;
  - To provide training and education to enable communities to recognize and respond to suicide risk and educate support systems of those children and adolescents at risk for suicide;
  - To ensure a seamless continuum of care for those at risk for suicide and their support networks;
  - To reduce barriers and increase access to mental/behavioral health services and supports;
  - To cultivate resources and leadership among attempt survivors and survivors of suicide loss and provide support and care for these individuals, while also implementing postvention strategies within communities; and
  - To refine and expand data collection and evaluation of suicide prevention initiatives

Overview: Suicide Prevention IVPP

Youth Suicide Prevention Program Priorities

- American Rescue Plan Act (ARPA)
  - Suicide and Crisis Lifeline - 988
    - Build capacity for 988 transition
  - Suicide Prevention Continuum of Care
    - Gap Analysis
    - Training: Collaborative Assessment and Management of Suicidality (CAMS)
    - Zero Suicide Website
  - Campus Suicide Prevention Center of Virginia (CSPCV)
    - High School Transition Curriculum

- CoreSIPP (CDC)
  - Resource identification and training support for black youth serving organizations
    - Gap analysis
    - Training plan

Overview: Suicide Prevention IVPP Cont.

- Garrett Lee Smith (SAMHSA)
  - Goal 1: Increase the capacity of Virginia's system infrastructure to improve early intervention and assessment services.
  - Goal 2: Increase the capacity of Virginia's system infrastructure to provide better suicide care and appropriate community-based MH.
  - Goal 3: Enhance the VDH Youth Suicide Prevention Program's capacity to monitor effectiveness of services and for research, technical assistance, and policy development.
  - Goal 4: Increase Virginia's capacity to improve its comprehensive approach to youth suicide prevention.

- General Funds
  - Campus Suicide Prevention Center of Virginia (CSPCV)
    - Project ECHO – over 70 Virginia campuses supported

- Maternal and Child Health Block Grant (HRSA)
  - Gatekeeper Training: CSPCV
    - 862 individuals trained (YTD)

- Maternal Mortality Grant (Office of Women's Health, HHS)
  - Campaign to address pregnancy associated deaths from domestic violence and suicide
  - Clinical Training: Assessing and Managing Suicide Risk (ASMR) and Counseling on Access to Lethal Means (CALM)
  - Gatekeeper Training (non-clinical): NAMI Connect

Project Highlight: 988 Suicide and Crisis Lifeline

Gap: Individual's calling 988 were not receiving timely in-state assistance due to routing and capacity issues within supporting call centers.

- 2020 (start of project) in-state answer rate at 66%
- 2023 – in-state answer rate consistently above 90%
- Volume of calls have doubled 33,815 (2020) to estimated 70k in 2023

Current Virginia 988 Trends

- Call volume increasing
  - 33,815 (2020)
  - 50,001 (2021)
  - 63,682 (2022)
  - *Estimated 70k in 2023*
- In-state answer rate continues to improve
  - 66% (2020)
  - 65% (2021)
  - 85% (2022)
  - *91% (2023) as of July*

June 2020
VDH IVPP assist DBHDS with Lifeline State Capacity Buidling Grant

February 2021
VDH IVPP support new 988 Planning Grant (988 to go live July 2022)

April 2021
988 coalition formed

March 2021
General Assembly creates Crisis Call Center Fund

July 2022
Initial 988 rollout to the public (nearly 80% increase in call volume compared to July of 2021)

February 2022
VDH identifies ARPA funding to support 988 staff buildup

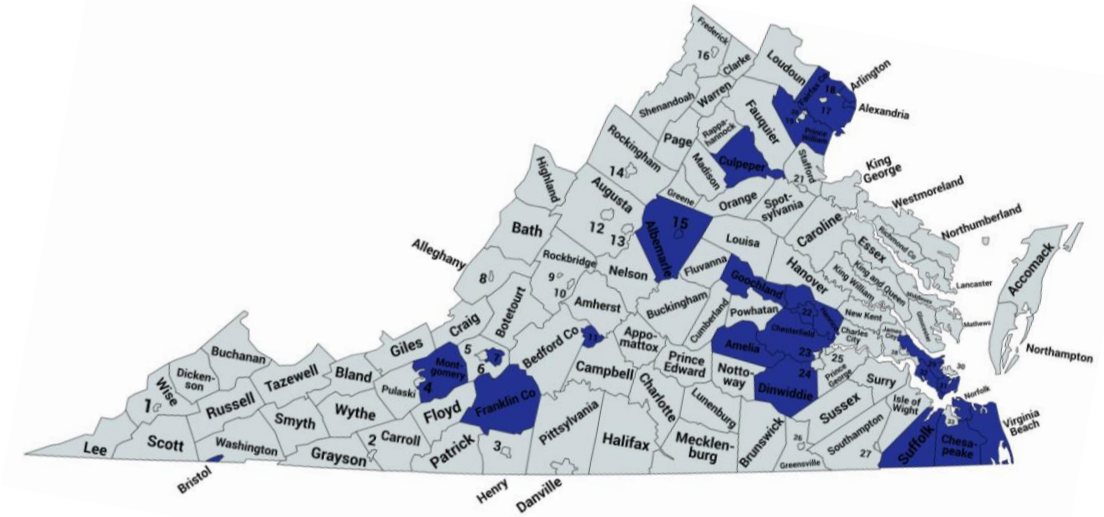
June 2023
VDH ARPA support for 988 ends

Project Highlight: CAMS Pilot

Gap: Many providers do not receive suicide specific training. No legislative requirement in Virginia.

- Collaborative Assessment and Management of Suicidality (CAMS)
- Evidence-based training supported by 7 RCTs in a variety of settings
  - Performs as good or better than TAU
  - Person centered; suicide specific
- Fills gap in provider training
- Project began January 2023
  - 1100 training seats
  - As of August 2023 – 140 individual providers participating
- Organization Partnerships
  - Virginia Academy of Clinical Psychologists (200 seats)
  - Northern Virginia Mental Health Institute (50 seats)
  - Virginia Association of Community Based Providers (rolling)
  - Virginia Board of Social Work (rolling)
  - Virginia Board of Psychologists (rolling)
  - Virginia Board of Counselors (rolling)
  - Campus Suicide Prevention Center of Virginia (rolling)

CAMS Adoption by Geographic Location, 2023



VDH VIRGINIA DEPARTMENT OF HEALTH

Project Highlight: Garrett Lee Smith (GLS)

Gap: Lack of provider knowledge concerning screening, assessment, and referral. Lack of coordinated systems level response to suicide. No coordinated Postvention infrastructure. Limited lethal means programming.

GLS – Youth Suicide Prevention (10-24)

- Begin Date: October 1, 2023
- Priority Areas
  - Zero Suicide Framework
    - Creation of the Zero Suicide Hub
  - Postvention
    - NAMI Virginia
    - Suicide Prevention Interagency Advisory Group
  - Schools
    - VDOE Suicide Prevention Guidelines
    - Sources of Strength
  - Lethal Means Safety
    - Lock & Talk Virginia
    - Virginia Safe Storage Map
    - Counseling on Access to Lethal Means

292 Gun Retail Partners

14K Medication Lock Boxes

24K Gun Locks Distributed

IVPP Suicide Prevention Partners

- Virginia Government: Department of Behavioral Health and Developmental Services (DBHDS), Department of Criminal Justice Services (DCJS), Virginia Department of Education (VDOE), Department of Veteran Services (DVS)
- National Partners: Suicide Prevention Resource Center (SPRC), Vibrant Emotional Health, SAMHSA, CDC
- Suicide Prevention Interagency Advisory Group (SPIAG)
  - Government, private, non-profit, advocate
  - 260 members
  - Bimonthly meetings
  - Coordinate cross-systems work
- Campus Suicide Prevention Center of Virginia (CSPCV)

SPIAG
Suicide Prevention Interagency Advisory Group

The Campus Suicide Prevention Center of Virginia

Contact Information

Tara Keen, MPH
Tara.Keen@vdh.virginia.gov
Injury and Violence Prevention Epidemiologist
Virginia Department of Health

Justin Wallace, MPH
Justin.Wallace@vdh.virginia.gov
Suicide Prevention Coordinator
Virginia Department of Health

Regulations Governing Durable Do Not Resuscitate Orders 12VAC5-66 (Fast Track Amendments)

Gary Brown

Director

Office of Emergency Medical 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: July 13, 2023

TO: Virginia State Board of Health

FROM: *Gary Brown, Office of Emergency Medical Services*

SUBJECT: 12VAC5-66 Fast Track Action –Amend Following Periodic Review

---

Enclosed for your review are proposed Fast Track amendments to the Regulations Governing Durable Do Not Resuscitate Orders.

A Periodic Review was completed pursuant to Executive Order 19 (2022) during which VDH indicated a need to amend the regulations. VDH recommends that the regulations be updated for consistency with the Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code.

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

townhall.virginia.gov

Fast-Track Regulation
Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC5-66
VAC Chapter title(s)	Regulations Governing Durable Do Not Resuscitate Orders
Action title	Amend Regulations as a Result of Periodic Review
Date this document prepared	June 30, 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 State Board of Health (Board) proposes to amend the Regulations Governing Durable Do Not Resuscitate Orders (12VAC5-66). The proposed amendments update the chapter to conform to the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*. Additionally, the amendments remove non-regulatory sections and provide greater clarity to the regulations.

Acronyms and Definitions

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

"Board" means the State Board of Health.
"Style Requirements" means the Registrar of Regulations' *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*

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 Board of Health is initiating this regulatory action to implement the results of a periodic review, which was conducted pursuant to Executive Order 19 (2022) and § 2.2-4017 of the Code of Virginia.

This rulemaking proposes the repeal of language that is not regulatory in nature and other changes to the text to conform with Style Requirements, and it is therefore expected to be noncontroversial and appropriate for the fast-track process.

Legal Basis

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

The promulgating agency is the State Board of Health.

Section 32.1-12 of the Code of Virginia authorizes the Board to "make, adopt, promulgate and enforce such regulations…as may be necessary to carry out the provisions of this [Title 32.1] and other laws of the Commonwealth administered by it, the Commissioner or the Department."

Section 32.1-111.4 of the Code of Virginia requires the Board to "prescribe by regulation…[p]rocedures…to authorize qualified emergency medical services personnel to follow Do Not Resuscitate Orders pursuant to § 54.1-2897.1."
Section 32.1-111.5 of the Code of Virginia requires the Board to "prescribe by

regulation…qualifications necessary for authorization to follow Do Not Resuscitate Orders pursuant to § 54.1-2897.1."

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.

This regulatory action is intended to implement the results of a periodic review conducted pursuant to Executive Order 19 (2022) and § 2.2-4017 of the Code of Virginia. It will repeal unnecessary and nonregulatory language and conform the Regulations to the Style Requirements, which will ensure that emergency medical services providers can efficiently access and understand the regulations governing DDNRs.

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.

This regulatory action repeals 12VAC5-66-20 and 12VAC5-66-30, and it amends 12VAC5-66-10, 12VAC5-66-40, 12VAC5-66-50, 12VAC5-66-60, 12VAC5-66-70, and 12VAC5-66-80. There are no new substantive provisions. Amendments are made to remove nonregulatory language and conform to the Style Requirements.

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 to the public, the agency, and Commonwealth is that the regulations will be more readable and will not include unnecessary, nonregulatory language. There are no disadvantages associated with the changes.

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

No other agency will be affected.

Localities Particularly Affected

No localities will be particularly affected.

Other Entities Particularly Affected

EMS agencies and providers will have clearer, more readable regulations regarding DDNRs.

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 is no projected economic impact on the Virginia Department of Health.
For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	None
For all agencies: Benefits the regulatory change is designed to produce.	The regulatory change ensures that the language is consistent with *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code.*

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.	None
Benefits the regulatory change is designed to produce.	The regulatory change ensures that the language is consistent with *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code.*

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.	There are no entities that will be affected by the regulatory change.
Agency's best estimate of the number of such entities that will be affected. Include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	There are no entities that will be affected by the regulatory change.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	There are no projected costs that will be affected by the regulatory change.
Benefits the regulatory change is designed to produce.	The regulatory change ensures that the language is consistent with *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code.*

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.

This analysis has been reported on the ORM Economic Impact form, Table 1c.

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

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.

This analysis has been reported on the ORM Economic Impact form, Table 1c.

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

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 State Board 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:

Mohamed Abbamin, Senior Policy Analyst

1041 Technology Park Dr.
Glen Allen, VA 23059
(P) 804-980-6984 (F) 804-371-3108
Mohamed.Abbamin@vdh.virginia.gov

In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will not be held regarding this rule-making.

Detail of Changes

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

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

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
12VAC5-66-10		This section lists relevant definitions for the chapter.	**Change:** • The definition for “agent” is removed because the term is not used anywhere in the regulation. • “Alternate Durable DNR jewelry” is amended to change “vendor” to “seller” and remove a substantive requirement. • “Durable Do Not Resuscitate Order” and “Other Do Not Resuscitate Order” are amended to conform to Style Requirements and include reference to physician orders for life sustaining treatment (POLST) forms. • The definitions for “Office of EMS” and “person authorized to consent on the patient’s behalf” are amended to be more concise. • The definition for “incapable of making an informed decision” is removed and incorporated into the definition for

			"person authorized to consent on the patient's behalf" • The definitions for "qualified emergency medical services personnel," and "qualified health care personnel" are amended to refer to the definitions in §32.1-111.1. **Intent:** The intent is to ensure that definitions are clear, concise, and conform to the Style Requirements. **Rationale:** Pursuant to 1VAC7-10-40, the Registrar may omit from publication and the Code Commission may omit from the Virginia Administrative Code (VAC) provisions which are non-regulatory in nature, such as defined words that are not used in the regulatory text. Furthermore, proper style and format, grammatical correctness, and consistency of language are required to conform to the journalistic style of the Virginia Register of Regulations. Finally, removing unnecessary language contributes a reduction in regulatory requirements in accordance with Executive Order 19 (2022). **Likely Impact**: The likely impact is that the chapter will be more readable.
12VAC5-66-20		The section contains no requirements and makes references to statutory authority for the regulations.	**Change:** Repeal 12VAC5-66-20. **Intent:** The intent is to remove unnecessary sections. **Rationale:** The rationale of the change is that authority sections are non-regulatory in nature and should not be included in regulations. Pursuant to 1VAC7-10-40, the Registrar may omit from publication and the Code Commission may omit from the Virginia Administrative Code (VAC) provisions which are non-regulatory in nature. The Code itself confers authority to regulate and each section of the VAC identifies the statutory authority, so the section is unnecessary. Removing unnecessary language contributes to the 25% reduction in regulatory requirements in accordance with Executive Order 19 (2022).

			Likely Impact: The likely impact is that the chapter will be more readable.
12VAC5-66-30		The section contains no requirements and makes references to the purpose of the regulations.	**Change:** Repeal 12VAC5-66-30. **Intent:** The intent is to remove unnecessary sections. **Rationale:** The rationale of the change is that the current language is non-regulatory. The Registrar, pursuant to 1VAC7-10-40 (C), has the authority to remove purpose statements from regulations, and as such, they should not be included in regulations. Removing unnecessary language contributes to the 25% reduction in regulatory requirements in accordance with Executive Order 19 (2022). **Likely Impact**: The likely impact is that the chapter will be more readable.
12VAC5-66-40		This section describes the Durable Do Not Resuscitate (DNR) Order Form, including its contents and effective period, as well as information regarding the validity of a DNR Order and its acceptable photocopies.	**Change:** This section is amended to comport with the Style Requirements. It additionally removes nonregulatory language regarding the general availability of forms. It is also amended to recognize that nurse practitioners and physician assistants are also authorized to issue DDNR Orders. **Intent:** The intent is to conform to the Style Requirements. **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 that the chapter will be more readable.
12VAC5-66-50.		This section describes authorized Alternate Durable DNR Jewelry, including its design and identifiability, who may	**Change:** This section is amended to comport with the Style Requirements. It additionally removes language that is redundant (e.g., that Alternate Durable DNR Jewelry qualifies as a Durable DNR Order,

		purchase and sell it, and what information is required for purchase.	which has been established in 12VAC5-66-10) and moves language regarding what information is required for display on Alternate Durable DNR Jewelry from 12VAC5-66-70 to this section. **Intent:** The intent is to conform to the Style Requirements. **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 redundant language enhances clarity and contributes to a reduction in regulatory requirements in accordance with Executive Order 19 (2022). Finally, language pertinent to a specific catchline (e.g., requirements for Alternate Durable DNR Jewelry) is more appropriate to include within that section (i.e., 12VAC5-66-50. Alternate Durable DNR Jewelry) than another (i.e., 12VAC5-66-70. Issuance of a Durable DNR Order). **Likely Impact:** The likely impact is that the chapter will be more readable.
12VAC5-66-60.		This section describes applicability of the chapter to Other DNR Orders.	**Change:** This section is amended to comport with the Style Requirements. **Intent:** The intent is to conform to the Style Requirements. **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 regulations will be more readable.
12VAC5-66-70		This section describes the process for issuance of Durable DNR Orders.	**Change:** This section is amended to comport with the Style Requirements, to remove nonregulatory language that is found verbatim in the Code of Virginia, to remove language related to Alternate Durable DNR Jewelry that is now located in 12VAC5-66-50, and to update and clarify

			who can issue a Durable DNR Order (physicians, nurse practitioners, or physician assistants as opposed to only physicians) and in what order they should issue copies of the Durable DNR Order Form. **Intent:** The intent is to conform to the Style Requirements and provide up-to-date information in accordance with the Code of Virginia. **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 redundant language enhances clarity and contributes to a reduction in regulatory requirements in accordance with Executive Order 19 (2022). Regarding the expansion of who is qualified to issue Durable DNR Orders, in the Health Care Decisions Act (§ 54.1-2981 *et seq*. of the Code of Virginia), § 54.1-2987.1 provides that a Durable Do Not Resuscitate Order may be issued by a physician. § 54.1-2952.2 provides that, "Whenever any law or regulation requires a signature…by a physician, it shall be deemed to include a signature…by a physician assistant." § 54.1-2957.02 provides that, "Whenever any law or regulation requires a signature…by a physician, it shall be deemed to include a signature…by a nurse practitioner." **Likely Impact:** The likely impact is that the chapter will be more readable.
12VAC5-66-80.		This section describes implementation procedures for Durable DNR Orders.	**Change:** This section is amended to comport with the Style Requirements, to remove nonregulatory language that is found verbatim in the Code of Virginia or similarly elsewhere in this chapter, and to change "should" to "shall" regarding the requirement for qualified health care personnel to administer resuscitative measures until the validity or a Durable

			DNR Order or Other DNR Order is confirmed. **Intent:** The intent is to conform to the Style Requirements and enhance overall clarity. **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 redundant language enhances clarity and contributes to the 25% reduction in regulatory requirements in accordance with Executive Order 19 (2022). Regarding the change of "If there is any question about the validity of a Durable DNR Order, resuscitative measures *should* be administered" to "If there is any question about the validity of a Durable DNR Order or Other DNR Order, resuscitative measures *shall* be administered," the original regulatory language followed an introduction that stated, "The following general principals shall apply to implementation of all Durable DNR Orders." That introductory clause has been removed in accordance with Style Requirements since what follows are distinct requirements and thus should be distinctly labeled subsections rather than subdivisions. As the removed clause included the word "shall," i.e., introducing a requirement, the "should" that followed in the original language—which could be misinterpreted as a permissive in spite of and sans the preceding "shall"—has been changed to "shall" to retain the requirement and in a clearer manner. **Likely Impact:** The likely impact is that the chapter will be more readable.

Office of Regulatory Management

Economic Review Form

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC 5-66
VAC Chapter title(s)	**Regulations Governing Durable Do Not Resuscitate Orders**
Action title	Amend DNR Regulations Following Periodic Review 2022
Date this document prepared	July 27, 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)	**There are no new substantive provisions.** **This regulatory action repeals 12VAC5-66-20 and 12VAC5-66-30, and it amends 12VAC5-66-10, 12VAC5-66-40, 12VAC5-66-50, 12VAC5-66-60, 12VAC5-66-70, and 12VAC5-66-80. Amendments are made to remove nonregulatory language and conform remaining language to the *Form and Style Requirements for the Virginia Register of Regulations* and Virginia Administrative Code.** **Regarding the expansion of who is qualified to issue Durable DNR Orders, § 54.1-2987.1 provides that a Durable Do Not Resuscitate Order may be issued by a physician. § 54.1-2952.2 provides that, "Whenever any law or regulation requires a signature…by a physician, it shall be deemed to include a signature…by a physician assistant." § 54.1-2957.02 provides that, "Whenever any law or regulation requires a signature…by a physician, it shall be deemed to include a signature…by a nurse practitioner." Thus, this change in the regulatory language is made to reflect existing authority granted to nurse practitioners and physician assistants by the Code of Virginia and is not considered a new substantive provision.** There are no direct or indirect monetized costs or benefits associated with this regulatory action.

(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)	The benefit is that the regulations will be more readable and will not include unnecessary, nonregulatory language.
(5) Information Sources	

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

(1) Direct & Indirect Costs &	Direct Costs: The proposed changes to the regulation do not alter the substantive rights or responsibilities of any person associated with a Durable Do Not Resuscitate Order. Thus, there are no direct or indirect

Benefits (Monetized)	monetized costs or benefits under the status quo relative to this regulatory action.	
(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)	If the regulatory language is not updated, non-regulatory, unnecessary, or unclear text will remain, making the regulation less clear and readable relative to the proposed changes.	
(5) Information Sources		

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

(1) Direct & Indirect Costs & Benefits (Monetized)	The proposed changes are the result of a periodic review and do not alter the substantive rights or responsibilities of any person associated with a Durable Do Not Resuscitate Order, and these regulations represent the least burdensome regulatory approach to meet the statutory mandate in § 32.1-111.4 (A)(3). As such, no other viable alternative approaches were identified and there are no direct or indirect monetized costs or benefits associated with an alternative.	
(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)	No non-monetized costs or benefits identified	
(5) Information Sources		

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 direct or indirect monetized costs or benefits to local partners associated with this regulatory action.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $0
(3) Other Costs & Benefits (Non-Monetized)	No non-monetized costs or benefits identified	
(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 direct or indirect monetized costs or benefits to families associated with this regulatory action.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $0
(3) Other Costs & Benefits (Non-Monetized)	A non-monetized benefit is that the regulations will be clearer, more readable, and will not contain non-regulatory or unnecessary language. There are no non-monetized costs associated with this change.	
(4) Information Sources		

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 direct or indirect monetized costs or benefits to small businesses associated with this regulatory action.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $0
(3) Other Costs & Benefits (Non-Monetized)	A non-monetized benefit is that the regulations will be clearer, more readable, and will not contain non-regulatory or unnecessary language. There are no non-monetized costs associated with this change.	
(4) Alternatives	No alternative approaches identified	
(5) Information Sources		

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
12VAC5-66-10	**Statutory:**	0	0	0	0
	Discretionary:	0	0	0	0
12VAC5-66-20	**Statutory:**	1 (G/S)	0	1 (G/S)	-1 (G/S)
	Discretionary:	0	0	0	0
12VAC5-66-30	**Statutory:**	1 (G/S)	0	1 (G/S)	-1 (G/S)
	Discretionary:	0	0	0	0
12VAC5-66-40	**Statutory:**	1 (G/S) 1 (R/S)	0	0	0
	Discretionary:	3 (G/D) 1 (R/D)	0	3 (G/D)	-3
12VAC5-66-50	**Statutory:**	0	0	0	0
	Discretionary:	4 (R/D)	1 (R/D) relocated from section 70	0	+1 (R/D)
12VAC5-66-60	**Statutory:**	0	0	0	0
	Discretionary:	4 (R/D)	0	0	0
12VAC5-66-70	**Statutory:**	2 (R/S)			
	Discretionary:	9 (R/D)		1 (R/D) relocated to section 50	-1 (R/D)
12VAC5-66-80	**Statutory:**	14 (R/S)	0	0	0
	Discretionary:	3 (R/D)	0	0	0

Project 7311 - Fast-Track

Department of Health

Amend DNR Regulations Following Periodic Review 2022

~~Part I~~

~~Definitions~~

12VAC5-66-10. Definitions.

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

~~"Agent" means an adult appointed by the declarant under an advance directive, executed or made in accordance with the provisions of § 54.1-2983 of the Code of Virginia to make health care decisions for him.~~

"Alternate Durable DNR jewelry" means a Durable DNR bracelet or necklace issued by a ~~vendor~~ seller approved by the Virginia Office of Emergency Medical Services. ~~A Durable DNR Order must be obtained by the patient, from a physician, to obtain Alternate Durable DNR jewelry.~~

"Board" means the State Board of Health.

"Cardiac arrest" means the cessation of a functional heartbeat.

"Commissioner" means the State Health Commissioner.

"Durable Do Not Resuscitate Order" or "Durable DNR Order" means a written physician's order issued pursuant to § 54.1-2987.1 of the Code of Virginia in a Durable Do Not Resuscitate Order ~~form or forms~~ authorized by the board to withhold cardiopulmonary resuscitation from an individual in the event of cardiac or respiratory arrest. For purposes of this chapter, cardiopulmonary resuscitation shall include cardiac compression, endotracheal intubation and other advanced airway management, artificial ventilation, defibrillation, administration of cardiac resuscitative medications, and related procedures. ~~As the terms "advance directive" and "Durable Do Not Resuscitate Order" are used in this article,~~ For the purposes of this chapter, a Durable Do Not Resuscitate Order or ~~other~~ Other DNR Order ~~is not and~~ shall not be construed as an advance directive. When used in these regulations, the term "Durable DNR Order" shall include any authorized Alternate Durable DNR jewelry issued in conjunction with an original Durable DNR Order. "Durable DNR Order" shall also include a physician order for scope of treatment (POST) or physician orders for life sustaining treatment (POLST) form. Durable DNR orders including POST or POLST forms shall be ~~completed~~ filled out and signed by a licensed practitioner and signed by the patient or patient's authorized representative.

"Emergency Medical Services" or "EMS" means the services rendered by an agency licensed by the Virginia Office of Emergency Medical Services, an equivalent agency licensed by another state or a similar agency of the federal government when operating within this Commonwealth.

"Emergency medical services agency" or "EMS agency" means any agency, licensed to engage in the business, service, or regular activity, whether or not for profit, of transporting or rendering immediate medical care to such persons who are sick, injured, wounded , or otherwise incapacitated or helpless.

~~"Incapable of making an informed decision" means the inability of an adult patient, because of mental illness, intellectual disability, or any other mental or physical disorder that precludes communication or impairs judgment, to make an informed decision about providing, withholding, or withdrawing a specific medical treatment or course of treatment because he is unable to understand the nature, extent, or probable consequences of the proposed medical decision, or to~~

~~make a rational evaluation of the risks and benefits of alternatives to that decision. For purposes of this article, persons who are deaf or dysphasic or have other communication disorders but who are otherwise mentally competent and able to communicate by means other than speech, shall not be considered incapable of making an informed decision. The determination that the patient is "incapable of making an informed decision" shall be made in accordance with § 54.1-2983.2 of the Code of Virginia.~~

"Office of EMS" or "OEMS" means the Virginia Office of Emergency Medical Services~~. The Virginia Office of Emergency Medical Services is a state office located~~ within the Virginia Department of Health (VDH).

"Other Do Not Resuscitate Order" or "Other DNR Order" means a written physician's order not to resuscitate a patient in the event of cardiac or respiratory arrest on a form other than the authorized state standardized Durable DNR Order Form , POST form, or POLST form under policies and procedures of the health care facility to which the individual who is the subject of the order has been admitted.

"Person authorized to consent on the patient's behalf" means any person authorized by law to consent on behalf of the patient incapable of making an informed decision as defined by §54.1-2982 or, in the case of a minor child, the parent or ~~parents~~ other legal guardian having custody of the child ~~or the child's legal guardian or as otherwise provided by law~~.

"Physician" means a person licensed to practice medicine in the Commonwealth of Virginia or in the jurisdiction where the treatment is to be rendered or withheld.

"Qualified emergency medical services personnel" ~~means personnel certified to practice as defined by § 32.1-111.1 of the Code of Virginia when acting within the scope of their certification.~~ shall have the same meaning as in § 32.1-111.1 of the Code of Virginia.

"Qualified health care facility" means a facility, program, or organization operated or licensed by the State Board of Health or by the Department of Behavioral Health and Developmental Services (DBHDS) or operated, licensed, or owned by another state agency.

"Qualified health care personnel" ~~means any qualified emergency medical services personnel and any licensed health care provider or practitioner functioning in any facility, program, or organization operated or licensed by the State Board of Health or by DBHDS or operated, licensed, or owned by another state agency.~~ shall have the same meaning as in § 32.1-111.1 of the Code of Virginia.

"Respiratory arrest" means cessation of breathing.

Statutory Authority

§§ 32.1-12 ~~and~~ , 32.1-111.4 , and 54.1-2987.1 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 18, Issue 12, eff. March 27, 2002; amended, Virginia Register Volume 27, Issue 21, eff. July 20, 2011; Volume 33, Issue 3, eff. November 19, 2016.

~~Part II~~

~~Purpose and Applicability~~

12VAC5-66-20. ~~Authority for regulation.~~ (Repealed.)

~~Section 54.1-2987.1 of the Code of Virginia vests authority for the regulation of Durable DNR Orders in the State Board of Health and directs the board to prescribe by regulation the procedures, including the requirements for forms to authorize qualified health care personnel to follow Durable DNR Orders. All EMS DNR Orders and all Durable Do Not Resuscitate Orders issued or in effect between July 1, 1999, and March 27, 2002, are to be considered valid Durable DNR Orders and shall remain valid until revoked.~~

~~**Statutory Authority**~~

~~§ 54.1-2987.1 of the Code of Virginia.~~

Historical Notes

Derived from Virginia Register Volume 18, Issue 12, eff. March 27, 2002.

12VAC5-66-30. ~~Purpose of regulations.~~ (Repealed.)

~~The board has promulgated these regulations in order to carry out the intent of Virginia law that a person shall have the opportunity to execute a Durable DNR Order that comports with his wishes.~~

~~**Statutory Authority**~~

~~§ 54.1-2987.1 of the Code of Virginia.~~

Historical Notes

Derived from Virginia Register Volume 18, Issue 12, eff. March 27, 2002.

~~Part III~~

~~Requirements and Provisions~~

12VAC5-66-40. The Durable Do Not Resuscitate Order Form.

The Durable DNR Order Form shall be a standardized document ~~as~~ approved by the board and consistent with ~~these regulations. The~~ this chapter, including following requirements~~ and provisions shall apply to the approved Durable DNR Order Form.~~ :

1. ~~Content of the Form -~~ A Durable DNR Order Form shall contain~~, from a physician with whom the patient has a bona fide physician/patient relationship, a do not resuscitate determination, signature and the date of issue, the signature of the patient or, if applicable, the person authorized to consent on the patient's behalf.~~ (i) a dated signature from a physician, nurse practitioner, or physician assistant with whom the patient has a bona fide physician/patient relationship; and (ii) the signature of the patient or the person authorized to consent on the patient's behalf.

2. ~~Effective Period for a Signed Durable DNR Order -~~ A signed Durable DNR Order shall remain valid until revoked in accordance with § 54.1-2987.1 of the Code of Virginia and 12VAC5-66-80 E or until rescinded, in accordance with accepted medical practice, by the provider who issued the Durable Do Not Resuscitate Order.

3. ~~Durable DNR Order Form -~~ A Durable DNR Order or Alternate Durable DNR jewelry that complies with 12VAC5-66-50 shall be valid for the purposes of withholding or withdrawing cardiopulmonary resuscitation by qualified health care personnel in the event of cardiac or respiratory arrest.

4. ~~Availability of the Durable DNR Order Form.~~ The Durable DNR Order Form ~~that complies with this section~~ or Alternate Durable DNR jewelry that complies with 12VAC5-66-50 or a legible photocopy of the Durable DNR Order Form shall be ~~maintained and~~ readily available to qualified health care personnel at the patient's current location ~~or residence~~.

~~5. Qualified health care personnel may honor a legible photocopy of a Durable DNR Form or Other Durable DNR Order as if it were an original.~~

~~6. A patient who is traveling outside his home or between health care facilities should have an original or photocopied Durable DNR Order, Other Durable DNR Order, or Alternate Durable DNR jewelry accompany him.~~

~~7. Distribution of Durable DNR Order Forms - The authorized Virginia Durable DNR Order Form shall be a standardized form available for download via the Internet from the Office~~

~~of Emergency Medical Services website. The downloadable form will contain directions for completing the form and three identical Durable DNR Order Forms: one original form to be kept by the patient, the second to be placed in the patient's permanent medical record, and the third to be used by the patient for requesting Alternate Durable DNR jewelry.~~

~~8. Hard copies of the Durable DNR Order Form shall also be made available to physicians or licensed health care facilities by the Office of EMS. The Office of EMS may utilize a vendor to print and distribute the Durable DNR Order Form and a nominal fee may be charged in an amount necessary to cover printing and shipping fees.~~

Statutory Authority

§§ 32.1-12 ~~and~~ , 32.1-111.4 , and 54.1-2987.1 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 18, Issue 12, eff. March 27, 2002; amended, Virginia Register Volume 27, Issue 21, eff. July 20, 2011.

12VAC5-66-50. Authorized ~~alternate~~ Alternate Durable DNR jewelry.

~~The board authorizes the use of Alternate Durable DNR jewelry in conjunction with the issuance of a Durable DNR Order. These~~ A. Alternate Durable DNR jewelry ~~items~~ shall be uniquely-designed ~~and~~ , uniquely-identifiable ~~bracelets and necklaces that are~~ , and available only from a ~~vendor~~ seller approved by the ~~Virginia Department of Health,~~ Office of EMS. ~~The Alternate Durable DNR jewelry must be purchased from the approved vendor by the person to whom a Durable DNR Order Form applies, or the person authorized to consent on the patient's behalf. An original Durable DNR Order Form must be obtained from a physician and provided to the vendor in order to receive Alternate Durable DNR jewelry. Such a necklace or bracelet may be utilized either to validate the Durable DNR Order Form or in place of an original Durable DNR Order Form in the event that the original order is not readily available at the site where the person to whom the order applies is found. In order to be honored by qualified health care personnel in place of the standard Durable DNR Order Form, the Alternate Durable DNR jewelry must contain the minimum information approved by the State Board of Health in 12VAC5-66-60.~~

B. Only the patient to whom a Durable DNR Order Form applies or the person authorized to consent on the patient's behalf may purchase Alternate Durable DNR jewelry and shall provide the following information to the approved seller to purchase Alternate Durable DNR jewelry:

1. The patient's full legal name;

2. The physician's, nurse practitioner's, or physician assistant's name and phone number; and

3. The Virginia Durable DNR issuance date.

C. Alternate Durable DNR jewelry shall display the words "Do Not Resuscitate" and the information listed in subsection B of this section.

Statutory Authority

§§ 32.1-12 ~~and~~ , 32.1-111.4 , and 54.1-2987.1 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 18, Issue 12, eff. March 27, 2002; amended, Virginia Register Volume 27, Issue 21, eff. July 20, 2011.

12VAC5-66-60. Other DNR Orders.

A. Nothing in these regulations shall be construed to preclude licensed health care practitioners from following any Other Do Not Resuscitate Order in accordance with the applicable policies and procedures of the health care facility in which they practice.

B. Qualified health care personnel ~~are authorized to~~ may honor ~~any~~ an Other Do Not Resuscitate ~~(~~DNR~~)~~ Order as if it were a Durable Do Not Resuscitate Order ~~when~~ if the Other DNR Order includes the information required in 12VAC5-66-40 and the patient is ~~currently~~ admitted to ~~a hospital or other~~ or in transit from a qualified health care facility ~~or is in transit from a qualified health care facility provided that such order includes the same information as listed in subdivision 1 of 12VAC5-66-40~~, except that an Other DNR Order shall not be required to include the signature of the patient or a person authorized to consent for the patient on the order itself.

C. Nothing in ~~these regulations~~ this chapter shall ~~prohibit~~ forbid qualified health care personnel from following ~~any~~ a direct verbal order issued by a licensed physician not to resuscitate a patient in cardiac or respiratory arrest when ~~such~~ the physician is physically present.

Statutory Authority

§§ 32.1-12 ~~and~~ , 32.1-111.4 , and 54.1-2987.1 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 18, Issue 12, eff. March 27, 2002; amended, Virginia Register Volume 27, Issue 21, eff. July 20, 2011.

~~Part IV~~

~~Implementation Procedures~~

12VAC5-66-70. Issuance of a Durable DNR Order.

~~A. A Durable DNR Order may be issued to a patient by a physician, with whom the patient has established a bona fide physician/patient relationship, as defined by the Board of Medicine in their current guidelines, only with the consent of the patient or, if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the person authorized to consent on the patient's behalf.~~

~~B. The use of the authorized Durable DNR Order Form is encouraged to provide uniformity throughout the health care continuum.~~

~~C. The authorized Durable DNR Order can be honored by qualified health care personnel in any setting.~~

~~D. Qualified health care personnel are authorized to honor only a Durable DNR Order on an authorized form or Alternate DNR jewelry, except as provided in 12VAC5-66-60 of these regulations.~~

~~E. Prior to~~ Before issuing a Durable DNR Order, the physician , nurse practitioner, or physician assistant shall explain to the patient or the person authorized to consent on the patient's behalf~~,~~ the alternatives available for response in the event of cardiac or respiratory arrest. If the ~~option of~~ patient or person authorize to consent on the patient's behalf chooses a Durable DNR Order ~~is agreed upon~~, the physician , nurse practitioner, or physician assistant shall ~~have the following responsibilities~~:

1. Explain the circumstances under which qualified health care personnel may follow a Durable DNR Order~~.~~ ;
2. Explain how to and who may revoke the Durable DNR Order~~.~~ ;
3. Document the patient's full legal name~~.~~ ;
4. Document the execution date of the Durable DNR Order~~.~~ ;
5. ~~Obtain~~ Require the signature of the patient or the person authorized to consent on the patient's behalf on all three ~~forms: the patient's copy, medical record copy, and the copy used for obtaining Alternate DNR jewelry.~~ copies of the Durable DNR Order Form pursuant to subsection B of this section;

6. ~~Make sure that~~ Clearly print the issuing physician's , nurse practitioner's, or physician assistant's name ~~is clearly printed and the form is signed.~~ and contact telephone number; and

7. ~~Record the contact telephone number for the issuing physician.~~ Sign the Durable DNR Order Form.

~~8. Issue the original Durable DNR Order Form, and the patient and Alternate DNR jewelry copies to the patient and maintain the medical record copy in the patient's medical file.~~

~~F. The person to whom a Durable DNR Order applies or the person authorized to consent on the patient's behalf must present the following information to the approved vendor in order to purchase and be issued an approved Alternate Durable DNR necklace or bracelet. The necklace or bracelet must contain the following information:~~

~~1. The following words: Do Not Resuscitate;~~

~~2. The patient's full legal name;~~

~~3. The physician's name and phone number; and~~

~~4. The Virginia Durable DNR issuance date.~~

B. The issuing physician shall issue three copies of a completed DNR Order Form as follows:

1. Copy one - to be kept by the patient;

2. Copy two - to be kept in the patient's permanent medical record; and

3. Copy three - to be used to order Alternate Durable DNR jewelry.

Statutory Authority

§§ 32.1-12 ~~and~~ , 32.1-111.4 , and 54.1-2987.1 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 18, Issue 12, eff. March 27, 2002, amended, Virginia Register Volume 27, Issue 21, eff. July 20, 2011.

12VAC5-66-80. Durable DNR Order implementation procedures.

A. Qualified health care personnel shall ~~comply with the following~~ follow the general procedures ~~and published Virginia Durable DNR Order Implementation Protocols~~ in this chapter when caring for a patient who is in cardiac or respiratory arrest and who ~~is known or suspected to~~ may have a Durable DNR Order in effect.

B. ~~Initial assessment and intervention. Perform~~ Qualified health care personnel shall initiate routine patient assessment and resuscitation or intervention until a valid Durable DNR Order~~,~~ ~~Alternate DNR jewelry,~~ or Other DNR Order can be confirmed~~, as follows:~~ .

C. Qualified health care personnel may withhold or terminate resuscitation efforts if:

1. ~~Determine the presence of a~~ An intact, unaltered original or photocopy of the Durable DNR Order~~,~~ Form, POST Form, or POLST Form; approved Alternate Durable DNR jewelry~~,~~ ; or Other DNR Order~~.~~ is located; and

~~2. If the patient is within a qualified health care facility or in transit between qualified health care facilities, any qualified health care personnel may honor an Other DNR Order as set forth in 12VAC5-66-60.~~

~~3. Determine that the Durable DNR form or Alternate DNR jewelry is not altered.~~

~~4. Verify,~~ 2. The identity of the patient to whom the Durable DNR Order or Other DNR Order was issued is verified ~~through driver's license or other~~ with identification ~~with~~ including a photograph and signature or by positive identification by a family member or other person who knows the patient~~, that the patient in question is the one for whom the Durable DNR Order, Alternate DNR jewelry, or Other DNR Order was issued~~.

~~5. If the Durable DNR Order, Alternate DNR jewelry, or Other DNR Order is intact, unaltered, and verified as issued for the patient, qualified health care personnel may consider it valid.~~

~~C. Resuscitative measures to be withheld or withdrawn.~~ D. In the event of cardiac or respiratory arrest of a patient with a valid Durable DNR Order~~, Alternate Durable DNR jewelry,~~ or Other DNR Order ~~under the criteria set forth in subsection B of this section,~~ qualified health care personnel shall withhold or withdraw cardiopulmonary resuscitation (CPR) unless otherwise directed by a physician physically present at the ~~patient~~ patient's location. CPR shall include:

1. Cardiac compression;

2. Artificial ventilation;

3. Defibrillation;

4. Endotracheal ~~Intubation~~ intubation or other advanced airway management , including supra-glottic devices ~~such as the LMA~~, or other airway devices that pass beyond the oral pharynx~~, such as the Combi Tube, PTL etc.~~; or

5. Administration of related procedures or cardiac resuscitation medications as prescribed by the patient's physician or medical protocols.

~~D. Procedures to provide comfort care or to alleviate pain. In order to provide comfort care or to alleviate pain for a patient with a valid Durable DNR Order of any type or Other DNR Order the following interventions may be provided, depending on the needs of the particular patient:~~ E. Qualified health care personnel may provide the following interventions to a patient with a valid Durable DNR Order or Other DNR Order to provide comfort care or to alleviate pain:

1. Airway management, including positioning, nasal or pharyngeal airway placement;

2. Suctioning;

3. Supplemental oxygen delivery devices;

4. Pain medications or intravenous fluids;

5. Bleeding control;

6. Patient positioning; or

7. Other therapies deemed necessary to provide comfort care or to alleviate pain.

~~E. Revocation.~~

~~1. If a patient is able to, and does, express to a health care provider or practitioner the desire to be resuscitated in the event of cardiac or respiratory arrest, such expression shall revoke the provider's or practitioner's authority to follow a Durable DNR Order or Other DNR Order. In no case shall any person other than the patient have authority to revoke a Durable DNR Order or Other DNR Order executed upon the request of and with the consent of the patient himself.~~

~~If the patient is a minor or is otherwise incapable of making an informed decision and the Durable DNR Order or Other DNR Order was issued upon the request and with the consent of the person authorized to consent on the patient's behalf, then the expression by said person to a health care provider or practitioner of the desire that the patient be resuscitated shall so revoke the provider's or practitioner's authority to follow a Durable DNR Order or Other DNR Order.~~

~~2. The expression of such desire to be resuscitated prior to cardiac or respiratory arrest shall constitute revocation of the order; however, a new order may be issued upon consent of the patient or the person authorized to consent on the patient's behalf.~~

~~3. The provisions of this section shall not authorize any qualified emergency medical services personnel or licensed health care provider or practitioner who is attending the~~

~~patient at the time of cardiac or respiratory arrest to provide, continue, withhold or withdraw treatment if such provider or practitioner knows that taking such action is protested by the patient incapable of making an informed decision. No person shall authorize providing, continuing, withholding or withdrawing treatment pursuant to this section that such person knows, or upon reasonable inquiry ought to know, is contrary to the religious beliefs or basic values of a patient incapable of making an informed decision or the wishes of such patient fairly expressed when the patient was capable of making an informed decision.~~

~~F. Documentation. When~~

F. A Durable DNR Order or Other DNR Order may only be revoked in accordance with § 54.1-2987.1.

G. If following a Durable DNR Order or Other DNR Order for a ~~particular~~ patient admitted to a qualified health care facility, qualified health care personnel shall document care rendered or withheld as required by facility policies and procedures. ~~When~~ If following a Durable DNR Order or Other DNR Order for a ~~particular~~ patient who is not admitted to a qualified health care facility or who is in transit from a health care facility, qualified health care personnel shall document in the patient's medical record the care rendered or withheld in the following manner:

~~1. Use standard patient care reporting documents (i.e. patient chart, pre-hospital patient care report).~~

~~2.~~ Describe assessment of the patient's cardiac or respiratory arrest status~~.~~ ;

~~3.~~ 2. Document which identification (e.g., Durable DNR Order Form, Alternate Durable DNR jewelry, ~~or~~ Other DNR Order , or alternate form of identification) was used to confirm Durable DNR status and that it was intact, not altered, ~~not canceled or~~ and not ~~officially~~ revoked~~.~~ ; and

~~4.~~ 3. Record the name of the ~~patient's physician who issued the~~ issuer of the patient's Durable DNR Order~~,~~ or Other DNR Order.

~~5. If the patient is being transported, keep the Durable DNR Order, Alternate Durable DNR jewelry, or Other DNR Order with the patient.~~

~~G. General considerations. The following general principles shall apply to implementation of all Durable DNR Orders.~~

~~1. If there is misunderstanding with family members or others present at the patient's location or if there are other concerns about following the Durable DNR Order or Other DNR Order, contact the patient's physician or EMS medical control for guidance.~~

~~2. If there is any question about the validity of a Durable DNR Order, resuscitative measures should must be administered until the validity of the Durable DNR Order or Other DNR Order is established.~~

H. If the patient is being transported, the Durable DNR Order or Other DNR Order shall remain with the patient.

I. If the patient's family or others present at the patient's location contest the Durable DNR Order or Other DNR Order, qualified health care personnel shall contact the patient's physician, nurse practitioner, or physician assistant or EMS medical control for guidance.

J. If there is any question about the validity of a Durable DNR Order or Other DNR Order, qualified health care personnel shall administer resuscitative measures until the validity is confirmed.

K. For the purposes of this section, "EMS medical control" means the direction and advice provided through a communications device to on-site and in-transit EMS personnel from a designated medical care facility staffed by appropriate personnel and operating under physician supervision.

Statutory Authority

§§ 32.1-12 ~~and~~ , 32.1-111.4 , and 54.1-2987.1 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 18, Issue 12, eff. March 27, 2002; amended, Virginia Register Volume 27, Issue 21, eff. July 20, 2011.

Regulations for the Licensure of Hospice
12VAC5-391
(Fast Track Amendments)

Rebekah E. Allen, JD

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: July 13, 2023

TO: State Board of Health

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

SUBJECT: Fast Track Action – Regulations for the Licensure of Hospice – Amend Regulation to Incorporate the 2022 FGI Guidelines

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Enclosed for your review are fast track amendments to the Regulations for the Licensure of Hospice (12VAC5-391-10 *et seq.*).

This Fast Track action is being utilized to conform 12VAC5-391-10 *et seq*. to the Code of Virginia and to update out-of-date regulatory provisions. Subsection B of § 32.1-162.5 of the Code of Virginia requires hospice facility regulations to include minimum standards for the design and construction of hospices that are consistent with the current edition of the Guidelines for Design and Construction of Hospital and Health Care Facilities issued by the Facility Guidelines Institute. The regulatory change was prompted by the release of the 2022 edition of the 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 Facility Guidelines to the current edition, published in May of 2022.

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

townhall.virginia.gov

Fast-Track Regulation
Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC5-391-10 *et seq.*
VAC Chapter title(s)	Regulations for the Licensure of Hospice
Action title	Amend Regulation to Incorporate the 2022 FGI Guidelines
Date this document prepared	July 13, 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.

Subsection B of § 32.1-162.5 of the Code of Virginia requires hospice facility regulations to include minimum standards for the design and construction of hospices that are 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.

Acronyms and Definitions

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

"Board" means the State Board of Health.

"FGI" means the Facility Guidelines Institute.

"FGI guidelines" means the Guidelines for Design and Construction of Residential Health, Care, and Support Facilities.

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.

Subsection B of § 32.1-162.5 of the Code of Virginia requires the Board to include minimum standards for design and construction of Hospice facilities consistent with the Hospice Care section of the current edition of the FGI Guidelines for Design and Construction of Hospital and Health Care Facilities.

The impetus of this regulatory action was the release of the 2022 edition of the FGI guidelines. This rulemaking is expected to be noncontroversial because the proposed amendments are non-discretionary, and only update the references to the FGI guidelines from the 2018 edition to the 2022 edition, therefore making it appropriate for the fast-track rulemaking process.

Legal Basis

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

Section 32.1-12 of the Code of Virginia gives the Board the responsibility to make, adopt, promulgate, and enforce such regulations as may be necessary to carry out the provisions of Title 32.1 of the Code of Virginia. Subsection A of § 32.1-162.5 of the Code of Virginia requires the Board to promulgate regulations governing the activities and services provided by hospices.

Subsection B of § 32.1-162.5 of the Code of Virginia requires the Board to include minimum standards for design and construction of Hospice facilities consistent with the Hospice Care section of the current edition of the FGI Guidelines for Design and Construction of Hospital and Health Care Facilities.

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 for the regulatory change is to ensure the regulations stay in compliance with the Code of Virginia § 32.1-162.5, requiring the Board to include minimum Hospice design and construction guidelines that are consistent with the current edition of the FGI guidelines. The regulatory change is essential to protect the health, safety, and welfare of the citizens of the Commonwealth because it standardizes space and equipment requirements and promotes safe practices and methods in planning, design, and construction. The goal of this regulatory change is to update the regulations to incorporate the 2022 edition. The problem this regulatory change is intended to solve is the out-of-date reference to the 2018 edition to ensure all facilities designing and constructing hospice facilities are adhering to the current version of the FGI guidelines.

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.

12VAC5-391-440
Updated the reference in subsection A from the 2018 edition to the 2022 edition of the FGI guidelines.

Documents Incorporated by Reference (12VAC5-391)
Updated the FGI guidelines from the 2018 edition to the 2022 edition. Added the web link to the Facility Guidelines Institute's website. Added August 2022 errata for the 2022 edition.

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.

This action is being used to conform 12VAC5-391-10 *et seq*. to the existing requirements in the Code of Virginia. The primary advantage to the public is that there will be a reduced confusion among the regulants regarding which edition of the FGI guidelines is the controlling edition. The primary advantage to the agency is conformity with the legal mandates set forth by the Code. There are no other pertinent matters of interest to the regulated community, government officials, or the public. There are no disadvantages to the public or the Commonwealth.

Requirements More Restrictive than Federal

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

The requirements contained in the FGI guidelines may be more restrictive than federal requirements, specifically 42 CFR § 418.110; however, Chapters 177 and 222 of the 2005 Acts of Assembly (codified as subsection B of § 32.1-162.5 of the Code) mandated the minimum requirements be consistent with the current edition of the applicable FGI guidelines, so the Board does not have the discretion to be less restrictive.

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

There are no other state agencies particularly affected.

Localities Particularly Affected

The Chesapeake Hospital authority may be affected if this entity were to construct a hospice facility. There are currently no projected costs, savings, fees, or revenues resulting from the regulatory change.

Other Entities Particularly Affected

Those entities interested in constructing, renovating, or altering a hospice facility will be affected by this 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	There are no projected costs, savings, fees, or revenues resulting from the regulatory change.

c) whether any costs or revenue loss can be absorbed within existing resources	
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 costs, savings, fees, or revenues resulting from the regulatory change.
For all agencies: Benefits the regulatory change is designed to produce.	The benefit of the regulatory change is that it fulfills the mandate from the Code of Virginia to update the regulation with the current version of the FGI guidelines.

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.	The Chesapeake Hospital Authority operates a licensed Hospice (Comfort Care Home Health & Hospice), however, they do not have a hospice facility. If this entity were to construct a facility, they would need to adhere to the 2022 FGI guidelines. There are no current projected costs, savings, fees, or revenues resulting from the regulatory change.
Benefits the regulatory change is designed to produce.	The benefit of the regulatory change is that entities will have a clear understanding of the FGI guidelines necessary to construct, renovate or alter a hospice facility.

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 entities likely to be affected by the regulatory change are entities who are constructing, renovating, or altering hospice facilities.
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.	The number of entities likely to be affected are the 88 licensed hospice facilities in Virginia, 20 of which are estimated to meet the definition of "small business". VDH is unable to quantify the number of entities that will construct a hospice facility, or the number of current facilities that will alter or renovate their facilities.
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;	As a result of the mandate to comply with the 2022 edition of the applicable FGI guidelines, VDH anticipates that there may be a quantifiable indirect cost equal to a 0.2% increase in construction costs for a model facility that is multiple stories of non-combustible construction and a 0.4% increase in construction costs for a model facility that is a single story of combustible

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.	construction, based on projections developed by FGI. VDH is unable to quantify a cost due to the cost variance between potential projects.
Benefits the regulatory change is designed to produce.	The benefit of the regulatory change is that entities will have a clear understanding of the FGI guidelines necessary to construct, renovate or alter a hospice facility.

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. The Code of Virginia requires the regulations for hospice facilities to incorporate the current version of the FGI guidelines, and amending the regulatory language is the least burdensome method of achieving this requirement.

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 to achieve the statutory requirement in § 32.1-162.5 of the Code of Virginia.

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 State Board 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 Rebekah Allen, Senior Policy Analyst for the Virginia Department of Health Office of Licensure and Certification, 9960 Mayland Drive, Suite 401, Henrico, VA 23233, (804) 367-2157, fax (804) 527-4502, and regulatorycomment@vdh.virginia.gov. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

Detail of Changes

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

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

Table 1: Changes to Existing VAC Chapter(s)

Current chapter - section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
391-440	N/A	The section requires hospice facilities to be designed and constructed according to section 3.2 of Part 3 of the 2018 Guidelines for Design and Construction of Residential Health, Care, and Support Facilities of the Facility Guidelines Institute.	**Change**: The amended language requires hospice facilities to be designed and constructed according to Part 1, Part 2, and Chapter 3.2 of Part 3 of the Guidelines for Design and Construction of Residential Health, Care, and Support Facilities, 2022 Edition (The Facility Guidelines Institute), as amended by the August 2022 Errata for Guidelines for Design and Construction of Residential Health, Care, and Support Facilities, 2022 Edition (The Facility Guidelines Institute). A few minor, non-substantive style and form changes were also made.

			Intent: The intent of this change is to remain in compliance with the Code mandate that requires the Board's Hospice regulation reference the most up-to-date version of the FGI guidelines. The intent of the style changes is to comply with the Registrar's *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code* **Rationale**: The rationale of this change is that the regulation will be in compliance with the mandate in the Code of Virginia. **Likely Impact**: The likely impact is that the regulatory requirement will be clearer for regulants.
Documents Incorporated by Reference (12VAC5-391)	N/A	2018 Guidelines for Design and Construction of Residential Health, Care, and Support Facilities, The Facility Guidelines Institute.	**Change**: Errata for Guidelines for Design and Construction of Residential Health, Care, and Support Facilities, The Facility Guidelines Institute, 2022 Edition, https://fgiguidelines.org/guidelines/errata-addenda/ (eff. 8/22). ~~2018~~ Guidelines for Design and Construction of Residential Health, Care, and Support Facilities, The Facility Guidelines Institute~~.~~, 2022 Edition, https://fgiguidelines.org. **Intent**: The intent of this changes is to reference the correct document incorporated by reference in 12VAC5-391-440. **Rationale**: The rationale for this change is that the documents incorporated by reference section are required to be cited correctly and in accordance with the Style Manual administered by the Virginia Registrar. **Likely Impact**: The likely impact is that regulants will have a greater understanding of which version of the FGI guidelines are required to be adhered to.

Office of Regulatory Management

Economic Review Form

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC 5-391
VAC Chapter title(s)	Regulations for the Licensure of Hospice
Action title	Amend Regulations to Incorporate the 2022 FGI Guidelines
Date this document prepared	July 13, 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)	• **Hospice facility construction, renovation, or alterations must comply with the applicable sections of the 2022 guidelines from the Facility Guidelines Institute.** **Direct Costs**: VDH is not aware of any quantifiable direct costs at this time. **Indirect Costs**: As a result of the mandate to comply with the 2022 edition of the applicable design and construction guidelines, VDH anticipates that there may be a quantifiable indirect cost equal to a 0.2% increase in construction costs for a model facility that is multiple stories of non-combustible construction and a 0.4% increase in construction costs for a model facility that is a single story of combustible construction, based on projections developed by FGI. VDH is unable to quantify a cost due to the cost variance between potential projects. **Direct Benefits**: VDH is not aware of any quantifiable direct benefits at this time. **Indirect Benefits**: VDH is not aware of any quantifiable indirect benefits at this time.	
(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)	VDH is not aware of any non-monetized costs at this time. The non-monetized benefit to the regulants is that there will be a reduced confusion among the regulants regarding which edition of the FGI Guidelines is the controlling edition. The FGI Guidelines standardize space and equipment requirements and promotes safe practices and methods in planning, design, and construction.	
(5) Information Sources	The Facility Guidelines Institute.	

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

(1) Direct & Indirect Costs & Benefits (Monetized)	There are no non-discretionary changes in this Fast Track.	
(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)		
(5) Information Sources		

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

(1) Direct & Indirect Costs & Benefits (Monetized)	There are no non-discretionary changes in this Fast Track.	
(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)		
(5) Information Sources		

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)	Local Partners will not be affected by direct or indirect quantifiable costs or benefits of the regulatory change as they are not subject to the requirements contained in this regulatory chapter and this will incur no direct cost or benefit.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a)	(b)
(3) Other Costs & Benefits (Non-Monetized)		
(4) Assistance		
(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)	Families will not be affected by direct or indirect quantifiable costs or benefits of the regulatory change as they are not subject to the requirements contained in this regulatory chapter and this will incur no direct cost or benefit.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a)	(b)
(3) Other Costs & Benefits (Non-Monetized)		
(4) Information Sources		

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)	• **Hospice facility construction, renovation, or alterations must comply with the applicable sections of the 2022 guidelines from the Facility Guidelines Institute. Of the 88 licensed hospice facilities in Virginia, VDH anticipates approximately 20 of them qualify as small businesses.** **Direct Costs**: VDH is not aware of any quantifiable direct costs for small businesses at this time. **Indirect Costs**: As a result of the mandate to comply with the 2022 edition of the applicable design and construction guidelines, VDH anticipates that there may be a quantifiable indirect cost equal to a 0.2% increase in construction costs for a model facility that is multiple stories of non-combustible construction and a 0.4% increase in construction costs for a model facility that is a single story of combustible construction, based on projections developed by FGI. VDH is unable to quantify a cost due to the cost variance between potential projects. **Direct Benefits**: VDH is not aware of any quantifiable direct benefits for small businesses at this time. **Indirect Benefits**: VDH is not aware of any quantifiable indirect benefits for small businesses at this time.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $0
(3) Other Costs & Benefits (Non-Monetized)	VDH is not aware of any non-monetized costs to small businesses at this time. The non-monetized benefit to small businesses is that there will be a reduced confusion regarding which edition of the FGI Guidelines is the controlling edition. The FGI Guidelines standardize space and equipment requirements and promotes safe practices and methods in planning, design, and construction.	

(4) Alternatives	There are no alternatives to the regulatory change because it is mandated by § 32.1-162.5 of the Code of Virginia.
(5) Information Sources	The Facility Guidelines Institute; Division of Acute Care Services, Office of Licensure and Certification.

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
12.5.391.440	**Statutory:**	211 (R/S)	2 (R/S)	0	+2
	Discretionary:	16 (R/D)	1 (R/D)	1 (R/D)	0

Project 6792 - Fast-Track

Department of Health

Amend Regulation to Incorporate the 2022 FGI Guidelines

12VAC5-391-440. General facility requirements.

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

In addition, hospice facilities shall be designed and constructed according to Part 1, Part 2, and ~~section~~ Chapter 3.2 of Part 3 of the ~~2018~~ Guidelines for Design and Construction of Residential Health, Care, and Support Facilities, 2022 Edition ~~of the~~ (The Facility Guidelines Institute), as amended by the August 2022 Errata for Guidelines for Design and Construction of Residential Health, Care, and Support Facilities, 2022 Edition (The Facility Guidelines Institute).

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

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

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

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

~~Employees shall~~ An employee may not utilize patient rooms ~~nor shall~~ and patients may not use bedrooms for employees ~~be used by patients~~.

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

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

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

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

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

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

Documents Incorporated by Reference (12VAC5-391)

Errata for Guidelines for Design and Construction of Residential Health, Care, and Support Facilities, The Facility Guidelines Institute, 2022 Edition, https://fgiguidelines.org/guidelines/errata-addenda/ (eff. 8/22).

~~2018~~ Guidelines for Design and Construction of Residential Health, Care, and Support Facilities, The Facility Guidelines Institute~~.~~, 2022 Edition, https://fgiguidelines.org.

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

Rebekah E. Allen, JD

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: August 22, 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 – Amend Regulation after Enactment of Chapter 1271 of the 2020 Acts of Assembly

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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 and to update out-of-date regulatory provisions. Chapter 1271 (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 (COPN) program in VDH. The amendments update 12VAC5-220-10 *et seq.* to reflect these statutory changes, 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.

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

townhall.virginia.gov

Fast-Track Regulation
Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-220-10 *et seq.*
VAC Chapter title(s)	Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations
Action title	Amend Regulation after Enactment of Chapter 1271 of the 2020 Acts of Assembly
Date this document prepared	August 22, 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 (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 (COPN) program in VDH. The amendments update 12VAC5-220-10 *et seq.* to reflect these statutory changes, 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.

Acronyms and Definitions

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

"Board" means the State Board of Health.

"Commissioner" means the State Health Commissioner.

"COPN" means certificate of public need.

"RPHA" means regional health planning agency.

"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.

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 mandate and impetus for this regulatory change are the changes to the Code of Virginia enacted by Chapter 1271 of the 2020 Acts of Assembly. The rulemaking is expected to be noncontroversial because it conforms the regulation to the statutory changes enacted by Chapter 1271 of the 2020 Acts of Assembly.

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. 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 states that the Board shall promulgate regulations that are consistent with Article 1.1 of Chapter 4 of Title 32.1 of the Code of Virginia.

The substantive amendments included in this action conform the regulation to Chapter 1271 of the 2020 Acts of Assembly.

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 for this change is that the regulation should be in conformity to the statutory provisions. The specific reasons the regulatory change is essential to protect the health, safety, or welfare of citizens are that 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; updating the regulations to reflect statutory mandates and to be more readable allows the regulants to better understand the requirements of this regulation. The goals of the regulatory change are to eliminate discrepancies between the statutes and regulations, to improve the readability and organization of the regulatory chapter, and to reduce regulatory requirements.

Substance

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

The following new substantive provisions and substantive changes to existing sections are proposed:

Part I. Definitions

Section 10. Definitions
Amends the definition of acquisition, amendment, applicant, application, application fees, capital expenditure, certificate, clinical health service, commissioner, construction, day, designated medically underserved areas, ex parte, health planning region, initiation of construction, inpatient beds, medical care facility, modernization, operating expenditure, operator, other plan, owner, person, physician office, predevelopment site work, primary medical care services, progress, project, public hearing, rural, and significant change. Adds definitions for charity care, CT, day, general hospital, good cause, hospital, MRI, nursing home, primary service area, RFA, State Health Services Plan, and work day. Repeals the definition of gamma knife surgery, medical service area, regional health plan, and State Medical Facilities Plan.

Part II. General Information

This Part header has been repealed.

Section 20. Authority for regulations
Repealed in its entirety.

Section 30. Purpose of chapter
Repealed in its entirety.

Section 40. Administration of chapter
Repealed in its entirety.

Section 50. Public meetings and public hearings
Repealed in its entirety.

Section 60. Official records
Repealed in its entirety.

Section 70. Application of chapter
Repealed in its entirety.

Section 80. Powers and procedures of chapter not exclusive
Repealed in its entirety.

Section 90. Annual report
Repealed in its entirety.

Part II. Mandatory Requirements
This Part header has been re-number from Part III to Part II.

Section 100. Requirements for reviewable medical care facility projects; exceptions
Renamed “Requirements for projects; exceptions.” Amended to incorporate all exemptions from COPN found in Chapter 1271 of the 2020 Acts of Assembly and to conform to *The Virginia Register of Regulations* style guidelines.

Section 105. Requirements for registration of the replacement of existing medical equipment
Renamed "Requirements for registration of medical equipment.” Amended to incorporate all registration changes for replacement medical equipment and new medical equipment found in Chapter 1271 of the 2020 Acts of Assembly and to conform to *The Virginia Register of Regulations* style guidelines.

Section 110. Requirements for registration of certain capital expenditures
Amended to conform to statutory requirements for capital expenditure registration for hospitals and non-hospitals, and to conform to *The Virginia Register of Regulations* style guidelines.

Section 140. Requirements for health maintenance organizations (HMO)
Repealed in its entirety.

Section 155. Requirements for the reporting of charity care
Amended to conform to statutory requirements for reporting charity care and to conform to *The Virginia Register of Regulations* style guidelines.

Part IV. Determination of Public Need (Required Considerations)
This Part header has been repealed.

Section 160. Required considerations
Repealed in its entirety.

Part V. Standard Review Process
This Part header has been re-number from Part V to Part III.

Section 180. Application forms
Amended to remove duplicative requirements for fees, to reflect current means by which applicants obtain applications from VDH, to move the filing deadline from the 40th day before the start of the review cycle to the 10th day before the start of the review cycle, and to conform to *The Virginia Register of Regulations* style guidelines.

Section 190. Review for completeness
Amended to conform to statutory requirements that prescribe what constitutes a completed application and to conform to *The Virginia Register of Regulations* style guidelines.

Section 200. One hundred ninety-day review cycle

Amended to remove types of services, facilities, and expenditures no longer reviewable under COPN, to update out-of-date terminology, to correct a typographical error in the table, and to conform to *The Virginia Register of Regulations* style guidelines.

Section 210. Requests for application (RFA)
Renamed to "Requests for application." Amended to conform to *The Virginia Register of Regulations* style guidelines.

Section 230. Review of complete application
Renamed "Review of completed application by the regional health planning agency." Amended section to narrow scope to application review by the RPHA, to conform to statutory requirements for reviews by RPHAs, and to conform to *The Virginia Register of Regulations* style guidelines.

Section 232. Review of completed application by the department
A new section about application review by VDH. Conforms to statutory requirements for reviews by VDH, updates deadlines so they all use the same time reference (*n*th day of review cycle), and conforms to *The Virginia Register of Regulations* style guidelines.

Section 234. Review of completed application by the commissioner
A new section about application review by the Commissioner. Conforms to statutory requirements for reviews by the Commissioner, updates deadlines so they all use the same time reference (*n*th day of review cycle), and conforms to *The Virginia Register of Regulations* style guidelines.

Section 236. Review period extensions
A new section about review period extensions by applicants. Conforms to statutory requirements and conforms to *The Virginia Register of Regulations* style guidelines.

Section 250. Amendment to an application
Amended to address amendments to applications in the absence of a public hearing and to conform to *The Virginia Register of Regulations* style guidelines.

Section 270. Action on an application
Repealed in its entirety.

Section 275. Conditions of approval
Amended to conform to statutory requirements for conditioning of COPNs and to conform to *The Virginia Register of Regulations* style guidelines.

Section 278. Noncompliance with conditions
Amended to conform to statutory requirements for noncompliance with COPN conditions and to conform to *The Virginia Register of Regulations* style guidelines.

Part VI. Expedited Review Process
This Part header has been re-numbered from Part VI to Part IV.

Section 280. Applicability
Renamed "Criteria for expedited review." Amended to conform to statutory requirements for expedited review and to conform to *The Virginia Register of Regulations* style guidelines.

Section 290. Application forms
Renamed "Application; review for completeness." Amended to remove duplicative requirements for fees, to reflect current means by which applicants obtain applications from VDH, to conform to statutory requirements that prescribe what constitutes a complete application, and to conform to *The Virginia Register of Regulations* style guidelines.

Section 310. Action on application

Amended to conform to statutory requirements for expedited review and to conform to *The Virginia Register of Regulations* style guidelines.

Part VII. New Nursing Home Bed Review Process

This Part header has been re-numbered from Part VII to Part V.

Section 325. Applicability

Amended to conform to *The Virginia Register of Regulations* style guidelines.

Section 335. Request for Applications (RFA)

Renamed "Request for applications." Amended to conform to *The Virginia Register of Regulations* style guidelines and for consistency with Section 10.

Section 365. Review for completeness

Amended to conform to statutory requirements that prescribe what constitutes a completed application and to conform to *The Virginia Register of Regulations* style guidelines.

Section 385. Review of complete application

Renamed "Review of completed application by the regional health planning agency." Amended section to narrow scope to application review by the RPHA, to conform to statutory requirements for reviews by RPHAs, and to conform to *The Virginia Register of Regulations* style guidelines.

Section 388. Review of completed application by the department

A new section about application review by VDH. Conforms to statutory requirements for reviews by VDH, updates deadlines so they all use the same time reference (*n*th day of review cycle), and conforms to *The Virginia Register of Regulations* style guidelines.

Section 392. Review of completed application by the commissioner

A new section about application review by the Commissioner. Conforms to statutory requirements for reviews by the Commissioner, updates deadlines so they all use the same time reference (*n*th day of review cycle), and conforms to *The Virginia Register of Regulations* style guidelines.

Section 394. Review period extensions

A new section about review period extensions by applicants. Conforms to statutory requirements and conforms to *The Virginia Register of Regulations* style guidelines.

Section 420. Action on an application

Repealed in its entirety.

Section 425. Conditions of approval

Amended to conform to statutory requirements for conditioning of COPNs and to conform to *The Virginia Register of Regulations* style guidelines.

Part VIII. Duration, Extension, and Revocation of Certificates

This Part header has been re-numbered from Part VIII to Part VI.

Section 460. Revocation of certificate

Amended to conform to statutory requirements for revocation of a COPN and to conform to *The Virginia Register of Regulations* style guidelines.

Part IX. Appeals

This Part header has been re-numbered from Part IX to Part VII.

Section 470. Judicial review

Amended to conform to statutory requirements for judicial review of a COPN and to conform to *The Virginia Register of Regulations* style guidelines.

Part X. Sanctions

This Part header has been re-numbered from Part X to Part VIII.

Section 480. Violation of rules and regulations

Amended to clarify that commencing a project without first registering it is grounds to refusing to issue a license for that project.

Section 490. Injunctive relief

Amended to clarify that section includes projects that are commenced without a registration and to conform to *The Virginia Register of Regulations* style guidelines.

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 that the regulations will be consistent with the statutory mandates from the General Assembly and more readable. The primary advantage to VDH and the Commonwealth is that the regulations will be in compliance with Chapter 1271 of the 2020 Acts of Assembly. There are no primary disadvantages to the public, VDH, or the Commonwealth. A pertinent matter of interest to the the regulated community is that the application deadline for COPN applications has been reduced from 40 days from the start of the applicable batch review cycle to 10 days from the start of the applicable batch review cycle. This regulatory change allows regulants 30 additional days to submit COPN applications; while the deadline has been reduced to 10 days, applicants are able to submit their applications at any time before that deadline.

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	The estimated costs resulting from this regulatory action on the department is $46,469 annually due to the projected decrease in COPN applications related to the additional exemptions. The agency may save staff time due to the potential reduction in the review load associated with COPN applications; however, this benefit cannot be calculated. Another potential cost saving for the agency is the reduction in public hearings associated with the removal of that requirement from the regulatory text; there were approximately 342 non-competing applications in the last 10 years, accounting for approximately 60% of all COPN applications received during that time period, so it can be estimated that the removal of that requirement will result in a decrease of public hearings. The reduction in the number of public hearings will yield a cost saving for the agency associated with the use of state cars, personal cars, and venue rental costs. There will be a shift in the workload for VDH staff due to new requirements, however, that shift cannot be currently calculated.

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.	Other state agencies that wish to begin a project that would require a COPN or registration with the COPN program may be effected; however, VDH is not aware of any applicable projects from these entities and therefore is unable to calculate the projected costs, savings, fees, or revenues resulting from the regulatory change on other state agencies.
For all agencies: Benefits the regulatory change is designed to produce.	The benefits of the regulatory changes are that the regulation will be in compliance with the statutory mandates from the General Assembly and will be more readable for other state agencies that wish to begin a project that would require a COPN or registration.

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.	Projects that now qualify as exempt will not require a COPN, which will result in a benefit of not paying application fees. The average COPN application cost is $8,119.46 per application, resulting in a cost saving to localities that are interested in beginning projects that would now qualify as exempt. Localities that prepare these applications may benefit from a cost savings if a project is exempt; however, the cost savings cannot be quantified due to the varying complexity of COPN applications, and the number of staff utilized by regulants to complete the application.
Benefits the regulatory change is designed to produce.	Style changes to the text will increase the clarity of the regulations, making them easier for localities to read and understand.

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 other entities likely to be affected by the regulatory change are any entities that are interested in beginning a project that would require a COPN or registration; however, VDH is not able to quantify the number of entities or who these entities would be.
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;	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 Centers qualify as small businesses.

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.	Projects that now qualify as exempt will not require a COPN, which will result in a benefit of not paying application fees. The average COPN application cost is $8,119.46 per application, resulting in a cost saving to entities that are interested in beginning projects that would now qualify as exempt. Other entities that prepare these applications may benefit from a cost savings if a project is exempt; however, the cost savings cannot be quantified due to the varying complexity of COPN applications, and the number of staff utilized by regulants to complete the application.
Benefits the regulatory change is designed to produce.	Style changes to the text will increase the clarity of the regulations, making them easier for regulated entities to read and understand.

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

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

Public Participation

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

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 terms used in the chapter.	**CHANGE:** The Board is proposing the following new edits: • Updated to reference the Code definition: ○ Application ○ Certificate of public need ○ Medical care facility ○ Person ○ Project

			• Moved the "good cause" definition from section 232 to the definitions section
			• Moved "Initiation of Construction"
			• Added a definition of the following terms:
			  ○ Charity care
			  ○ CT
			  ○ Day
			  ○ General hospital
			  ○ Hopsital
			  ○ MRI
			  ○ Nursing home
			  ○ PET
			  ○ Primary service area
			  ○ RFA
			  ○ Work day
			• Struck completely:
			  ○ Gamma knife
			  ○ Medical service area
			  ○ Regional health plan
			• Style changes
			
			INTENT: The intent of the new requirements is update the terminology to be consistent with the Code of Virginia and current practice.
			
			RATIONALE: The rationale for the new requirements is the regulatory text should conform to statutory requirements.
			
			LIKELY IMPACT: The likely impact of the new requirement is improved clarity for readers.

220-20	N/A	This section references the statutory authority for the COPN program and regulations.	**CHANGE:** The Board is proposing to repeal this section. **INTENT:** The intent of the repeal is to remove non-regulatory provisions from the regulation **RATIONALE:** The rationale for the repeal is that only regulatory requirements should appear in the regulations. The cited statutes themselves sufficiently establish the authority for the regulations, which are cited at the end of every section of the regulation. Thus, a standalone authority section is unnecessary, **LIKELY IMPACT:** The likely impact of the repeal is reduced confusion for readers.
220-30	N/A	**Purpose of chapter.**	**CHANGE:** The Board is proposing to repeal this section.

		The board has promulgated this chapter to set forth an orderly administrative process for making public need decisions.	**INTENT:** The intent of the repeal is to remove non-regulatory provisions from the regulation **RATIONALE:** The rationale for the repeal is that only regulatory requirements should appear in the regulations. The Registrar of regulations, pursuant to 1VAC7-10-40 (C), is permitted to omit purpose statements from publication in the *Virginia Register of Regulations* or inclusion in the Virginia Administrative Code. **LIKELY IMPACT:** The likely impact of the repeal is reduced confusion for readers.
220-40	N/A	**Administration of chapter.** This chapter is administered by the following: 1. The Board of Health is the governing body of the Virginia Department of Health. The Board of Health has the authority to promulgate and prescribe such rules and regulations as it deems necessary to effectuate the purposes of the Act. 2. The State Health Commissioner is the executive officer of the Virginia Department of Health. The commissioner is the designated decision maker in the process of determining public need under the Act.	**CHANGE:** The Board is proposing to repeal this section. **INTENT:** The intent of the repeal is to remove non-regulatory provisions from the regulation **RATIONALE:** The rationale for the repeal is that only regulatory requirements should appear in the regulations. The responsibilities of the Board, VDH, and the Commissioner included in this section are sufficiently established in the Code of Virginia and are unnecessary to include here. **LIKELY IMPACT:** The likely impact of the repeal is reduced confusion for readers.
220-50	N/A	**Public meetings and public hearings.** All meetings and hearings convened to consider any certificate of public need application shall be open to the public in accordance with the provisions of the Virginia Freedom of Information Act (§ 2.1-340 et seq.) of the Code of Virginia.	**CHANGE:** The Board is proposing to repeal this section. **INTENT:** The intent of the repeal is to remove non-regulatory provisions from the regulation **RATIONALE:** The rationale for the repeal is that conduct of public meetings are controlled by the Virginia Freedom of Information Act, which these regulations cannot supersede. **LIKELY IMPACT:** The likely impact of the repeal is reduced confusion for readers.
220-60	N/A	**Official records.** Written information including staff evaluations and reports and correspondence developed or	**CHANGE:** The Board is proposing to repeal this section.

		utilized or received by the commissioner during the review of a medical care facility project shall become part of the official project record maintained by the Department of Health and shall be made available to the applicant, competing applicant and review bodies. Other persons may obtain a copy of the project record upon request. All records are subject to the Virginia Freedom of Information Act.	**INTENT:** The intent of the repeal is to remove non-regulatory provisions from the regulation **RATIONALE:** The rationale for the repeal is that the preservation, disposition, and dissemination of public records are controlled by the Virginia Public Records Act and the Virginia Freedom of Information Act, which these regulations cannot supersede. Specific provisions regarding the creation of, maintenance of, and access to COPN records are sufficiently addressed in the relevant sections of the regulation. **LIKELY IMPACT:** The likely impact of the repeal is reduced confusion for readers.
220-70	N/A	**Application of chapter.** This chapter has general applicability throughout the Commonwealth. The requirements of the Virginia Administrative Process Act (§ 9-6.14:1 et seq.) of the Code of Virginia apply to their promulgation.	**CHANGE:** The Board is proposing to repeal this section. **INTENT:** The intent of the repeal is to remove non-regulatory provisions from the regulation **RATIONALE:** The rationale for the repeal is that the promulgation, amendment, and application of regulations are controlled by the Virginia Administrative Process Act, which these regulations cannot supersede. **LIKELY IMPACT:** The likely impact of the repeal is reduced confusion for readers.
220-80	N/A	**Powers and procedures of chapter not exclusive.** The commissioner and the board reserve the right to authorize any procedure for the enforcement of this chapter that is not inconsistent with the provisions set forth herein and the provisions of Article 1.1 (§ 32.1-102.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia.	**CHANGE:** The Board is proposing to repeal this section. **INTENT:** The intent of the repeal is to remove non-regulatory provisions from the regulation **RATIONALE:** The rationale for the repeal is that only regulatory requirements should appear in the regulations. The rights of the board, department, and commissioner with regard to enforcement are sufficiently established in the Code of Virginia and need not be repeated here. **LIKELY IMPACT:** The likely impact of the repeal is reduced confusion for readers.
220-90	N/A	**Annual report.** This section contains report requirements.	**CHANGE:** The Board is proposing to repeal this section.

			INTENT: The intent of the repeal is to remove obsolete requirements from the regulation **RATIONALE:** The rationale for the repeal is that Chapter 1271 of the 2020 Acts of the Assembly repealed the requirement that an annual report be submitted. **LIKELY IMPACT:** The likely impact of the repeal is reduced confusion for readers.
220-100	N/A	**Requirements for reviewable medical care facility projects; exceptions.** This section details the requirements for projects and the exemptions that exist for those projects.	**CHANGE:** The Board is proposing style and form changes to the existing language, the inclusion of registrations prior to the initiation of a project as a requirement, and the inclusion of new exemptions for: • Certain bed relocations • Certain nursing homes **INTENT:** The intent of the new requirements is to incorporate all COPN exemption changes found in Chapter 1271 of the 2020 Acts of Assembly. **RATIONALE:** The rationale for the new requirements is the regulatory text should conform to both statutory requirements and to *The Virginia Register of Regulations* style guidelines. **LIKELY IMPACT:** The likely impact of the new requirement is improved clarity for readers.
220-105	N/A	**Requirements for registration of the replacement of existing medical equipment.** This section requires the registration of replacement medical equipment or the acquisition of certain medical equipment listed in the definition of a “project”	**CHANGE:** The Board is proposing to: • Add registration requirements for new medical equipment capital expenditures, replacement medical equipment capital expenditures • Prohibit the department from requiring the registration of replacement medical equipment for certain provisions • Strike the original language for how the registration needs to be submitted and replace it with language that follows the *The Virginia Register of Regulations* style guidelines **INTENT:** The intent of the new requirements is to incorporate all registration changes for medical

			equipment found in Chapter 1271 of the 2020 Acts of Assembly. **RATIONALE:** The rationale for the new requirements is the regulatory text should conform to both statutory requirements and to *The Virginia Register of Regulations* style guidelines. **LIKELY IMPACT:** The likely impact of the new requirement is improved clarity for readers.
220-110	N/A	**Requirements for registration of certain capital expenditures.** Sets the registration requirements for capital expenditures	**CHANGE:** The Board is proposing the following new amendments: • Strike the previous capital expenditure registration requirement and replace it with the new requirements from Chapter 1271 of the 2020 Acts of Assembly • Style changes **INTENT:** The intent of the new requirements is to incorporate all registration changes for capital expenditure found in Chapter 1271 of the 2020 Acts of Assembly. **RATIONALE:** The rationale for the new requirements is the regulatory text should conform to both statutory requirements and to *The Virginia Register of Regulations* style guidelines. **LIKELY IMPACT:** The likely impact of the new requirement is improved clarity for readers.
220-140	N/A	**Requirements for health maintenance organizations (HMO).** An HMO must obtain a certificate of public need prior to initiating a project. Such HMO must also adhere to the requirements for the acquisition of medical care facilities if appropriate. See definition of "project" and 12VAC5-220-10.	**CHANGE:** The Board is proposing to repeal this section. **INTENT:** The intent of the repeal is to remove obsolete provisions **RATIONALE:** The rationale for the repeal is that HMOs are covered by the definition of “person” and therefore are already obligated to comply with COPN statutes and regulations. **LIKELY IMPACT:** The likely impact of the repeal is reduced confusion for readers.
220-155	N/A	**Requirements for the reporting of charity care.** Every medical care facility subject to the requirements of Article 1.1 (§ 32.1-102.1 et seq.)	**CHANGE:** The Board is proposing the following new requirements: **Requirements for the reporting of charity care.**

		of Chapter 4 of Title 32.1 of the Code of Virginia, other than a nursing home, that is not a medical care facility for which a certificate with conditions imposed pursuant to § 32.1-102.4 F of the Code of Virginia has been issued and that provides charity care, as defined in § 32.1-102.1 of the Code of Virginia, shall annually report to the commissioner the amount of charity care provided.	A. ~~Every~~ If a medical care facility ~~subject to the requirements of Article 1.1 (§ 32.1-102.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia, other than a nursing home, that is not a medical care facility for which a certificate with conditions imposed pursuant to § 32.1-102.4 F of the Code of Virginia has been issued and that provides charity care, as defined in § 32.1-102.1 of the Code of Virginia,~~ has a certificate of public need with conditions imposed pursuant to subsection B of § 32.1-102.4 of the Code of Virginia and provides charity care, the medical facility shall ~~annually~~ report to the ~~commissioner~~ department annually the amount of charity care provided by submitting that information to the nonprofit organization described in § 32.1-276.4 of the Code of Virginia. B. No provision of this section shall apply to a nursing home. **INTENT:** The intent of the new requirements is to address charity care reporting requirements for non-nursing homes. **RATIONALE:** The rationale for the new requirements is the regulatory text should conform to both statutory requirements and to *The Virginia Register of Regulations* style guidelines. **LIKELY IMPACT:** The likely impact of the new requirement is improved clarity for readers.
220-160	N/A	**Required considerations.** In determining whether a public need exists for a proposed project, the applicable requirements of § 32.1-102.2:1 of the Code of Virginia will be considered.	**CHANGE:** The Board is proposing to repeal this section. **INTENT:** The intent of the repeal is to remove duplicative requirements from the regulation. **RATIONALE:** The rationale for the repeal is that these requirements should be addressed in context of the review application. **LIKELY IMPACT:** The likely impact of the repeal is reduced confusion for readers.
220-180	N/A	**Application forms.**	**CHANGE:** The Board is proposing the following amendments:

		Sets the requirements for the letter of intent and applications for projects.	• Updated the text to reflect current practice of the application forms and their availability on the department's website • Reduced the application submission deadline from 40 days prior to the first day of the batch review cycle to 5 p.m. 10 days before the first day of the batch review cycle • Style changes **INTENT:** The intent of the new requirements is to remove duplicative requirements for fees, to reflect current means by which applicants obtain applications from VDH, to move the filing deadline from the 40th day before the start of the review cycle to the 10th day before the start of the review cycle. **RATIONALE:** The rationale for the new requirements is to reduce the regulatory burden by giving applicants more time to submit their applications and that the regulatory text should conform to both statutory requirements and to *The Virginia Register of Regulations* style guidelines. **LIKELY IMPACT:** The likely impact of the new requirement is improved clarity for readers and reduced regulatory burden.
220-190	N/A	**Review for completeness.** Sets the completeness review requirements for the department and the regional health planning agency.	**CHANGE:** The Board is proposing the following amendments: • Reduced the timeline for notification by the department from 15 days following the receipt of an application to 10 days • Style changes **INTENT:** The intent of the new requirements is to remove and amend requirements in the regulation that were changed by Chapter 1271 of the 2020 Acts of Assembly. **RATIONALE:** The rationale for the new requirements is the regulatory text should conform to both statutory requirements and to *The Virginia Register of Regulations* style guidelines. **LIKELY IMPACT:** The likely impact of the new requirement is improved clarity for readers.

220-200	N/A	**One hundred ninety-day review cycle.** Sets forth the batch groups and the scheduled review cycles for the batch groups.	**CHANGE:** The Board is proposing the following amendments: • Removed "mental retardation facilities" throughout and replaced the term with "intermediate care facilities for individuals with intellectual disabilities" • Corrected the "D/F" batch group cycles to "D" and "F/D" • Removed "obstetrical services" throughout • Removed "selected therapeutic facilities/services" from the table • Removed bed relocation and capital expenditures from batch group A • Removed "alcoholics or drug addicts" throughout and replaced the term with "individuals with substance use disorder" • Removed "Substance abuse" and replaced the term with "substance use disorder" • Removed bed relocations from batch group C • Removed "nuclear medicine imagery" from batch group D • Removed bed relocations from batch group E • Added "Steroestatic radiotherapy" to batch group F/D • Added CT, MRI, and PET scanning to batch group F/D • Removed "extended care facility" from batch group G • Removed bed relocations from batch group G • Style changes **INTENT:** The intent of the new requirements is to remove types of services, facilities, and expenditures no longer reviewable under COPN, to update out-of-date terminology, and to correct a typographical error in the table. **RATIONALE:** The rationale for the new requirements is that the regulatory text should conform to *The Virginia Register of Regulations* style guidelines and use consistent terminology through the chapter.

			LIKELY IMPACT: The likely impact of the new requirements is improved clarity for readers.
220-210	N/A	**Requests for application (RFA).** Allows the commissioner to request the submission of applications for certain services and facilities.	**CHANGE:** The Board is proposing the following amendments: • Changed "State Medical Facilities Plan" to "State Health Services Plan" • Style changes **INTENT:** The intent of the new requirements is improve the readability of the section. **RATIONALE:** The rationale for the new requirements is that the regulatory text should conform to statutory requirements and *The Virginia Register of Regulations* style guidelines and use consistent terminology through the chapter. **LIKELY IMPACT:** The likely impact of the new requirements is improved clarity for readers and reflects statutory changes.
220-230	N/A	**Review of complete application.** Sets the requirements for the review of a complete application for the regional health planning agency, the department, and the commissioner.	**CHANGE:** The Board is proposing the following amendments: • Removal of language related to the review requirements for the department and the commissioner (moved to the new sections) • Removed the requirement to conduct no more than 2 meetings, with at least one of those meetings needing to be a public hearing • Added language that requires the department to perform certain duties when a regional health planning agency does not exist • Removed health care providers and specifically identifiable consumer groups from the list of entities the regional health planning agency is required to notify • Style changes **INTENT:** The intent of the new requirements is to reorganize the requirements related to RPHA's application review so that it is linear and uses the same time calculation (*n*th day of review cycle) for all required deadlines and to narrow the scope of the section to just the RPHA's review.

			RATIONALE: The rationale for the new requirements is the regulatory text should conform to both statutory requirements and to *The Virginia Register of Regulations* style guidelines, as well as describe the regulatory requirements in a logical order. **LIKELY IMPACT:** The likely impact of the new requirements is improved clarity for readers.
N/A	220-232	This is a new section.	**CHANGE:** The Board is proposing the following: • Moved the language regarding the departments review of an application from section 230 to a new section • Style changes to correct the language pulled from 230 **INTENT:** The intent of the new requirements is to reorganize the requirements related to VDH's application review so that it is linear and uses the same time calculation (*n*th day of review cycle) for all required deadlines. **RATIONALE:** The rationale for the new requirements is the regulatory text should conform to both statutory requirements and to *The Virginia Register of Regulations* style guidelines, as well as describe the regulatory requirements in a logical order. **LIKELY IMPACT:** The likely impact of the new requirements is improved clarity for readers.
N/A	220-234	This is a new section.	**CHANGE:** The Board is proposing the following: • Moved language related to the commissioner's review of an application from 230 and 270 to the new section • Style changes **INTENT:** The intent of the new requirements is to reorganize the requirements related to the Commissioner's application review so that it is linear and uses the same time calculation (*n*th day of review cycle) for all required deadlines.

			RATIONALE: The rationale for the new requirements is the regulatory text should conform to both statutory requirements and to *The Virginia Register of Regulations* style guidelines, as well as describe the regulatory requirements in a logical order. **LIKELY IMPACT:** The likely impact of the new requirements is improved clarity for readers.
N/A	220-236	This is a new section.	**CHANGE:** The Board is proposing the following: • Moved language from section 230 and created a new section for the extension of the review period • Style changes **INTENT:** The intent of the new requirements is address who may extend review periods for a COPN application. **RATIONALE:** The rationale for the new requirements is the regulatory text should conform to both statutory requirements and to *The Virginia Register of Regulations* style guidelines. **LIKELY IMPACT:** The likely impact of the new requirements is improved clarity about when review periods may be extended and by whom.
220-250	N/A	**Amendment to an application.** The applicant shall have the right to amend an application at any time. Any amendment which is made to an application following the public hearing and prior to the issuance of a certificate unless otherwise specified in this chapter shall constitute a new application and shall be subject to the review requirements set forth in Part V of this chapter. If such amendment is made subsequent to the issuance of a certificate of public need, it shall be reviewed in accordance with 12VAC5-220-130.	**CHANGE:** The Board is proposing the following amendments: • Style changes • Changes Part V or Part III • Added language to cover the amendment process if a public hearing is not held **INTENT:** The intent of the new requirements is address when an amendment to an application constitutes a new application when there is no public hearing held **RATIONALE:** The rationale for the new requirements is that statutory changes from Chapter 1271 of the 2020 Acts of Assembly removed the requirement for a public hearing for every application, thus necessitating the amendment of this section to address application amendments in the absence of a public hearing.

			LIKELY IMPACT: The likely impact of the new requirements is improved clarity for readers.
220-270	N/A	**Action on an application.** Sets the requirements for the commissioner in their review of an application, conditions of approval, and extensions.	**CHANGE:** The Board is proposing to repeal this section. **INTENT:** The intent of the repeal is to remove requirements that are obsolete or have been addressed in other sections of the regulation. **RATIONALE:** The rationale for the repeal is that the regulations should conform to statutory provisions and should only be addressed once rather than multiple times throughout a regulatory chapter. **LIKELY IMPACT:** The likely impact of the repeal is reduced confusion for readers.
N/A	220-275	This is a new section.	**CHANGE:** The Board is proposing the following: • Moved language from section 270 regarding the conditions of approval • Added new language for conditional approval, financial assistance policies, and circumstantial review of conditions from Chapter 1271 of the 2020 Acts of Assembly • Style changes **INTENT:** The intent of the new requirements is to conform to statutory changes regarding which conditions are mandatory or discretionary and what obligations the COPN holder and the commissioner have regarding conditions on a COPN. **RATIONALE:** The rationale for the new requirements is the regulatory text should conform to both statutory requirements and to *The Virginia Register of Regulations* style guidelines. **LIKELY IMPACT:** The likely impact of the new requirements is improved clarity for readers.
N/A	220-278	This is a new section.	**CHANGE:** The Board is proposing the following: • Moved the language about noncompliance from 270 to this new section

			• Amended the date the civil penalty begins to align with Chapter 1271 of the 2020 Acts of Assembly • Style Changes **INTENT:** The intent of the new requirements is to conform to statutory changes regarding the administrative consequences for failing to comply with COPN conditions. **RATIONALE:** The rationale for the new requirements is the regulatory text should conform to both statutory requirements and to *The Virginia Register of Regulations* style guidelines. **LIKELY IMPACT:** The likely impact of the new requirements is improved clarity for readers.
220-280	N/A	**Applicability.** Capital expenditures as contained in subdivision 8 of "project" as defined in § 32.1-102.1 of the Code of Virginia or projects that involve relocation at the same site of 10 beds or 10% of the beds, whichever is less, from one existing physical facility to another, when the cost of such relocation is less than $5 million, shall be subject to an expedited review process.	**CHANGE:** The Board is proposing the following amendments: • Updated the Code reference • Removed the bed relocation and capital expenditure language **INTENT:** The intent of the new requirements is to conform to statutory changes regarding which projects are eligible for expedited review. **RATIONALE:** The rationale for the new requirements is the regulatory text should conform to both statutory requirements and to *The Virginia Register of Regulations* style guidelines. **LIKELY IMPACT:** The likely impact of the new requirements is improved clarity for readers.
220-290	N/A	**Application forms.** Sets the application form requirements and the review of completeness requirements for the department and regional health planning agency	**CHANGE:** The Board is proposing the following amendments: • Rewritten to reflect the completeness review requirements of the standard review cycle for clarity and to adhere to Chapter 1271 of the 2020 Acts of Assembly • Style changes **INTENT:** The intent of the new requirements is to reflect how applicants currently obtain applications, to remove duplicative fee information, and to

			conform to statutory changes regarding what constitutes a completed application. **RATIONALE:** The rationale for the new requirements is the regulatory text should conform to both statutory requirements and to *The Virginia Register of Regulations* style guidelines. **LIKELY IMPACT:** The likely impact of the new requirements is improved clarity for readers.
220-310	N/A	**Action on application.** Sets the requirements for the commissioner's action on an expedited application.	**CHANGE:** The Board is proposing the following amendments: • Style changes **INTENT:** The intent of the new amendments is to improve readability. **RATIONALE:** The rationale for the new requirements is the regulatory text should conform to both statutory requirements and to *The Virginia Register of Regulations* style guidelines. **LIKELY IMPACT:** The likely impact of the new requirements is improved clarity for readers.
220-325	N/A	**Applicability**. Sets the types of projects that are subject to the nursing home bed review process	**CHANGE:** The Board is proposing the following amendments: • Removal of "intermediate care facility" and "extended care facility" from the language • Style changes **INTENT:** The intent of the new requirements is to improve readability and remove obsolete language. **RATIONALE:** The rationale for the new requirements is that the regulatory text should conform to both statutory requirements and to *The Virginia Register of Regulations* style guidelines. **LIKELY IMPACT:** The likely impact of the new requirements is improved clarity for readers.
220-335	N/A	**Request for Applications (RFA).** Allows the commissioner to request the submission of applications for certain services and facilities.	**CHANGE:** The Board is proposing the following amendments: • Changed "State Medical Facilities Plan" to "State Health Services Plan" • Style changes

			INTENT: The intent of the new requirements is improve the readability of the section. **RATIONALE:** The rationale for the new requirements is that the regulatory text should conform to statutory provisions and *The Virginia Register of Regulations* style guidelines and use consistent terminology through the chapter. **LIKELY IMPACT:** The likely impact of the new requirements is improved clarity for readers.
220-365	N/A	**Review for completeness.** The department is required to notify an applicant within 15 days following the receipt of an application. Sets the requirements for a complete application.	**CHANGE:** The Board is proposing the following amendments: • Updated the language to conform to Chapter 1271 of the 2020 Acts of Assembly • Style changes **INTENT:** The intent of the new requirements is to remove and amend requirements in the regulation that were changed by Chapter 1271 of the 2020 Acts of Assembly. **RATIONALE:** The rationale for the new requirements is the regulatory text should conform to both statutory requirements and to *The Virginia Register of Regulations* style guidelines. **LIKELY IMPACT:** The likely impact of the new requirement is improved clarity for readers.
220-385	N/A	**Review of complete application.** Sets the requirements for the review of a complete application for the regional health planning agency, the department, and the commissioner.	**CHANGE:** The Board is proposing the following amendments: • Removal of language related to the review requirements for the department and the commissioner (moved to the new sections) • Removed the requirement to conduct no more than 2 meetings, with at least one of those meetings needing to be a public hearing • Added language that requires the department to perform certain duties when a regional health planning agency does not exist • Removed health care providers and specifically identifiable consumer groups from the list of entities the regional health

			planning agency is required to notify • Style changes **INTENT:** The intent of the new requirements is to reorganize the requirements related to RPHA's application review so that it is linear and uses the same time calculation (*n*th day of review cycle) for all required deadlines and to narrow the scope of the section to just the RPHA's review. **RATIONALE:** The rationale for the new requirements is the regulatory text should conform to both statutory requirements and to *The Virginia Register of Regulations* style guidelines, as well as describe the regulatory requirements in a logical order. **LIKELY IMPACT:** The likely impact of the new requirements is improved clarity for readers.
N/A	220-388	This is a new section.	**CHANGE:** The Board is proposing the following: • Moving the language regarding the departments review of an application from section 230 to a new section • Style changes to correct the language pulled from 230 **INTENT:** The intent of the new requirements is to reorganize the requirements related to VDH's application review so that it is linear and uses the same time calculation (*n*th day of review cycle) for all required deadlines. **RATIONALE:** The rationale for the new requirements is the regulatory text should conform to both statutory requirements and to *The Virginia Register of Regulations* style guidelines, as well as describe the regulatory requirements in a logical order. **LIKELY IMPACT:** The likely impact of the new requirements is improved clarity for readers.
N/A	220-392	This is a new section.	**CHANGE:** The Board is proposing the following: • Moved language related to the commissioner's review of an

			application from 230 and 270 to the new section • Style changes **INTENT:** The intent of the new requirements is to reorganize the requirements related to the Commissioner's application review so that it is linear and uses the same time calculation (*n*th day of review cycle) for all required deadlines. **RATIONALE:** The rationale for the new requirements is the regulatory text should conform to both statutory requirements and to *The Virginia Register of Regulations* style guidelines, as well as describe the regulatory requirements in a logical order. **LIKELY IMPACT:** The likely impact of the new requirements is improved clarity for readers.
N/A	220-394	This is a new section.	**CHANGE:** The Board is proposing the following: • Moved language from section 230 and created a new section for the extension of the review period • Style changes **INTENT:** The intent of the new requirements is address who may extend review periods for a COPN application. **RATIONALE:** The rationale for the new requirements is the regulatory text should conform to both statutory requirements and to *The Virginia Register of Regulations* style guidelines. **LIKELY IMPACT:** The likely impact of the new requirements is improved clarity about when review periods may be extended and by whom.
220-420	N/A	**Action on an application.** Sets the requirements for the commissioner in their review of an application, conditionals of approval, and extensions.	**CHANGE:** The Board is proposing to repeal this section. **INTENT:** The intent of the repeal is to remove duplicative regulatory requirements already addressed in the chapter **RATIONALE:** The rationale for the repeal is that a regulatory requirement should only be addressed once instead of in multiple sections.

			LIKELY IMPACT: The likely impact of the repeal is reduced confusion for readers.
N/A	220-425	This is a new section.	**CHANGE:** The Board is proposing the following: **Conditions of approval.** The commissioner may condition the approval of an application for a project on the agreement of the applicant to: 1. Comply with a schedule for completion; or 2. Comply with a maximum expenditure amount. **INTENT:** The intent of the new requirements is specify what conditions the commissioner may attach to a COPN for new nursing home beds. **RATIONALE:** The rationale for the new requirements is the regulatory text should conform to both statutory requirements and to *The Virginia Register of Regulations* style guidelines. **LIKELY IMPACT:** The likely impact of the new requirements is improved clarity about what conditions may be placed on a COPN for new nursing home beds.
220-460	N/A	**Revocation of a certificate** Allows the commissioner to revoke a certificate under certain conditions	**CHANGE:** The Board is proposing the following amendments: • Added the requirement for the commissioner to revoke a certificate for the failure to comply with Code requirements or for misrepresenting intentions or facts while obtaining that certificate • Updated the original revocation requirements to be an optional action by the commissioner for revocation instead of a required action • Style changes **INTENT:** The intent of the new requirements is to separately address the grounds for mandatory revocation of a COPN and discretionary revocation of a COPN. **RATIONALE:** The rationale for the new requirements is the regulatory text should conform to both statutory requirements

			and to *The Virginia Register of Regulations* style guidelines. **LIKELY IMPACT:** The likely impact of the new requirements is improved clarity about when revocation of a COPN by the Commissioner is mandated or discretionary.
220-470	N/A	**Judicial review.** Appeals to a circuit court shall be governed by the Virginia Administrative Process Act, § 2.2-4000 et seq. of the Code of Virginia, and Part Two A of the Rules of the Supreme Court of Virginia.	**CHANGE:** The Board is proposing the following amendments: • Added the deemed approval language from section 230 • Style changes **INTENT:** The intent of the new requirements is address to whether deemed approvals may be subject to judicial review, who is deemed to be a person showing good cause in the case of a deemed approval, and the court's ability to require a bond from an appellant. These requirements and references to the appropriate Code sections were moved from section 230. **RATIONALE:** The rationale for the new requirements is the regulatory text should conform to both statutory requirements and to *The Virginia Register of Regulations* style guidelines. **LIKELY IMPACT:** The likely impact of the new requirements is improved clarity about what decisions may be appealed to circuit court and by whom.
220-480	N/A	**Violation of rules and regulations.** Commencing any project without a certificate required by this chapter shall constitute grounds for refusing to issue a license for such project.	**CHANGE:** The Board is proposing the following amendments: **Violation of rules and regulations.** Commencing any project without a certificate or a registration required by this chapter shall constitute grounds for refusing to issue a license for ~~such~~ that project. **INTENT:** The intent of the new requirements is to clarify that a license may be refused for a project is commenced without a registration **RATIONALE:** The rationale for the new requirements is that the regulatory text should conform to both statutory requirements and to *The Virginia Register of Regulations* style guidelines.

			LIKELY IMPACT: The likely impact of the new requirements is improved clarity about licensure consequences for projects commenced with registration.
220-490	N/A	**Injunctive relief.** On petition of the commissioner, the Board of Health or the Attorney General, the circuit court of the county or city where a project is under construction or is intended to be constructed, located or undertaken shall have jurisdiction to enjoin any project which is constructed, undertaken or commenced without a certificate or to enjoin the admission of patients to the project or to enjoin the provision of services through the project	**CHANGE:** The Board is proposing the following amendments: **Injunctive relief.** On petition of the commissioner, the ~~Board of Health~~ board, ~~or~~ the Attorney General, or the circuit court of the county or city where a project is under construction or is intended to be constructed, located, or undertaken shall have jurisdiction to enjoin: 1. ~~any~~ Any project ~~which~~ that is constructed, undertaken, or commenced without a certificate or registration; or ~~to enjoin~~ 2. ~~the~~ The admission of patients to the project; or ~~or to enjoin~~ 3. ~~the~~ The provision of services through the project. **INTENT:** The intent of the new requirements is to clarify that injunctive relief is available if a project is commenced without a registration. **RATIONALE:** The rationale for the new requirements is that the regulatory text should conform to both statutory requirements and to *The Virginia Register of Regulations* style guidelines. **LIKELY IMPACT:** The likely impact of the new requirements is improved clarity about available judicial relief for projects commenced with registration.

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	Amend Regulation after Enactment of Chapter 1271 of the 2020 Acts of Assembly
Date this document prepared	August 22, 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)	**Amended to include the new COPN exemptions and capital expenditure requirements.** • **Direct Monetized Benefit**: Projects that now qualify as exempt will not require a COPN, which will result in a benefit of not paying application fees and saving staff time creating and filing applications. To apply for a COPN, a fee must be paid, so projects that are exempt will not have an associated application fee. The average COPN application cost is $8,119.46 per application, and the estimated number of projects that would be removed from COPN review is 5.6 annually. • **Direct Monetized Cost**: The department will lose revenue due to the decrease in the number of fees paid that is estimated at $45,469 annually. • **Indirect Monetized Benefit**: The agency may save staff time due to the potential reduction in the review load. Regulants that prepare these submissions will benefit from a cost savings due to the reduction of COPN application submissions for projects that are now exempt; the cost savings cannot be quantified due to the varying complexity of COPN applications, and the number of staff utilized by regulants to complete the application. • **Indirect Monetized Cost**: None **Amended to include the new registration requirements.** • **Direct Monetized Benefit**: Projects that now qualify as exempt will not require a registration, which will result in a benefit of saving staff time creating and filing registrations. • **Direct Monetized Cost**: None. • **Indirect Monetized Benefit**: None. • **Indirect Monetized Cost**: None. **Updated public hearing requirements to conform with 2020 changes.** • **Monetized Direct Benefits**: There is no longer a requirement for the regional health planning agency to hold at least one public hearing for a COPN application except in certain cases, such as competing applications. There were approximately 342 non-competing applications in the last 10 years, accounting for approximately 60% of all COPN applications received during that time period, so it can be estimated that the removal of that requirement will result in a decrease of public hearings. The reduction in the number of public hearings will yield a cost saving for the agency associated with the use of state cars, personal cars, and venue rental costs.

	• **Monetized Direct Costs:** None. • **Monetized Indirect Benefits:** None • **Monetized Indirect Costs:** None. **Repealed 270 and created a new section 275, added required conditions of approval for a certificate of public need.** • **Monetized Direct Benefits**: None. • **Monetized Direct Costs:** Providers are now required to adhere to charity care conditions placed on the approval of a COPN. Providers who do not already provide charity care may incur a cost due to the requirement to accept patients who yield a lower reimbursement rate. This cost cannot be quantified by VDH as VDH is not aware of the number of providers that do not already provide charity care. The condition to provide a financial assistance policy to patients may yield a cost to providers and facilities, however, VDH is unable to quantify this as VDH is not aware of how many facilities and providers do not provide a financial assistance policy already. • **Monetized Indirect Benefits:** None. • **Monetized Indirect Costs:** None. **Amended the noncompliance timeline.** • **Monetized Direct Costs**: For the purposes of determining the amount of a civil penalty to be imposed in an instance of noncompliance, the noncompliance timeline is now to be calculated from the day the certificate is issued instead of the day the noncompliance is cited. This will result in a cost to regulants who are noncompliant; however, VDH cannot quantify this cost. This change is non-discretionary and was amended in § 32.1-102.4 in Ch 1271 (2020). There are no monetized direct or indirect costs and benefits associated with the following regulatory changes: • **Updated definitions to adhere to the Code.** • **Repeal of sections entirely comprised of non-regulatory language.** • **Clarified that the application deadline is 5 p.m. on the due date, changed the submission date from 40 days prior to the beginning of the batch cycle to 10 days.** • **Updated the completeness provisions from 15 days to 10 days.** • **Updated regulation regarding the determination of completeness for an application conform to 2020 changes.** • **Updated batch cycle to match 2020 changes and corrected scrivener errors in batch groups.**

	• **Added required circumstances for revocation of a certificate of public need by the commissioner.** • **Added failure to register a project as cause for injunctive relief against a project.** • **Added failure to obtain the required registrations before starting a project to the grounds for refusing a license for that project.**

(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	$0	

(4) Other Costs & Benefits (Non-Monetized)	**Non-monetized benefits:** • Decreasing the review period of completeness will allow applicants to have more time to submit their applications for a COPN to the department. • Style changes to the text will increase the clarity of the regulations, making them easier for the public to read and understand. These changes will also bring those sections of the regulation into conformity with the Form and Style Manual administered by the Virginia Registrar of regulations. • Patients who are subject to the charity care conditions will now be able to utilize these new facilities, increasing the availability of low-cost medical care available to that patient. **Non-monetized costs:** • There will be a shift in the workload for VDH staff due to new requirements, however, that shift cannot be currently monetized.
(5) Information Sources	VDH COPN Division; U.S. Bureau of Labor Statistics; DPB Fiscal Impact Statement for SB764.

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

(1) Direct & Indirect Costs & Benefits (Monetized)	**Nondiscretionary changes have been omitted from this analysis.** There are no monetized direct or indirect costs and benefits associated with the following regulatory changes: • **Updated definitions to adhere to the Code.** • **Repeal of sections entirely comprised of non-regulatory language.**

	• **Clarified that the application deadline is 5 p.m. on the due date, changed the submission date from 40 days prior to the beginning of the batch cycle to 10 days.**	
(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)	**Non-monetized Costs:** • Style changes to the text increase the clarity of the regulations, making them easier for the public to read and understand. Without these changes, the regulation will remain difficult to read and understand. **Non-monetized Benefits:** • None.	
(5) Information Sources	VDH COPN Division.	

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

(1) Direct & Indirect Costs & Benefits (Monetized)	**Nondiscretionary changes have been omitted from this analysis. There are no alternatives to updating the definitions or repealing non-regulatory sections.** **Clarified that the application deadline is 5 p.m. on the due date, changed the submission date from 40 days prior to the beginning of the batch cycle to 10 days.** • The alternative to this change would be to use a different time (i.e. 6 p.m., 10 p.m., etc.) however, there is no evidence that this change would result in a different cost and benefit calculation.	
(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 direct or indirect costs and benefits associated with the discretionary regulatory changes.	
(5) Information Sources	None.	

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)	**Local Partners who may be impacted are other state agencies and localities that may seek to pursue a project for which a COPN or registration is required.** **Amended to include the new COPN exemptions and capital expenditure requirements.** • **Direct Monetized Benefit**: Projects that now qualify as exempt will not require a COPN, which will result in a benefit of not paying application fees and saving staff time creating and filing applications. To apply for a COPN, a fee must be paid, so projects that are exempt will not have an associated application fee. The average COPN application cost is $8,119.46 per application, and the estimated number of projects that would be removed from COPN review is 5.6 annually. • **Direct Monetized Cost**: The department will lose revenue due to the decrease in the number of fees paid that is estimated at $45,469 annually. • **Indirect Monetized Benefit**: The agency will potentially save staff time due to the potential reduction in the review load. Regulants that prepare these submissions will benefit from a cost savings due to the reduction of COPN application submissions for projects that are now exempt; the cost savings cannot be quantified due to the varying complexity of COPN applications, and the number of staff utilized by regulants to complete the application. • **Indirect Monetized Cost**: None **Amended to include the new registration requirements.** • **Direct Monetized Benefit**: Projects that now qualify as exempt will not require a registration, which will result in a benefit of saving staff time creating and filing registrations. • **Direct Monetized Cost**: None. • **Indirect Monetized Benefit**: None. • **Indirect Monetized Cost**: None. **Updated public hearing requirements to conform with 2020 changes.** • **Monetized Direct Benefits**: There is no longer a requirement for the regional health planning agency to hold at least one public hearing for a COPN application except in certain cases, such as competing applications. There were approximately 342 non-

	competing applications in the last 10 years, accounting for approximately 60% of all COPN applications received during that time period, so it can be estimated that the removal of that requirement will result in a decrease of public hearings. • **Monetized Direct Costs:** None. • **Monetized Indirect Benefits:** The reduction in the number of public hearings will yield a cost saving for the agency associated with the use of state cars, personal cars, and venue rental costs. • **Monetized Indirect Costs:** None. **Repealed 270 and created a new section 275, added required conditions of approval for a certificate of public need.** • **Monetized Direct Benefits**: None. • **Monetized Direct Costs:** Providers are now required to adhere to charity care conditions placed on the approval of a COPN. Providers who do not already provide charity care may incur a cost due to the requirement to accept patients who yield a lower reimbursement rate. This cost cannot be quantified by VDH as VDH is not aware of the number of providers that do not already provide charity care. The condition to provide a financial assistance policy to patients may yield a cost to providers and facilities, however, VDH is unable to quantify this as VDH is not aware of how many facilities and providers who do not provide a financial assistance policy already. • **Monetized Indirect Benefits:** None. • **Monetized Indirect Costs:** None. **Amended the noncompliance timeline.** • **Monetized Direct Costs**: The noncompliance timeline is now to be calculated from the day the certificate is issued instead of the day the noncompliance is cited. This will result in a cost to regulants who are noncompliant; however, VDH cannot quantify this cost. There are no monetized direct or indirect costs or benefits associated with the regulatory changes: • **Updated definitions to adhere to the Code.** • **Repeal of sections entirely comprised of non-regulatory language.** • **Clarified that the application deadline is 5 p.m. on the due date, changed the submission date from 40 days prior to the beginning of the batch cycle to 10 days.** • **Updated the completeness provisions from 15 days to 10 days.** • **Updated regulation regarding the determination of completeness for an application conform to 2020 changes.**

	• **Updated batch cycle to match 2020 changes and corrected scrivener errors in batch groups.** • **Added required circumstances for revocation of a certificate of public need by the commissioner.** • **Added registrations to the grounds for refusing a license.** • **Added failure to register a project as cause for injunctive relief against a project.**	
(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) Other Costs & Benefits (Non-Monetized)	There are no non-monetized direct or indirect costs and benefits associated with the discretionary regulatory changes.	
(4) Assistance	There is no assistance that will be required by the agency for these regulatory changes.	
(5) Information Sources	VDH COPN Division; U.S. Bureau of Labor Statistics; DPB Fiscal Impact Statement for SB764.	

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)	**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

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)	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 Centers qualify as small businesses; however, entities that qualify as a "small business" can anticipate the impacts below: **Amended to include the new COPN exemptions and capital expenditure requirements.** • **Direct Monetized Benefit**: Projects that now qualify as exempt will not require a COPN, which will result in a benefit of not paying application fees and saving staff time creating and filing applications. To apply for a COPN, a fee must be paid, so projects that are exempt will not have an associated application fee. The average COPN application cost is $8,119.46 per application, and the estimated number of projects that would be removed from COPN review is 5.6 annually. • **Direct Monetized Cost**: The department will lose revenue due to the decrease in the number of fees paid that is estimated at $45,469 annually. • **Indirect Monetized Benefit**: The agency will potentially save staff time due to the potential reduction in the review load. Regulants that prepare these submissions will benefit from a cost savings due to the reduction of COPN application submissions for projects that are now exempt; the cost savings cannot be quantified due to the varying complexity of COPN applications, and the number of staff utilized by regulants to complete the application. • **Indirect Monetized Cost**: None **Amended to include the new registration requirements.** • **Direct Monetized Benefit**: Projects that now qualify as exempt will not require a registration, which will result in a benefit of saving staff time creating and filing registrations. • **Direct Monetized Cost**: None. • **Indirect Monetized Benefit**: None. • **Indirect Monetized Cost**: None. **Updated public hearing requirements to conform with 2020 changes.** • **Monetized Direct Benefits**: There is no longer a requirement for the regional health planning agency to hold at least one public hearing for a COPN application except in certain cases, such as competing applications. There were approximately 342 non-competing applications in the last 10 years, accounting for approximately 60% of all COPN applications received during that

	time period, so it can be estimated that the removal of that requirement will result in a decrease of public hearings. • **Monetized Direct Costs:** None. • **Monetized Indirect Benefits:** The reduction in the number of public hearings will yield a cost saving for the agency associated with the use of state cars, personal cars, and venue rental costs. • **Monetized Indirect Costs:** None. **Repealed 270 and created a new section 275, added required conditions of approval for a certificate of public need.** • **Monetized Direct Benefits**: None. • **Monetized Direct Costs:** Providers are now required to adhere to charity care conditions placed on the approval of a COPN. Providers who do not already provide charity care may incur a cost due to the requirement to accept patients who yield a lower reimbursement rate. This cost cannot be quantified by VDH as VDH is not aware of the number of providers that do not already provide charity care. The condition to provide a financial assistance policy to patients may yield a cost to providers and facilities, however, VDH is unable to quantify this as VDH is not aware of how many facilities and providers who do not provide a financial assistance policy already. • **Monetized Indirect Benefits:** None. • **Monetized Indirect Costs:** None. **Amended the noncompliance timeline.** • **Monetized Direct Costs**: The noncompliance timeline is now to be calculated from the day the certificate is issued instead of the day the noncompliance is cited. This will result in a cost to regulants who are noncompliant; however, VDH cannot quantify this cost. There are no monetized direct or indirect costs and benefits associated with the following regulatory changes: • **Updated definitions to adhere to the Code.** • **Repeal of sections entirely comprised of non-regulatory language.** • **Clarified that the application deadline is 5 p.m. on the due date, changed the submission date from 40 days prior to the beginning of the batch cycle to 10 days.** • **Updated the completeness provisions from 15 days to 10 days.** • **Updated regulation regarding the determination of completeness for an application conform to 2020 changes.** • **Updated batch cycle to match 2020 changes and corrected scrivener errors in batch groups.**

	• **Added required circumstances for revocation of a certificate of public need by the commissioner.** • **Added registrations to the grounds for refusing a license.** • **Added failure to register a project as cause for injunctive relief against a project.**	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) -$45,469	(b) +$45,469
(3) Other Costs & Benefits (Non-Monetized)	There are no non-monetized costs and benefits to small business.	
(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 and has limited these amendments to those mandated by the General Assembly.	
(5) Information Sources	VDH COPN Division; U.S. Bureau of Labor Statistics; DPB Fiscal Impact Statement for SB764.	

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
12.5.220.50	**Statutory:**	2 (G/S)		-2 (G/S)	-2
	Discretionary:				
12.5.220.60	**Statutory:**	11 (G/S)		-11 (G/S)	-11
	Discretionary:				
12.5.220.90	**Statutory:**				
	Discretionary:	3 (G/D)		-3 (G/D)	-3
12.5.220.100	**Statutory:**	2 (G/S) 3 (R/S)	+1 (R/S)		+1
	Discretionary:				
12.5.220.105	**Statutory:**	8 (R/S)	+17 (R/S)	-8 (R/S)	+9
	Discretionary:				
12.5.220.110	**Statutory:**	2 (G/S) 2(R/S)	+2 (R/S)		+2
	Discretionary:	2 (G/D) 4(R/D)			
12.5.220.140	**Statutory:**	2 (R/S)		-2 (R/S)	-2
	Discretionary:				
12.5.220.160	**Statutory:**	1 (G/S)		-1 (G/S)	-1
	Discretionary:				
12.5.220.180	**Statutory:**	1 (G/S) 1 (R/S)			-2
	Discretionary:	2 (G/D) 6 (R/S)	+1 (G/D)	-1 (G/D) -1 (R/D)	-1
12.5.220.190	**Statutory:**	3 (G/S)	+1 (G/S)	-1 (G/S)	0
	Discretionary:	3 (G/D) 4 (R/D)			
12.5.220.230	**Statutory:**	49 (G/S)	+7 (G/S)	-34 (G/S)	-27
	Discretionary:				
12.5.220.232	**Statutory:**		+12 (G/S)		+12
	Discretionary:				
12.5.220.234	**Statutory:**		+21 (G/S)		+21
	Discretionary:				
12.5.220.236	**Statutory:**		+1 (G/S)		+1
	Discretionary:				
	Statutory:	16 (G/S)		-16 (G/S)	-16

12.5.220.270	**Discretionary:**	4 (G/D)		-4 (G/D)	-4
12.5.220.275	**Statutory:**		+11 (G/S)		+11
	Discretionary:				
12.5.220.278	**Statutory:**		+5 (G/S)		+5
	Discretionary:				
12.5.220.280	**Statutory:**	8 (G/S)	+1 (G/S)	-2 (G/S)	-1
	Discretionary:				
12.5.220.290	**Statutory:**	10 (G/S)	+2 (G/S)	-3 (G/S)	-1
	Discretionary:		+2 (G/D)	-1 (G/D)	+1
12.5.220.325	**Statutory:**				
	Discretionary:	10 (G/D)		-6 (G/D)	-6
12.5.220.365	**Statutory:**	8 (G/S) 3 (R/S)	+1 (G/S)	-1 (G/S)	0
	Discretionary:				
12.5.220.385	**Statutory:**	49 (G/S)	+7 (G/S)	-34 (G/S)	-27
	Discretionary:				
12.5.220.388	**Statutory:**		+12 (G/S)		+12
	Discretionary:				
12.5.220.392	**Statutory:**		+21 (G/S)		+21
	Discretionary:				
12.5.220.394	**Statutory:**		+1 (G/S)		+1
	Discretionary:				
12.5.220.420	**Statutory:**				
	Discretionary:	11 (G/D)		-11 (G/D)	-11
12.5.220.425	**Statutory:**		+1 (G/S)		+1
	Discretionary:				
12.5.220.460	**Statutory:**		+1 (R/S)		+1
	Discretionary:	4 (R/D)		-2 (R/D)	-2
12.5.220.470	**Statutory:**	2 (G/S)	+6 (G/S)		+6
	Discretionary:				
12.5.220.480	**Statutory:**	1 (R/S)	+3 (G/S)		+3
	Discretionary:				
12.5.220.490	**Statutory:**	2 (G/S)	+1 (G/S)		+1
	Discretionary:				

Project 7636 - Fast-Track

Department of Health

Amend Regulation after Enactment of Chapter 1271 of the 2020 Acts of Assembly

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~~, including the donation or lease of a medical care facility~~. An acquisition of a medical care facility shall not include~~, but excluding 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 of public need, ~~and includes~~ including those factors that constitute a significant change as defined in this chapter~~. An amendment shall not include~~ , but excluding 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~~ that submits 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.~~ has the same meaning as ascribed to the term in § 32.1-102.1 of the Code of Virginia.

"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~~ on 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~~ including 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~~ on behalf of a medical care facility. Capital expenditures need not be made by a medical care facility so long as they are made ~~in~~ on behalf of a medical care facility by any person. ~~See definition of "person."~~

"Certificate" or "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.~~ has the same meaning as ascribed to the term "certificate" in § 32.1-102.1 of the Code of Virginia.

"Charity care" has the same meaning as ascribed to the term in § 32.1-102.1 of the Code of Virginia.

"Clinical health service" ~~means a single diagnostic, therapeutic, rehabilitative, preventive or palliative procedure as defined~~ has the same meaning as ascribed to the term 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~~ primary service area and ~~which~~ that 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 care 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.~~

"CT" means computed tomography.

"Date of issuance" means the date of the commissioner's decision awarding a certificate of public need.

"Day" means a calendar day. For purposes of project review, any scheduled deadlines that fall on a weekend or state holiday shall be advanced to the next work day.

"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~~ and excludes a meeting between the persons identified in (i) and staff of the department.

"General hospital" has the same meaning as ascribed to the term in 12VAC5-410-10.

"Good cause" means that (i) there is significant relevant information not previously presented at and not available at the time of the public hearing or by the close of the public comment period, (ii) there have been significant changes in factors or circumstances relating to the application subsequent to the public hearing or after the close of the public comment period, or (iii) there is a substantial material mistake of fact or law in the department staff's report on the application or in the report submitted by the health planning agency.

~~"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~~ has the same meaning as ascribed to the term in § 32.1-102.1 of the Code of Virginia.

"Hospital" has the same meaning as ascribed to the term in § 32.1-123 of the Code of Virginia.

"Informal fact-finding conference" means a conference held pursuant to § 2.2-4019 of the Code of Virginia.

"Initiation of construction" 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.

"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~~ has the same meaning as ascribed to the term in § ~~32.1-102.1~~ 32.1-3 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."~~

"MRI" means magnetic resonance imaging.

"Nursing home" has the same meaning as ascribed to the term in § 32.1-123 of the Code of Virginia.

"Operating expenditure" means any expenditure by or ~~in~~ on 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"~~ "Other plan" means any ~~plan(s)~~ plan that ~~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~~ 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" has the same meaning as ascribed to the term in § 32.1-3 of the Code of Virginia. ~~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.~~

"PET" means positron emission tomography.

~~"Physician's~~ "Physician office" means a place, owned or operated by a licensed physician or group of physicians practicing in any legal form whatsoever~~,~~ ~~which~~ that is designed and equipped solely for the provision of fundamental medical care, whether diagnostic, therapeutic, rehabilitative, preventive or palliative to ambulatory patients, and ~~which~~ that 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,~~ including soil testing, clearing, grading, and extension of utilities and power lines to the site.

"Primary medical care services" means a first-contact, whole-person medical and health ~~services~~ service delivered by broadly trained, generalist physicians, nurses, and other professionals~~, intended to include, without limitation,~~ including ~~obstetrics/gynecology~~ obstetrics and gynecology, family practice, internal medicine, and pediatrics.

"Primary service area" means the geographic territory from which at least 75% of patients come or are expected to come to an existing or proposed medical care facility, 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 an existing or proposed medical care facility.

"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.~~ action described in subsection B of § 32.1-102.1:3 of the Code of Virginia.

"Public hearing" means a proceeding conducted by a regional health planning agency or the department 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.

"RFA" means a request for applications.

"Rural" means any territory, population, ~~and~~ or housing ~~units~~ unit that ~~are~~ is 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~~ that:

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; or

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; or

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~~ "State Health Services Plan" means 12VAC5-230.

"Work day" means any day that is not a Saturday, Sunday, legal holiday, or day that the department is closed. For the purposes of this chapter, any day on which the Governor authorizes the closing of the state government shall be considered a legal holiday.

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, Virginia Register Volume 10, Issue 17, eff. June 15, 1994; amended, Virginia Register Volume 13, Issue 7, eff. January 24, 1997; Volume 14, Issue 12, eff. April 2, 1998; Volume 19, Issue 8, eff. February 3, 2003; Volume 20, Issue 26, eff. September 27, 2004; Volume 24, Issue 11, eff. March 5, 2008.

12VAC5-220-20. ~~Authority for regulations.~~ (Repealed.)

~~The Virginia Medical Care Facilities Certificate of Public Need Law, which is codified as Article 1.1 (§ 32.1-102.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia, requires the owners or sponsors of medical care facility projects to secure a certificate of public need from the State Health Commissioner prior to initiating such projects. Sections 32.1-102.2 and 32.1-12 of the Code of Virginia direct the Board of Health to promulgate and prescribe such rules and regulations as are deemed necessary to effectuate the purposes of this statute.~~

~~**Statutory Authority**~~

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

Historical Notes

Derived from VR355-30-000 § 2.1, eff. June 30, 1993; amended, Virginia Register Volume 10, Issue 17, eff. June 15, 1994; amended, Virginia Register Volume 13, Issue 7, eff. January 24, 1997.

12VAC5-220-30. ~~Purpose of chapter.~~ (Repealed.)

~~The board has promulgated this chapter to set forth an orderly administrative process for making public need decisions.~~

~~Statutory Authority~~

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

Historical Notes

Derived from VR355-30-000 § 2.2, eff. June 30, 1993; amended, Virginia Register Volume 10, Issue 17, eff. June 15, 1994.

12VAC5-220-40. ~~Administration of chapter.~~ (Repealed.)

~~This chapter is administered by the following:~~

~~1. The Board of Health is the governing body of the Virginia Department of Health. The Board of Health has the authority to promulgate and prescribe such rules and regulations as it deems necessary to effectuate the purposes of the Act.~~

~~2. The State Health Commissioner is the executive officer of the Virginia Department of Health. The commissioner is the designated decision maker in the process of determining public need under the Act.~~

~~Statutory Authority~~

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

Historical Notes

Derived from VR355-30-000 § 2.3, eff. June 30, 1993; amended, Virginia Register Volume 10, Issue 17, eff. June 15, 1994; amended, Virginia Register Volume 13, Issue 7, eff. January 24, 1997.

12VAC5-220-50. ~~Public meetings and public hearings.~~ (Repealed.)

~~All meetings and hearings convened to consider any certificate of public need application shall be open to the public in accordance with the provisions of the Virginia Freedom of Information Act (§ 2.1-340 et seq.) of the Code of Virginia.~~

~~Statutory Authority~~

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

Historical Notes

Derived from VR355-30-000 § 2.4, eff. June 30, 1993; amended, Virginia Register Volume 10, Issue 17, eff. June 15, 1994.

12VAC5-220-60. ~~Official records.~~ (Repealed.)

~~Written information including staff evaluations and reports and correspondence developed or utilized or received by the commissioner during the review of a medical care facility project shall become part of the official project record maintained by the Department of Health and shall be made available to the applicant, competing applicant and review bodies. Other persons may obtain a copy of the project record upon request. All records are subject to the Virginia Freedom of Information Act.~~

~~Statutory Authority~~

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

Historical Notes

Derived from VR355-30-000 § 2.5, eff. June 30, 1993; amended, Virginia Register Volume 10, Issue 17, eff. June 15, 1994.

12VAC5-220-70. ~~Application of chapter.~~ (Repealed.)

~~This chapter has general applicability throughout the Commonwealth. The requirements of the Virginia Administrative Process Act (§ 9-6.14:1 et seq.) of the Code of Virginia apply to their promulgation.~~

~~Statutory Authority~~

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

Historical Notes

Derived from VR355-30-000 § 2.6, eff. June 30, 1993; amended, Virginia Register Volume 10, Issue 17, eff. June 15, 1994; amended, Virginia Register Volume 13, Issue 7, eff. January 24, 1997.

12VAC5-220-80. ~~Powers and procedures of chapter not exclusive.~~ (Repealed.)

~~The commissioner and the board reserve the right to authorize any procedure for the enforcement of this chapter that is not inconsistent with the provisions set forth herein and the provisions of Article 1.1 (§ 32.1-102.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia.~~

~~Statutory Authority~~

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

Historical Notes

Derived from VR355-30-000 § 2.7, eff. June 30, 1993; amended, Virginia Register Volume 10, Issue 17, eff. June 15, 1994.

12VAC5-220-90. ~~Annual report.~~ (Repealed.)

~~Pursuant to § 32.1-102.12 of the Code of Virginia, the commissioner shall annually report to the Governor and the General Assembly on the status of Virginia's certificate of public need program.~~

~~Statutory Authority~~

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

Historical Notes

Derived from VR355-30-000 § 2.8, eff. June 30, 1993; amended, Virginia Register Volume 10, Issue 17, eff. June 15, 1994; amended, Virginia Register Volume 19, Issue 8, eff. February 3, 2003; Volume 26, Issue 2, eff. November 1, 2009.

Part II

Mandatory Requirements

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

A. ~~Prior to initiating a reviewable medical care facility project the~~ A ~~owner or sponsor~~ person shall obtain a certificate of public need or registration, as required by law, from the commissioner prior to initiating a project by or on behalf of a medical care facility. ~~In the case of an acquisition of an existing medical care facility, the notification requirement set forth in 12VAC5-220-120 shall be met.~~

B. Projects involving a temporary increase in the total number of beds in an existing hospital or nursing home shall be exempt from the requirement for a certificate, for a period of no more than 30 days, if the commissioner has determined that a natural or man-made disaster has caused the evacuation of a hospital or nursing home and that a public health emergency exists due to a shortage of hospital or nursing home beds.

C. A person shall be exempt from obtaining a certificate of public need for a project that:

1. Relocates up to 10 beds or 10 percent of the beds, whichever is fewer from one existing medical care facility to another existing medical care facility at the same site in any two-year period;

2. Uses up to 10 percent of beds as nursing home beds by a medical care facility that is licensed as a hospital; or

3. Relocates up to 10 beds or 10 percent of the beds, whichever is fewer from one existing medical care facility licensed as a nursing home to any other existing medical care facility licensed as a nursing home in any three-year period that is:

a. Owned or controlled by the same person; and

b. Located within the same planning district or within another planning district out of which at least 10 times the number of beds have been authorized by statute to be relocated from one or more medical care facilities in that other planning district and at least half of those beds have not been replaced.

D. A nursing home shall be exempt from obtaining a certificate of public need when the nursing home is affiliated with a facility that, on January 1, 1982, and thereafter:

1. Operates as a nonprofit institution;

2. Is licensed jointly by the department as a nursing home and by the Department of Social Services as an assisted living facility; and

3. Restricts the admissions such that:

a. Admissions to a facility are only allowed pursuant to the terms of a "life care contract" guaranteeing that the full complement of services offered by a facility are available to a resident as and when needed;

b. Admissions to an assisted living facility unit of a facility are restricted to individuals defined as ambulatory by the Department of Social Services; and

c. Admissions to a nursing home unit of a facility are restricted to an individual who is a resident at the assisted living unit of the facility.

Statutory Authority

§§ 32.1-12 ~~and~~, 32.1-102.2 , and 32.1-102.1:3 of the Code of Virginia.

Historical Notes

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

12VAC5-220-105. Requirements for registration of ~~the replacement of existing~~ medical equipment.

~~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.~~

A. A person shall register any capital expenditure for the purchase of new medical equipment for the provision of:

1. Lithotripsy;

2. Stereotactic radiosurgery;

3. Stereotactic radiotherapy performed using a linear accelerator or other medical equipment that uses concentrated doses of high-energy X-rays to perform external beam radiation therapy;

4. Obstetrical services;

5. Nuclear imaging services; or

6. Proton beam therapy.

B. A person shall register any capital expenditure for the replacement of medical equipment for the provision of:

1. Cardiac catheterization;

2. CT scanning;

3. MRI scanning;

4. Open heart surgery;

5. PET scanning;

6. Radiation therapy; or

7. Proton beam therapy.

C. The department may not require the registration of replacement medical equipment for the provision of:

1. Lithotripsy;

2. Stereotactic radiosurgery;

3. Nuclear imaging services;

4. Obstetrical services; or

5. Stereotactic radiotherapy performed using a linear accelerator or other medical equipment that uses concentrated doses of high-energy X-rays to perform external beam radiation therapy.

D. A person shall submit the registration for the purchase of medical equipment described in subsections A and B of this section in writing:

1. To the commissioner and the appropriate regional health planning agency;

2. At least 30 days before a person is contractually obligated to make a capital expenditure for the purchase of medical equipment;

3. Accompanied by the fee prescribed, if applicable; and

4. On forms available on the department's website that identify:

a. The specific unit of medical equipment to be replaced, if applicable;

b. The specific unit of medical equipment to be purchased;

c. The estimated capital cost of the medical equipment; and

d. If applicable, documentation that the equipment to be replaced has previously been authorized or exempted as allowed by law.

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.

12VAC5-220-110. Requirements for registration of certain capital expenditures.

A. ~~At least 30 days before any 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.~~ A person shall register in writing with the commissioner at least 30 days before the person is contractually obligated to make a capital expenditure at or on behalf of a:

1. General hospital if the capital expenditure is $5 million or more; and

2. Medical care facility that is not a general hospital if the capital expenditure is between $5 million and the amount established in subsection B of this section.

B. ~~The threshold contained in subsection A of this section shall be adjusted~~ The department shall determine the threshold amount for the registration of capital expenditures prescribed in subdivision A 2 of this section using the formula in this subsection and adjust the threshold 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."~~ A person shall submit information concerning:

1. The purpose of the expenditure; and

2. The projected impact that the expenditure will have upon the charges for services.

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.~~ The department shall annually:

1. Publish the threshold amount in the General Notices section of the Virginia Register of Regulations; and

2. Post the threshold amount on the department's website.

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.

12VAC5-220-140. ~~Requirements for health maintenance organizations (HMO).~~ (Repealed.)

~~An HMO must obtain a certificate of public need prior to initiating a project. Such HMO must also adhere to the requirements for the acquisition of medical care facilities if appropriate. See definition of "project" and 12VAC5-220-10.~~

~~**Statutory Authority**~~

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

Historical Notes

Derived from VR355-30-000 § 3.5, eff. June 30, 1993; amended, Virginia Register Volume 10, Issue 17, eff. June 15, 1994; amended, Virginia Register Volume 13, Issue 7, eff. January 24, 1997.

12VAC5-220-155. Requirements for the reporting of charity care.

A. ~~Every~~ If a medical care facility ~~subject to the requirements of Article 1.1 (§ 32.1-102.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia, other than a nursing home, that is not a medical care facility for which a certificate with conditions imposed pursuant to § 32.1-102.4 F of the Code of Virginia has been issued and that provides charity care, as defined in § 32.1-102.1 of the Code of Virginia,~~ has a certificate of public need with conditions imposed pursuant to subsection B of § 32.1-102.4 of the Code of Virginia and provides charity care, the medical facility shall ~~annually~~ report to the ~~commissioner~~ department annually the amount of charity care provided by submitting that information to the nonprofit organization described in § 32.1-276.4 of the Code of Virginia.

B. No provision of this section shall apply to a nursing home.

Statutory Authority

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

Historical Notes

Derived from Virginia Register Volume 35, Issue 24, eff. August 23, 2019.

12VAC5-220-160. ~~Required considerations.~~ (Repealed.)

~~In determining whether a public need exists for a proposed project, the applicable requirements of § 32.1-102.2:1 of the Code of Virginia will be considered.~~

~~**Statutory Authority**~~

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

Historical Notes

Derived from VR355-30-000 § 4.1, eff. June 30, 1993; amended, Virginia Register Volume 10, Issue 17, eff. June 15, 1994; Volume 19, Issue 8, eff. February 29, 2003; Volume 20, Issue 26, eff. September 27, 2004; Volume 25, Issue 1, eff. October 15, 2008; Volume 26, Issue 2, eff. November 1, 2009.

Part III

Standard Review Process

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~~,~~.

B. An applicant shall file a letter of intent by the later of:

~~(i)~~ 1. 30 days prior to the submission of an application for a project included within a particular batch group; or

~~(ii)~~ 2. 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~~ that are proposed for the same planning district or ~~medical~~ primary service area.

C. The letter shall identify the :

~~the owner,~~ 1. Owner;

~~the type~~ 2. Type of project for which an application is requested~~, and~~;

~~the proposed~~ 3. Proposed scope ~~(size)~~ of the project, including:

a. Number of beds; or

b. Number of equipment units; and

4. ~~location~~ Location of the proposed project.

D. The department shall ~~transmit application forms to the applicant within seven days of the receipt of the letter of intent~~ make the application forms available on its website. 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.~~ E. The department shall collect application fees for applications that request a certificate of public need. The fee required 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.

~~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~~ F. An applicant must submit an application to be received by the department no later than 5 p.m. on the 10th day 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~~ G. An applicant shall transmit ~~the document~~ an application 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, by hand, with a signed receipt to be provided.

H. No application shall be deemed to have been submitted until the 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, Virginia Register Volume 10, Issue 17, eff. June 15, 1994; amended, Virginia Register Volume 14, Issue 12, eff. April 2, 1998; Volume 19, Issue 8, eff. February 3, 2003; Volume 26, Issue 2, eff. November 1, 2009.

12VAC5-220-190. Review for completeness.

~~The applicant shall be notified by the department within 15 days following receipt of the application if additional information is required to complete the application or the application is complete as submitted. No application shall be reviewed until the department has determined that it is complete. To be complete,~~

A. The department shall consider an application complete if an applicant:

1. Answers all questions ~~must be answered~~ to the satisfaction of the commissioner in an application; ~~and~~

2. Supplies all requested documents in an application; and

3. Submits the application fee.

~~supplied, when applicable and the application fee submitted. Additional information required to complete an application shall be submitted to the department and the appropriate regional health planning agency at least five days prior to the first day of a review cycle to be considered complete for review in the same review cycle. (See 12VAC5-220-200.)~~

B. The department shall notify an applicant within 10 days following receipt of the application if the application is complete as submitted.

C. The department may not review an application until the application is determined to be complete.

Statutory Authority

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

Historical Notes

Derived from VR355-30-000 § 5.3, eff. June 30, 1993; amended, Virginia Register Volume 10, Issue 17, eff. June 15, 1994.

12VAC5-220-200. One hundred ninety-day review cycle.

A. The department shall review the following groups of completed applications in accordance with the following 190-day scheduled review cycles and the following descriptions of projects within each group, except as provided for in 12VAC5-220-220.

BATCH GROUP	GENERAL DESCRIPTION	REVIEW CYCLE	
		Begins	Ends
A	General Hospitals/ ~~Obstetrical Services/~~ Neonatal Special Care Services	Feb. 10 Aug. 10	Aug. 18 Feb. 16
B	Open Heart Surgery/Cardiac Catheterization/Ambulatory Surgery Centers/Operating Room Additions/Transplant Services	Mar. 10 Sep. 10	Sep. 16 Mar. 19
C	Psychiatric Facilities/Substance Abuse Treatment/ ~~Mental Retardation Facilities~~	Apr. 10 Oct. 10	Oct. 17 Apr. 18
~~D/F~~ D	Diagnostic Imaging Facilities/Services ~~Selected Therapeutic Facilities/Services~~	May 10 Nov. 10	Nov. 16 May 19
E	Medical Rehabilitation Beds/Services	June 10 Dec. 10	Dec. 17 Jun. 18
~~D/F~~ F/D	Selected Therapeutic Facilities/Services Diagnostic Imaging Facilities/Services	July 10 Jan. 10	Jan. 16 Jul. 18

G	~~Nursing Home Beds at Retirement Communities/Bed Relocations/Miscellaneous Expenditures by Nursing Homes~~ Nursing Homes/Intermediate Care Facilities for Individuals with Intellectual Disabilities	Jan. 10 Mar. 10 May 10 July 10 Sep. 10 Nov. 10	Jul. 18 Sep. 16 Nov. 16 Jan. 16 Mar. 19 May 19

B. Batch Group A includes:

1. The establishment of a general hospital~~.~~ ;

2. An increase in the total number of general acute care beds in an existing or authorized general hospital ~~.~~ ; and

~~3. The relocation at the same site of 10 general hospital beds or 10% of the general hospital beds of a medical care facility, whichever is less, from one existing physical facility to another in any two-year period if such relocation involves a capital expenditure with an expenditure exceeding the threshold amount as determined using the formula contained in subsection B of this section (see 12VAC5-220-280).~~

~~4.~~ 3. The introduction into an existing medical care facility of any new neonatal special care ~~or obstetrical~~ services that the facility has not provided in the previous 12 months.

~~5. Any capital expenditure with an expenditure exceeding the threshold amount as determined using the formula contained in subsection B of this section and not defined as a project category included in Batch Groups B through G, by or in behalf of a general hospital.~~

C. Batch Group B includes:

1. The establishment of a specialized center, clinic, or portion of a ~~physician's~~ physician office developed for the provision of outpatient or ambulatory surgery or cardiac catheterization services ~~.~~ ;

2. An increase in the total number of operating rooms in an existing medical care facility or establishment of operating rooms in a new facility ~~.~~ ;

3. The introduction into an existing medical care facility of any new cardiac catheterization, open heart surgery, or organ or tissue transplant services that the facility has not provided in the previous 12 months ~~.~~ ;

4. The addition by an existing medical care facility of any medical equipment for the provision of cardiac catheterization ~~.~~ ;

5. Any capital expenditure with an expenditure exceeding the threshold amount as determined using the formula contained in subsection ~~B~~ I of this section and not defined as a project category in Batch Group A or Batch Groups C through G, by or ~~in~~ on behalf of a specialized center, clinic, or portion of a ~~physician's~~ physician office developed for the provision of outpatient or ambulatory surgery or cardiac catheterization services ~~.~~ ; and

6. Any capital expenditure with an expenditure exceeding the threshold amount as determined using the formula contained in subsection ~~B~~ I of this section and not defined as a project category in Batch Group A or Batch Groups C through G, by or ~~in~~ on behalf

of a medical care facility, that is primarily related to the provision of surgery, cardiac catheterization, open heart surgery, or organ or tissue transplant services.

D. Batch Group C includes:

1. The establishment of a mental hospital, psychiatric hospital, intermediate care facility established primarily for the medical, psychiatric or psychological treatment and rehabilitation ~~of alcoholics or drug addicts~~ for individuals with substance use disorder, or ~~mental retardation facility.~~ individuals with intellectual disabilities;

2. An increase in the total number of beds in an existing or authorized mental hospital, psychiatric hospital, intermediate care facility established primarily for the medical, psychiatric or psychological treatment and rehabilitation ~~of alcoholics or drug addicts~~ for individuals with substance use disorder, or ~~mental retardation facility.~~ individuals with intellectual disabilities;

3. An increase in the total number of mental hospital, psychiatric hospital, ~~substance abuse~~ substance use disorder treatment and rehabilitation, or mental retardation beds in an existing or authorized medical care facility that is not a dedicated mental hospital, psychiatric hospital, intermediate care facility established primarily for the medical, psychiatric or psychological treatment and rehabilitation ~~of alcoholics or drug addicts~~ for individuals with substance use disorder, or ~~mental retardation facility.~~ individuals with intellectual disabilities;

~~4. The relocation at the same site of 10 mental hospital, psychiatric hospital, substance abuse treatment and rehabilitation, or mental retardation beds or 10% of the mental hospital, psychiatric hospital, substance abuse treatment and rehabilitation, or mental retardation beds of a medical care facility, whichever is less, from one existing physical facility to another in any two-year period if such relocation involves a capital expenditure with an expenditure exceeding the threshold amount as determined using the formula contained in subsection B of this section (see 12VAC5-220-280).~~

~~5.~~ 4. The introduction into an existing medical care facility of any new psychiatric or ~~substance abuse~~ substance use disorder treatment service that the facility has not provided in the previous 12 months ~~.~~ ;

~~6.~~ 5. Any capital expenditure with an expenditure exceeding the threshold amount as determined using the formula contained in subsection ~~B~~ I of this section and not defined as a project category in Batch Groups A and B or Batch Groups ~~D/F~~ D through G, by or ~~in~~ on behalf of a mental hospital, psychiatric hospital, intermediate care facility established primarily for the medical, psychiatric or psychological treatment and rehabilitation ~~of alcoholics or drug addicts~~ for individuals with substance use disorder, or ~~mental retardation facilities.~~ individuals with intellectual disabilities; and

~~7.~~ 6. Any capital expenditure with an expenditure exceeding the threshold amount as determined using the formula contained in subsection ~~B~~ I of this section and not defined as a project category in Batch Groups A and B or Batch Groups ~~D/F~~ D through G, by or in behalf of a medical care facility, ~~which~~ that is primarily related to the provision of mental health, psychiatric, ~~substance abuse~~ substance use disorder treatment or rehabilitation, or ~~mental retardation services~~ individuals with intellectual disabilities.

E. Batch Group ~~D/F~~ D includes:

1. The establishment of a specialized center, clinic, or ~~that~~ portion of a ~~physician's~~ physician office developed for the provision of ~~computed tomographic (CT)~~ CT scanning, ~~magnetic resonance imaging (MRI)~~ MRI scanning, ~~magnetic source imaging (MSI), positron emission tomographic (PET)~~ or PET scanning~~, or nuclear medicine imaging,~~

~~except for the purpose of nuclear cardiac imaging~~ that the medical care facility has not provided in the in the previous 12 months ~~.~~ ;

2. The introduction into an existing medical care facility of any new ~~computed tomography (CT)~~ CT scanning, ~~magnetic resonance imaging (MRI)~~ MRI scanning, ~~magnetic source imaging (MSI), positron emission tomographic (PET)~~ or PET scanning, or nuclear medicine imaging services, except for the purpose of nuclear cardiac imaging that the medical care facility has not provided in the previous 12 months ~~.~~ ;

3. The addition by an existing medical care facility of any equipment for the provision of ~~computed tomography (CT)~~ CT scanning, ~~magnetic resonance imaging (MRI)~~ MRI scanning, ~~magnetic source imaging (MSI),~~ or ~~positron emission tomographic (PET)~~ or PET scanning ~~.~~ that the medical care facility has not provided in the previous 12 months;

4. Any capital expenditure with an expenditure exceeding the threshold amount as determined using the formula contained in subsection ~~B~~ I of this section and not defined as a project category in Batch Groups A, B, C, E, and G, by or ~~in~~ on behalf of a specialized center, clinic, or ~~that~~ portion of a ~~physician's~~ physician office developed for the provision of ~~computed tomographic (CT)~~ CT scanning, ~~magnetic resonance imaging (MRI)~~ MRI scanning, ~~magnetic source imaging (MSI), positron emission tomographic (PET)~~ or PET scanning ~~, or nuclear medicine imaging, except that portion of a physician's office dedicated to providing nuclear cardiac imaging.~~ ; and

5. Any capital expenditure with an expenditure exceeding the threshold amount as determined using the formula contained in subsection ~~B~~ I of this section and not defined as a project category in Batch Groups A, B, C, E, and G, by or ~~in~~ on behalf of a medical care facility, ~~which~~ that is primarily related to the provision of ~~computed tomographic (CT)~~ CT scanning, ~~magnetic resonance imaging (MRI)~~ MRI scanning, ~~magnetic source imaging (MSI),~~ ~~positron emission tomographic (PET)~~ or PET scanning ~~, or nuclear medicine imaging, except for the purpose of nuclear cardiac imaging~~ .

F. Batch Group E includes:

1. The establishment of a medical rehabilitation hospital ~~.~~ ;

2. An increase in the total number of beds in an existing or authorized medical rehabilitation hospital ~~.~~ ;

3. An increase in the total number of medical rehabilitation beds in an existing or authorized medical care facility that is not a dedicated medical rehabilitation hospital ~~.~~ ;

~~4. The relocation at the same site of 10 medical rehabilitation beds or 10% of the medical rehabilitation beds of a medical care facility, whichever is less, from one existing physical facility to another in any two-year period, if such relocation involves a capital expenditure with an expenditure exceeding the threshold amount as determined using the formula contained in subsection B of this section (see 12VAC5-220-280).~~

~~5.~~ 4. The introduction into an existing medical care facility of any new medical rehabilitation service that the facility has not provided in the previous 12 months ~~.~~ ;

~~6.~~ 5. Any capital expenditure with an expenditure exceeding the threshold amount as determined using the formula contained in subsection ~~B~~ I of this section and not defined as a project category in Batch Groups A, B, C, ~~D/F~~ D, F/D , and G, by or ~~in~~ on behalf of a medical rehabilitation hospital ~~.~~ ; and

~~7.~~ 6. Any capital expenditure with an expenditure exceeding the threshold amount as determined using the formula contained in subsection ~~B~~ I of this section and not defined as a project category in Batch Groups A, B, C, ~~D/F~~ D, F/D , and G, by or ~~in~~ on behalf of a medical care facility, that is primarily related to the provision of medical rehabilitation services.

G. Batch Group ~~D/F~~ F/D includes:

1. The establishment of a specialized center, clinic, or ~~that~~ portion of a ~~physician's~~ physician office developed for the provision of ~~gamma knife surgery, lithotripsy, or~~ radiation therapy, stereotactic radiotherapy other than radiotherapy performed using a linear accelerator or other medical equipment that uses concentrated doses of high-energy x-rays to perform external beam radiation therapy, CT scanning, MRI scanning, or PET scanning that the medical care facility has not provided in the previous 12 months~~.~~;

2. Introduction into an existing medical care facility of any new ~~gamma knife surgery, lithotripsy, or~~ radiation therapy services, stereotactic radiotherapy other than radiotherapy performed using a linear accelerator or other medical equipment that uses concentrated doses of high-energy x-rays to perform external beam radiation therapy, CT scanning, MRI scanning, or PET scanning that the medical care facility has not provided in the previous 12 months~~.~~;

3. The addition by an existing medical care facility of any medical equipment for the provision of ~~gamma knife surgery, lithotripsy, or~~ radiation therapy, stereotactic radiotherapy other than radiotherapy performed using a linear accelerator or other medical equipment that uses concentrated doses of high-energy x-rays to perform external beam radiation therapy, CT scanning, MRI scanning, or PET scanning that the medical care facility has not provided in the previous 12 months~~.~~;

4. Any capital expenditure with an expenditure exceeding the threshold amount as determined using the formula contained in subsection ~~B~~ I of this section and not defined as a project in Batch Groups A, B, C, E, and G, by or ~~in~~ on behalf of a specialized center, clinic, or ~~that~~ portion of a ~~physician's~~ physician office developed for the provision of ~~gamma knife surgery, lithotripsy, or~~ radiation therapy, stereotactic radiotherapy other than radiotherapy performed using a linear accelerator or other medical equipment that uses concentrated doses of high-energy x-rays to perform external beam radiation therapy, CT scanning, MRI scanning, or PET scanning~~.~~; and

5. Any capital expenditure with an expenditure exceeding the threshold amount as determined using the formula contained in subsection ~~B~~ I of this section and not defined as a project in Batch Groups A, B, C, E, and G, by or ~~in~~ on behalf of a medical care facility, ~~which~~ that is primarily related to the provision of ~~gamma knife surgery, lithotripsy, or~~ radiation therapy, stereotactic radiotherapy other than radiotherapy performed using a linear accelerator or other medical equipment that uses concentrated doses of high-energy x-rays to perform external beam radiation therapy, CT scanning, MRI scanning, or PET scanning.

H. Batch Group G includes:

1. The establishment of a nursing home~~,~~ or intermediate care facility~~, or extended care facility~~ of a continuing care retirement community by a continuing care provider registered with the State Corporation Commission pursuant to Chapter 49 (§ 38.2-4900 et seq.) of Title 38.2 of the Code of Virginia~~.~~;

2. The establishment of a nursing home~~,~~ or intermediate care facility~~, or extended care facility~~ that does not involve an increase in the number of nursing home ~~facility~~ beds within a planning district~~.~~;

3. An increase in the total number of beds in an existing or authorized nursing home~~,~~ or intermediate care facility~~, or extended care facility~~ of a continuing care retirement community by a continuing care provider registered with the State Corporation Commission pursuant to Chapter 49 (§ 38.2-4900 et seq.) of Title 38.2 of the Code of Virginia~~.~~;

4. An increase in the total number of beds in an existing or authorized nursing home~~,~~ or intermediate care facility~~, or extended care facility~~ that does not involve an increase in the number of nursing home ~~facility~~ beds within a planning district~~.~~;

~~5. The relocation at the same site of 10 nursing home, or intermediate care facility, or extended care facility beds or 10% of the nursing home, intermediate care facility, or extended care facility beds of a medical care facility, whichever is less, from one physical facility to another in any two-year period, if such relocation involves a capital expenditure with an expenditure exceeding the threshold amount as determined using the formula contained in subsection B of this section (see 12VAC5-220-280).~~

~~6.~~ 5. Any capital expenditure with an expenditure exceeding the threshold amount as determined using the formula contained in subsection ~~B~~ I of this section and not defined as a project category in Batch Groups A through ~~D/F~~ F/D , by or ~~in~~ on behalf of a nursing home~~,~~ or intermediate care facility, ~~or extended care facility, which~~ that does not increase the total number of beds of the medical care facility~~.~~; and

~~7.~~ 6. Any capital expenditure with an expenditure exceeding the threshold amount as determined using the formula contained in subsection ~~B~~ I of this section and not defined as a project category in Batch Groups A through ~~D/F~~ F/D , by or ~~in~~ on behalf of a medical care facility, that is primarily related to the provision of nursing home~~,~~ or intermediate care, ~~or extended care services,~~ and does not increase the number of beds of the medical care facility.

~~B. The capital expenditure threshold referenced in subsection A of this section shall be adjusted~~ I. The department shall determine the threshold amount for capital expenditures prescribed in subsections B through H of this section using the formula in this subsection and adjust this threshold 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. Annually, the~~ J. The department shall annually:

1. ~~(i) publish~~ Publish the threshold amount in the General Notices section of the Virginia Register of Regulations; and

2. ~~(ii) post~~ Post the threshold amount on its website.

Statutory Authority

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

Historical Notes

Derived from VR355-30-000 § 5.4, eff. June 30, 1993; amended, Virginia Register Volume 10, Issue 17, eff. June 15, 1994; Volume 13, Issue 7, eff. January 24, 1997; Volume 14, Issue 12, eff. April 2, 1998; Volume 19, Issue 8, eff. February 3, 2003; Volume 20, Issue 2, eff. November 5, 2003; 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.

12VAC5-220-210. ~~Requests for application (RFA)~~ Request for applications.

A. The commissioner may request the submission of applications ~~for his consideration which~~ that address a specific need for services and facilities as identified in the ~~State Medical Facilities Plan~~ State Health Services Plan. The department shall ~~give notice of such RFA~~ :

1. Give notice of an RFA in a newspaper of general circulation in the locality or the planning district where the specific services or facility is requested ~~.~~ ;

~~Such notice shall be published~~ 2. Publish the notice at least 120 days prior to the first day of the appropriate review cycle for the type of project being requested ~~.~~ ; and

~~A~~ 3. Make available upon request a written copy of an RFA ~~shall also be available upon request from the department and the regional health planning agency in the appropriate geographic area~~.

B. The process for adoption of an RFA by the commissioner for projects listed in § 32.1-102.3:2 A, B, and C of the Code of Virginia are set forth in 12VAC5-220-335.

Statutory Authority

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

Historical Notes

Derived from VR355-30-000 § 5.5, eff. June 30, 1993; amended, Virginia Register Volume 10, Issue 17, eff. June 15, 1994; amended, Virginia Register Volume 13, Issue 7, eff. January 24, 1997; Volume 26, Issue 2, eff. November 1, 2009.

12VAC5-220-230. Review of ~~complete~~ completed application by the regional health planning agency.

A. ~~Review cycle. At the close of the work day on the tenth day of the month, the department shall provide written notification to applicants specifying the acceptance date and review schedule of completed applications, including the date for any informal fact-finding conference that may be held between the eightieth and ninetieth day of the review cycle.~~ The regional health planning agency shall:

1. Post notice of an application and a summary of the proposed project on the department's website within 10 calendar days following the start of the review cycle, to include:

a. Information about how comments may be submitted; and

b. The date the public comment period expires, which shall be no later than 45 calendar days following the date of the public notice;

~~conduct no more than two meetings, one of which must be a public hearing conducted by the regional health planning agency board or a subcommittee of the board and~~

2. Upon notification by the department of the acceptance date of a completed application:

a. Provide written notification of its review schedule to the applicant;

b. Notify by mail the local governing bodies in the planning district that may be affected by the proposed project; and

c. Give notice of the public hearing, if applicable, at least nine days prior to the public hearing, in a newspaper of general circulation in the county or city in which a project is proposed or a contiguous county or city that shall include:

(i) The date, time, and location of the public hearing ; and

(ii) The date, time, and location of the meeting where the regional health planning agency will make its final recommendation on an application;

3. Conduct a public hearing in the case of competing applications or in response to a written request by an elected local government representative, a member of the General Assembly, the commissioner, the applicant, or a member of the public;

4. Create a verbatim record of the public hearing that includes any comments of the local governing bodies of the planning district and all other public comments;

5. Maintain the verbatim record for at least one year following the final decision on a certificate of public need application and provide a copy of the verbatim record to the department;

~~provide~~ 6. Provide applicants with an opportunity, prior to the vote, to respond to any comments made about the project by the regional health planning agency staff, any information in a staff report, the comments of local governing bodies in the ~~health~~ planning district, all other public comments, or comments by those voting ~~in~~;

~~completing its~~ 7. Complete the review and recommendation by the ~~sixtieth~~ 60th day of the review cycle ~~.~~ or other period in accordance with the applicant's request for extension; and

8. Submit the health planning agency's recommendations on the application and the reasons for the recommendations to the department within 10 calendar days after the completion of the review or other period in accordance with the applicant's request for extension.

~~By the seventieth day of the review cycle, the department shall complete its review and recommendation of an application and transmit the same to the applicants and other appropriate persons. By the seventy-fifth day of the review cycle, the department shall transmit to the applicant and the appropriate other persons its determination whether an informal fact-finding conference is necessary. An informal fact-finding conference shall be held when (i) determined necessary by the department or (ii) requested by any person seeking to be made a party to the case for good cause. Any person seeking to be made a party to the case for good cause shall file, no later than four days after the department has completed its review and recommendation of an application and has transmitted the same to the applicants and to persons who have prior to the issuance of the report requested a copy in writing, written notification with the commissioner, applicants and other competing applicants, and regional health planning agency stating the grounds for good cause and providing the factual basis therefor under oath.~~

~~For purposes of this section, "good cause" means that (i) there is significant, relevant information not previously presented at and not available at the time of the public hearing, (ii) there have been significant changes in factors or circumstances relating to the application subsequent to the public hearing, or (iii) there is a substantial material mistake of fact or law in the department staff's report on the application or in the report submitted by the regional health planning agency. See § 32.1-102.6 of the Code of Virginia.~~

~~B. Time period for review. The review period shall begin on the first day of the applicable review cycle within which an application is determined to be complete, in accordance with scheduled batch review cycles described in 12VAC5-220-200. If the application is not determined to be complete for the applicable batch cycle within 40 calendar days from the date of submission, the application may be refiled in the next applicable batch cycle.~~

~~If the regional health planning agency has not completed its review by the sixtieth day of the review cycle, or such other period in accordance with the applicant's request for extension, and submitted its recommendation within 10 calendar days after the completion of its review, the department shall, on the eleventh day after expiration of the regional health planning agency's review period, proceed as if the regional health planning agency has recommended approval of the proposed project.~~

~~In any case in which an informal fact-finding conference is not held, the project record shall be closed on the earlier of (i) the date established for holding the informal fact-finding conference or (ii) the date that the department determines that an informal fact-finding conference is not necessary. See 12VAC5-220-230 A.~~

~~In any case in which an informal fact-finding conference is held, a date shall be established for closing of the record that shall not be more than 30 calendar days after the date for holding the informal fact-finding conference.~~

~~C. Determination by the commissioner. If a determination whether a public need exists for a project is not made by the commissioner within 45 calendar days of the closing of the record, the commissioner shall notify the applicant or applicants and any persons seeking to show good cause, in writing, that the application or the applications of each shall be deemed approved 25 calendar days after the expiration of such 45-calendar-day period, unless the receipt of recommendations from the person performing as hearing officer permits the commissioner to issue his case decision within that 25-calendar-day period. The validity or timeliness of the aforementioned notice shall not, in any event, prevent, delay or otherwise impact the effectiveness of this section.~~

~~In any case when a determination whether a public need exists for a project is not made by the commissioner within 70 calendar days after closing of the record, the application shall be deemed approved and a certificate shall be granted.~~

~~If a determination whether a public need for a project exists is not made by the commissioner within 45 calendar days of the closing of the record, any person who has filed an application competing in the relevant batch review cycle or who has filed an application in response to the relevant Request for Applications issued pursuant to 12VAC5-220-355 may, prior to the application being deemed approved, petition for immediate injunctive relief pursuant to § 2.2-4030 of the Code of Virginia, naming as respondents the commissioner and all parties to the case. During the pendency of proceeding, no applications shall be deemed to be approved. In such a proceeding, the provisions of § 2.2-4030 of the Code of Virginia shall apply.~~

~~Deemed approvals shall be construed as the commissioner's case decision on the application pursuant to the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia) and shall be subject to judicial review on appeal as the commissioner's case decision in accordance with such act.~~

~~Any person who has sought to participate in the department's review of such deemed-to-be-approved application as a person showing good cause who has not received a final determination from the commissioner concerning such attempt to show good cause shall be deemed to be a person showing good cause for purposes of appeal of a deemed-to-be-approved certificate.~~

~~In any appeal of the commissioner's case decision granting a certificate of public need pursuant to a Request for Applications issued pursuant to § 32.1-102.3:2 of the Code of Virginia, the court may require the appellant to file a bond pursuant to § 8.01-676.1 of the Code of Virginia, in such sum as shall be fixed by the court for protection of all parties interested in the case decision, conditioned on the payment of all damages and costs incurred in consequence of such appeal.~~

~~The applicants, and only the applicants, shall have the authority to extend any of the time periods for review of the application, which are specified in 12VAC5-220-230. If all applicants consent to extending any time period in this section, the commissioner, with the concurrence of the applicants, shall establish a new schedule for the remaining time periods.~~

~~For purposes of project review, any scheduled deadlines that fall on a weekend or state holiday shall be advanced to the next work day.~~

~~D. Regional health planning agency required notifications. Upon notification of the acceptance date of a complete application as set forth in subsection A of this section, the regional health planning agency shall provide written notification of its review schedule to the applicant. The regional health planning agency shall notify the local governing bodies in the planning district, health care providers and specifically identifiable consumer groups who may be affected by the proposed project directly by mail and shall also give notice of the public hearing in a newspaper of general circulation in such county or city wherein a project is proposed or a contiguous county or city at least nine days prior to such public hearing. Such notification by the regional health planning agency shall include: (i) the date and location of the public hearing which shall be conducted on the application except as otherwise provided in this chapter, in the county or city wherein a project is proposed or a contiguous county or city and (ii) the date, time, and place the final recommendation of the regional health planning agency shall be made. The regional health planning agency shall maintain a verbatim record of the public hearing that includes any comments of the local governing bodies of the health planning district and all other public comments. A copy of the verbatim record shall be provided to the department. Such public hearing record shall be maintained for at least a one-year time period following the final decision on a certificate of public need application. See definition of "public hearing."~~

~~E. Ex parte contact. After commencement of a public hearing and before a final decision is made, there shall be no ex parte contacts between the State Health Commissioner and any person acting on behalf of the applicant or holder of a certificate or any person opposed to the issuance or in favor of revocation of a certificate of public need, unless written notification has been provided. See definition of "ex parte."~~

B. If there is no regional health planning agency for the planning district in which a project is proposed, the department shall:

1. Post notice of an application and a summary of the proposed project on the department's website, which shall include:

a. Information about how comments may be submitted; and

b. The date the public comment period expires, which shall be no later than 45 calendar days following the date of the public notice;

2. Notify by mail the local governing bodies in the planning district that may be affected by the proposed project;

3. Give notice of the public hearing, if applicable, at least nine days prior to the public hearing, in a newspaper of general circulation in the county or city in which a project is proposed or a contiguous county or city that shall include:

a. Date, time, and location of the public hearing; and

b. Date, time, and location of the meeting where the department shall make its final recommendation on an application;

4. Conduct a public hearing in the case of competing applications or in response to a written request by an elected local government representative, a member of the General Assembly, the commissioner, the applicant, or a member of the public; and

5. Create a verbatim record of the public hearing that includes any comments of the local governing bodies of the planning district and all other public comments.

Statutory Authority

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

Historical Notes

Derived from VR355-30-000 § 5.7, eff. June 30, 1993; amended, Virginia Register Volume 10, Issue 17, eff. June 15, 1994; amended, Virginia Register Volume 13, Issue 7, eff. January 24,

1997; Volume 14, Issue 12, eff. April 2, 1998; Volume 19, Issue 8, eff. February 3, 2003; Volume 20, Issue 26, eff. September 27, 2004.

12VAC5-220-232. Review of completed application by the department.

A. The review period shall begin on the first day of the applicable review cycle within which an application is determined to be complete, in accordance with scheduled review cycles. If the department determines an application for the applicable review cycle to not be complete within 30 calendar days from the date of submission, the application may be refiled in the next applicable review cycle.

B. The department shall:

1. Provide written notification to an applicant no later than 5 p.m. on the first day of the review cycle that specifies:

a. The acceptance date of the completed application;

b. The review schedule of completed applications; and

c. The date for any informal fact-finding conference, which shall be held between the 80th and 90th day of the review cycle;

2. Complete the review and recommendation of a completed application by the 70th day of the review cycle that ensures:

a. The applicable requirements of subsection B of §32.1-102.3 of the Code of Virginia are considered; and

b. The recommendation is consistent with the most recent applicable provisions of the State Health Services Plan;

3. Notify the applicant and other appropriate persons of the recommendation by the 70th day of the review cycle;

4. Proceed as if the regional health planning agency has recommended approval of a project by the 71st day of the review cycle if the regional health planning agency has not:

a. Completed its review by the 60th day of the review cycle;

b. Completed its review in accordance with an applicant's request for extension, if applicable; or

c. Submitted its recommendation within 10 days after the completion of its review; and

5. Notify the applicant and other appropriate persons by the 75th day of the review cycle its determination whether an informal fact-finding conference is necessary.

C. The department shall hold an informal fact-finding conference if the department determines it to be necessary or if requested by any person seeking to be made a party to the case for good cause.

D. Any person seeking to be made a party to the case for good cause shall provide written notification stating the grounds and factual basis for good cause:

1. No later than four days after the department has completed its review and recommendation of an application has transmitted the same to the applicant and to other appropriate persons who have prior to the issuance of the report requested a copy; and

2. To the commissioner, applicants and other competing applicants, and regional health planning agency.

E. If an informal fact-finding conference is not held, the project record shall be closed on the earlier of the date:

1. Established for holding the informal fact-finding conference; or

2. That the department determines that an informal fact-finding conference is not necessary.

F. If an informal fact-finding conference is held, the presiding officer shall establish a date for closing of the project record that shall not be more than 30 calendar days after the date of the informal fact-finding conference.

Statutory Authority

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

12VAC5-220-234. Review of completed application by the commissioner.

A. After commencement of a public hearing and before a final decision is made, there shall be no ex parte contacts between the commissioner and any person acting on behalf of the applicant or holder of a certificate or any person opposed to the issuance or in favor of revocation of a certificate of public need, unless written notification has been provided pursuant to § 32.1-102.6 C of the Code of Virginia.

B. In determining whether a public need exists for a proposed project, the commissioner shall:

1. Consider all applicable requirements of subsection B of § 32.1-102.3 of the Code of Virginia; and

2. Ensure the determination is consistent with the most recent applicable provisions of the State Health Services Plan, except as provided in subsections C and D of this section.

C. Upon presentation of appropriate evidence, the commissioner may find that the provisions of the State Health Services Plan are:

1. Not relevant to a rural locality's needs;

2. Inaccurate;

3. Outdated;

4. Inadequate; or

5. Otherwise inapplicable.

D. If the commissioner makes a finding pursuant to subsection C of this section, the commissioner:

1. May make a determination whether a public need exists for a project consistent with that finding; and

2. Shall initiate procedures to make appropriate amendments to the State Health Services Plan.

E. The commissioner shall:

1. Provide written notice of the determination to the applicant and the regional health planning agency;

2. Issue the approved schedule and maximum capital expenditure for a project with the certificate of public need, if applicable; and

3. Include the following in the written determination:

a. The reasons for the determination;

b. The factors and bases considered in making the determination;

c. The remedies available for appeal of the determination; and

d. The progress reporting requirements, if applicable.

F. With the consent of the applicant, the commissioner may determine a public need exists for a portion of a project. The commissioner shall consult with the applicant prior to making the determination. The consultation may be subject to the ex parte provision of this section.

G. Except as provided in subdivision G 2 of this subsection, the commissioner shall make a determination whether a public need exists for a project no later than 45 days after the closing of the project record.

1. The commissioner shall notify in writing the applicants or any other persons seeking to show good cause that the application, or application of each, shall be deemed approved 25 days after the expiration of the 45-day period.

2. If the receipt of recommendations from the presiding officer does not permit the commissioner to make the determination by the 45th day after the closing of the project record but does permit the commissioner to make a determination by the 70th day after the closing of the project record, the commissioner shall notify in writing the applicants or any other persons seeking to show good cause.

3. The commissioner may combine the notices prescribed in subdivisions G 1 and G 2 of this section into a single notice, if applicable.

4. The validity or timeliness of any notice prescribed by this subsection may not, in any event, prevent, delay, or otherwise impact the effectiveness of this section.

H. If the commissioner has not made a determination whether a public need for a project exists by the 45th day of the closing of the project record, any person who has filed an application competing in the relevant review cycle or who has filed an application in response to the relevant RFA may, prior to the application being deemed approved, petition for immediate injunctive relief pursuant to § 2.2-4030 of the Code of Virginia.

1. The person petitioning for immediate injunctive relief shall name as respondents the commissioner and all parties to the case.

2. During the pendency of proceeding, no applications shall be deemed to be approved.

3. The provisions of § 2.2-4030 of the Code of Virginia shall apply to the proceeding.

I. An application shall be deemed approved and a certificate shall be granted if the commissioner does not make a determination whether a public need exists for a project by the 70th day after the closing of the project record.

Statutory Authority

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

12VAC5-220-236. Review period extensions.

A. An applicant may extend any of the time periods for review of the application prescribed in 12VAC5-220-230, 12VAC5-220-232, and 12VAC5-220-234. If there are competing applications, the applicants may extend any of the time periods of review of the applications only by mutual consent of all applicants.

B. If a time period for the review of an application has been extended pursuant to subsection A of this section, the commissioner shall establish a new schedule for the remaining time periods.

Statutory Authority

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

12VAC5-220-250. Amendment to an application.

~~The~~ A. An applicant ~~shall have the right to~~ may amend an application at any time.

~~Any~~ B. Except as otherwise provided in this chapter, if a public hearing is held, an amendment ~~which~~ that is made to an application following the public hearing and prior to the issuance of a certificate ~~unless otherwise specified in this chapter~~ shall:

~~constitute~~ 1. Constitute a new application; and

~~shall be~~ 2. Be subject to the review requirements set forth in Part ~~V~~ III of this chapter.

C. Except as otherwise provided in this chapter, if no public hearing is held, an amendment that is made to an application following the close of the public comment period and prior to the issuance of a certificate unless otherwise specified in this chapter shall:

1. Constitute a new application; and

2. Be subject to the review requirements set forth in Part III of this chapter.

D. If ~~such amendment is made~~ the applicant amends the application subsequent to the issuance of a certificate of public need, it shall be reviewed in accordance with 12VAC5-220-130.

Statutory Authority

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

Historical Notes

Derived from VR355-30-000 § 5.9, eff. June 30, 1993; amended, Virginia Register Volume 10, Issue 17, eff. June 15, 1994; amended, Virginia Register Volume 13, Issue 7, eff. January 24, 1997.

12VAC5-220-270. ~~Action on an application.~~ (Repealed.)

~~A. Commissioner's responsibility. Decisions as to approval or disapproval of applications or a portion thereof for certificates of public need shall be rendered by the commissioner. Any decision to issue or approve the issuance of a certificate shall be consistent with the most recent applicable provisions of the State Medical Facilities Plan. However, if the commissioner finds, upon presentation of appropriate evidence, that the provisions of either such plan are not relevant to a rural locality's needs, inaccurate, outdated, inadequate or otherwise inapplicable, the commissioner, consistent with such finding, may issue or approve the issuance of a certificate and shall initiate procedures to make appropriate amendments to such plan.~~

~~Conditions of approval. The commissioner may condition the approval of an application for a project (i) on the agreement by the applicant to provide an acceptable level of care at a reduced rate to indigents, or (ii) on the agreement of the applicant to provide care to persons with special needs, or (iii) upon the agreement of the applicant to facilitate the development and operation of primary medical care services in designated medically underserved areas of the applicant's service area. The terms of such agreements shall be specified in writing prior to the commissioner's decision to approve a project. Any person willfully refusing, failing or neglecting to honor such agreement shall be subject to a civil penalty of $100 per violation per day from the date of receipt from the department of written notice of noncompliance until the date of compliance. Upon information and belief that a person has failed to honor such agreement in accordance with this provision, the department shall notify the person in writing and 15 days shall be provided for response in writing including a plan for immediate correction. In the absence of an adequate response or necessary compliance or both, a judicial action shall be initiated in accordance with the provisions of § 32.1-27 of the Code of Virginia.~~

~~B. Notification process-extension of review time. The commissioner shall make a final determination on an application for a certificate of public need and provide written notification detailing the reasons for such determination to the applicant with a copy to the regional health planning agency within the time frames specified in 12VAC5-220-230 B unless authorization is given by the applicant or applicants to extend the time period. Such written notification shall also reference the factors and bases considered in making a decision on the application and, if applicable, the remedies available for appeal of such decision and the progress reporting requirements. The commissioner may approve a portion of a project provided the portion to be approved is agreed to by the applicant following consultation, which may be subject to the ex parte provision of this chapter, between the commissioner and the applicant.~~

~~Statutory Authority~~

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

Historical Notes

Derived from VR355-30-000 § 5.11, eff. June 30, 1993; amended, Virginia Register Volume 10, Issue 17, eff. June 15, 1994; amended, Virginia Register Volume 13, Issue 7, eff. January 24, 1997; Volume 19, Issue 8, eff. February 3, 2003.

12VAC5-220-275. Conditions of approval.

A. The commissioner shall condition the approval of an application for a project on the agreement of the applicant to:

1. Provide care to individuals who are eligible for benefits under:

a. Title XVIII of the Social Security Act (42 U.S.C. § 1395 et seq.);

b. Title XIX of the Social Security Act (42 U.S.C. § 1396 et seq.); and

c. 10 U.S.C. § 1071 et seq.; and

2. Either:

a. Provide an acceptable level of care at a reduced rate to indigents or accept patients requiring special needs;

b. Facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area; or

c. Both.

B. The commissioner may condition the approval of an application for a project on the agreement of the applicant to:

1. Comply with a schedule for completion; or

2. Comply with a maximum expenditure amount.

C. A certificate of public need holder shall:

1. Develop a financial assistance policy that includes specific eligibility criteria and procedures for applying charity care;

2. Provide the financial assistance policy to a patient at the time of admission, discharge, or at the time services are provided; and with any billing statement sent to an uninsured patient;

3. Post the financial assistance policy conspicuously in a public area of the medical care facility to which the certificate was issued; and

4. Post the financial assistance policy on a website maintained by the certificate holder.

D. The commissioner shall review the conditions imposed on a certificate of public need every 3 years. In determining whether a condition imposed on a certificate of public need is appropriate, the commissioner shall consider a change in circumstance of the certificate holder resulting from changes:

1. In the financing or delivery of health care services;

2. To the Commonwealth's program of medical assistance services; and

3. In other specific circumstances of the certificate holder.

E. The commissioner shall specify the conditions for approval in writing prior to the decision to approve a project.

Statutory Authority

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

12VAC5-220-278. Noncompliance with conditions.

A. A person refusing, failing, or neglecting to comply with the conditions on a certificate of public need shall be subject to a civil penalty of $100 per violation per day until the date of compliance.

B. For the purpose of determining the amount of a civil penalty imposed pursuant to this section, the date that the person began providing services in accordance with the original certificate of public need shall be the date from which the period of non-compliance shall be calculated.

C. The department shall notify a person in writing upon information and belief that a person has refused, failed, or neglected to comply with the conditions on a certificate of public need and the amount of the civil penalty imposed.

D. A person shall, within 15 days of receipt of the department's notification, provide a response in writing to the department that includes a plan for immediate correction.

E. In the absence of an adequate response, necessary compliance, or both, a judicial action shall be initiated in accordance with the provisions of § 32.1-27 of the Code of Virginia.

Statutory Authority

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

Part IV

Expedited Review Process

12VAC5-220-280. ~~Applicability~~ Criteria for expedited review.

~~Capital expenditures~~ A capital expenditure as contained in ~~subdivision 8 of "project" as defined in § 32.1-102.1~~ subdivision B 8 of § 32.1-102.1:3 of the Code of Virginia ~~or projects that involve relocation at the same site of 10 beds or 10% of the beds, whichever is less, from one existing physical facility to another, when the cost of such relocation is less than $5 million,~~ shall be subject to an expedited review process except when the full review process is requested by the applicant.

Statutory Authority

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

Historical Notes

Derived from VR355-30-000 § 6.1, eff. June 30, 1993; amended, Virginia Register Volume 10, Issue 17, eff. June 15, 1994; amended, Virginia Register Volume 14, Issue 12, eff. April 2, 1998; Volume 19, Issue 8, eff. February 3, 2003; Volume 26, Issue 2, eff. November 1, 2009.

12VAC5-220-290. Application ~~forms~~; review for completeness.

A. ~~Obtaining application forms. Application forms for an expedited review~~ The department shall ~~be available from the department upon the request of the applicant~~ make the application forms for an expedited review available on its website. ~~The department shall transmit application forms to the applicant within seven days of receipt of such request.~~

B. ~~Application fees.~~ The department shall collect an application ~~fees~~ fee pursuant to 12VAC5-220-180 for an ~~applications~~ application that ~~request~~ requests a certificate of public need under the expedited review process. ~~No application will be reviewed until the required application fee is paid as provided in 12VAC5-220-180 B.~~

C. The department shall consider an application complete if the applicant:

1. Answers all questions on an application;

2. Supplies all requested documents in an application; and

3. Submits the application fee.

D. The department shall notify an applicant within 10 days following receipt of the application if the application is complete as submitted.

E. The department may not review an application until the application is determined to be complete.

~~C. Filing application forms.~~ F. The department and the regional health planning agency shall:

~~All~~ 1. Review all expedited review requests for a certificate of public need in accordance with the expedited review process ~~shall be reviewed by the department and the regional health planning agency which shall each forward~~ ; and

2. Submit a recommendation to the commissioner within ~~40~~ 30 days from the date the submitted application has been deemed complete.

~~No application for expedited review shall be reviewed until the application form has been received by the department and the appropriate regional health planning agency, has been deemed complete, and the application fee has been paid to the department.~~

Statutory Authority

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

Historical Notes

Derived from VR355-30-000 § 6.2, eff. June 30, 1993; amended, Virginia Register Volume 10, Issue 17, eff. June 15, 1994; amended, Virginia Register Volume 14, Issue 12, eff. April 2, 1998.

12VAC5-220-310. Action on application.

A. ~~Decisions to approve any project under the expedited review process shall be rendered by the~~ The commissioner shall:

1. Render a decision to approve a project that is determined to meet the criteria for expedited review within 45 days of the determination that the application ~~the receipt of such completed request.~~

2. ~~The commissioner shall approve~~ Approve and issue a certificate for any project which is determined to meet the criteria for expedited review set forth in 12VAC5-220-280.

B. If the commissioner determines that a project does not meet the criteria for an expedited review ~~set forth in 12VAC5-220-280, the applicant will be notified~~ the commissioner shall notify the applicant in writing of ~~such~~ the determination within 45 days of the ~~receipt of such request~~ determination that the application is complete. ~~In such cases, the department will forward the appropriate forms to the project applicant for use in filing an application for review of a project in the appropriate review cycle in accordance with Part V of this chapter.~~

C. Any project ~~which~~ that the commissioner determines does not qualify for an expedited review ~~in accordance with 12VAC5-220-280, as determined by the commissioner,~~ shall be exempted from the requirements ~~of 12VAC5-220-180 A and B~~ in subsections A, B, C and E of 12VAC5-220-180 when ~~such~~ the project is filed for consideration in accordance with Part ~~V~~ III of this chapter.

Statutory Authority

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

Historical Notes

Derived from VR355-30-000 § 6.4, eff. June 30, 1993; amended, Virginia Register Volume 10, Issue 17, eff. June 15, 1994.

Part V

New Nursing Home Bed Review Process

12VAC5-220-325. Applicability.

~~The following categories of projects~~ A project ~~as determined by the State Health Commissioner shall be subject to the nursing home bed review process when they involve~~ that involves an increase in the number of nursing home ~~facility~~ beds in Virginia ~~. (For Continuing Care Retirement Community nursing home beds, see Part V (12VAC5-220-170 et seq.) of this chapter.)~~ shall be subject to the nursing home bed review process if the project:

1. ~~The establishment of~~ Establishes a nursing home ~~, intermediate care facility, or extended care facility,~~ except ~~when such~~ if the nursing home ~~, intermediate care facility, or extended care facility~~ is proposed by a continuing care retirement community and the project is sponsored by a continuing care provider registered with the State Corporation Commission pursuant to Chapter 49 (§ 38.2-4900 et seq.) of Title 38.2 of the Code of Virginia ~~.~~ ;

2. ~~An increase in~~ Increases the total number of beds in an existing or authorized nursing home ~~, intermediate care facility, or extended care facility~~, except ~~when~~ if the nursing home ~~, intermediate care facility, or extended care facility~~ is a component of a continuing care retirement community and the project is sponsored by a continuing care provider registered with the State Corporation Commission pursuant to Chapter 49 (§ 38.2-4900 et seq.) of Title 38.2 of the Code of Virginia ~~.~~ ;

3. ~~An increase in~~ Increases the total number of nursing home beds ~~, intermediate care facility beds, or extended care facility beds~~ in an existing or authorized medical care facility which is not a dedicated nursing home~~, intermediate care facility, or extended care facility.~~ ; or

4. ~~The introduction~~ Introduces into ~~any~~ an existing medical care facility ~~of any~~ a new nursing home service such as ~~intermediate care facility services, extended care facility services or~~ skilled nursing facility services ~~,~~ except ~~when such~~ if the medical care facility is an existing nursing home as defined in § 32.1-123 of the Code of Virginia.

Statutory Authority

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

Historical Notes

Derived from Virginia Register Volume 13, Issue 7, eff. January 24, 1997.

12VAC5-220-335. Request for ~~Applications (RFA)~~ applications.

A. Pursuant to § 32.1-102.3:2 A, B, and C of the Code of Virginia, ~~the commissioner shall periodically issue a Request for Applications (RFA). An RFA~~ the commissioner shall ~~be issued at least~~ issue an RFA annually.

~~A RFA from project applicants proposing projects which~~ B. An RFA that would ~~result in an~~ increase ~~in~~ the number of nursing home beds ~~are~~ provided shall be based on analyses of the need for increases in the nursing home bed supply in each ~~of Virginia's~~ planning ~~districts~~ district in accordance with the applicable standards included in the ~~State Medical Facilities Plan~~ State Health Services Plan. ~~Such RFAs~~

C. An RFA shall ~~also~~ include a schedule for the review of applications submitted in response to the RFA ~~which~~ that allows for at least 120 days between the day ~~on which~~ the RFA is issued and the first day of the review cycle for ~~such~~ the applications.

Statutory Authority

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

Historical Notes

Derived from Virginia Register Volume 13, Issue 7, eff. January 24, 1997; amended, Virginia Register Volume 26, Issue 2, eff. November 1, 2009.

12VAC5-220-365. Review for completeness.

~~The applicant shall be notified by the department within 15 days following receipt of the application if additional information is required to complete the application or the application is complete as submitted. No application shall be reviewed until the department has determined that it is complete. To be complete, all questions and information items requested on the application must be completely addressed and the application fee submitted. Additional information required to complete an application shall be submitted to the department and the appropriate regional health planning agency at least five days prior to the first day of the review cycle, as specified in the RFA, to be considered in the review cycle.~~

A. The department shall consider an application complete if an applicant:

1. Answers all questions to the satisfaction of the commissioner in an application;

2. Supplies all requested documents in an application; and

3. Submits the application fee.

B. The department shall notify an applicant within 10 days following receipt of the application if the application is complete as submitted.

C. The department may not review an application until the application is determined to be complete.

Statutory Authority

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

Historical Notes

Derived from Virginia Register Volume 13, Issue 7, eff. January 24, 1997.

12VAC5-220-385. Review of ~~complete~~ completed application by the regional health planning agency.

A. ~~Review cycle. At the close of the work day on the tenth day of the month, the department shall provide written notification to applicants specifying the acceptance date and review schedule of completed applications, including the date for any informal fact-finding conference that may be held between the eightieth and ninetieth day of the review cycle.~~ The regional health planning agency shall:

1. Post notice of an application and a summary of the proposed project on the regional health planning agency's website to include:

a. Information about how comments may be submitted; and

b. The date the public comment period expires;

~~conduct no more than two meetings, one of which must be a public hearing conducted by the regional health planning agency board or a subcommittee of the board and~~

2.Upon notification by the department of the acceptance date of a completed application:

a. Provide written notification of the review schedule to the applicant;

b. Notify by mail the local governing bodies in the planning district that may be affected by the proposed project; and

c. Give notice of the public hearing, if applicable, at least nine days before the public hearing, in a newspaper of general circulation in the county or city in which a project is proposed or a contiguous county or city that shall include:

(i) The date, time, and location of the public hearing ; and

(ii) The date, time, and location of the meeting where the regional health planning agency shall make the final recommendation on an application;

3. Conduct a public hearing in the case of competing applications or in response to a written request by an elected local government representative, a member of the General Assembly, the commissioner, the applicant, or a member of the public;

4. Create a verbatim record of the public hearing that includes any comments of the local governing bodies of the planning district and all other public comments;

5. Maintain the verbatim record for at least one year following the final decision on a certificate of public need application and provide a copy of the verbatim record to the department;

6. ~~provide~~ Provide applicants with an opportunity, prior to the vote, to respond to any comments made about the project by the regional health planning agency staff, any information in a staff report, the comments of local governing bodies in the ~~health~~ planning district, all other public comments, or comments by those voting ~~in~~;

7. ~~completing~~ Complete its review and recommendation by the ~~sixtieth~~ 60th day of the cycle~~.~~; and

8. Submit the health planning agency's recommendations on the application and the reasons for the recommendations to the department within 10 calendar days after the completion of its review or such other period in accordance with the applicant's request for extension.

~~By the seventieth day of the review cycle, the department shall complete its review and recommendation of an application and transmit the same to the applicants and other appropriate persons. By the seventy-fifth day of the review cycle, the department shall transmit to the applicant and the appropriate other persons its determination whether an informal fact-finding conference is necessary. An informal fact-finding conference shall be held when (i) determined necessary by the department or (ii) requested by any person seeking to be made a party to the case for good cause. Any person seeking to be made a party to the case for good cause shall file, no later than four days after the department has completed its review and recommendation of an application and has transmitted the same to the applicants and to persons who have prior to the issuance of the report requested a copy in writing, written notification with the commissioner, applicants and other competing applicants, and regional health planning agency stating the grounds for good cause and providing the factual basis therefor under oath.~~

~~For purposes of this section, "good cause" means that (i) there is significant, relevant information not previously presented at and not available at the time of the public hearing, (ii) there have been significant changes in factors or circumstances relating to the application subsequent to the public hearing, or (iii) there is a substantial material mistake of fact or law in the department staff's report on the application or in the report submitted by the regional health planning agency. See § 32.1-102.6 of the Code of Virginia.~~

~~B.Time period for review. The review period shall begin on the first day of the applicable review cycle within which an application is determined to be complete, in accordance with scheduled batch review cycles described in 12VAC5-220-200. If the application is not determined to be complete for the applicable batch cycle within 40 calendar days from the date of submission, the application may be refiled in the next applicable batch cycle.~~

~~If the regional health planning agency has not completed its review by the sixtieth day of the review cycle, or such other period in accordance with the applicant's request for extension, and submitted its recommendation within 10 calendar days after the completion of its review, the department shall, on the eleventh day after expiration of the regional health planning agency's~~

review period, proceed as if the regional health planning agency has recommended approval of the proposed project.

In any case in which an informal fact-finding conference is not held, the project record shall be closed on the earlier of (i) the date established for holding the informal fact-finding conference or (ii) the date that the department determines that an informal fact-finding conference is not necessary. See 12VAC5-220-230 A.

In any case in which an informal fact-finding conference is held, a date shall be established for closing of the record that shall not be more than 30 calendar days after the date for holding the informal fact-finding conference.

C. Determination by the commissioner. If a determination whether a public need exists for a project is not made by the commissioner within 45 calendar days of the closing of the record, the commissioner shall notify the applicant or applicants and any persons seeking to show good cause, in writing, that the application or the applications of each shall be deemed approved 25 calendar days after the expiration of such 45-calendar-day period, unless the receipt of recommendations from the person performing as hearing officer permits the commissioner to issue his case decision within that 25-calendar-day period. The validity or timeliness of the aforementioned notice shall not, in any event, prevent, delay or otherwise impact the effectiveness of this section.

In any case when a determination whether a public need exists for a project is not made by the commissioner within 70 calendar days after closing of the record, the application shall be deemed approved and a certificate shall be granted.

If a determination whether a public need for a project exists is not made by the commissioner within 45 calendar days of the closing of the record, any person who has filed an application competing in the relevant batch review cycle or who has filed an application in response to the relevant Request for Applications issued pursuant to 12VAC5-220-355 may, prior to the application being deemed approved, petition for immediate injunctive relief pursuant to § 2.2-4030 of the Code of Virginia, naming as respondents the commissioner and all parties to the case. During the pendency of proceeding, no applications shall be deemed to be approved. In such a proceeding, the provisions of § 2.2-4030 of the Code of Virginia shall apply.

Deemed approvals shall be construed as the commissioner's case decision on the application pursuant to the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia) and shall be subject to judicial review on appeal as the commissioner's case decision in accordance with such act.

Any person who has sought to participate in the department's review of such deemed-to-be-approved application as a person showing good cause who has not received a final determination from the commissioner concerning such attempt to show good cause shall be deemed to be a person showing good cause for purposes of appeal of a deemed-to-be-approved certificate.

In any appeal of the commissioner's case decision granting a certificate of public need pursuant to a Request for Applications issued pursuant to § 32.1-102.3:2 of the Code of Virginia, the court may require the appellant to file a bond pursuant to § 8.01-676.1 of the Code of Virginia, in such sum as shall be fixed by the court for protection of all parties interested in the case decision, conditioned on the payment of all damages and costs incurred in consequence of such appeal.

The applicants, and only the applicants shall have the authority to extend any of the time periods for review of the application, which are specified in 12VAC5-220-230. If all applicants consent to extending any time period in this section, the commissioner, with the concurrence of the applicants, shall establish a new schedule for the remaining time periods.

~~D. Regional health planning agency required notifications. Upon notification of the acceptance date of a complete application as set forth in subsection A of this section, the regional health planning agency shall provide written notification of its review schedule to the applicant. The regional health planning agency shall notify the local governing bodies in the planning district, health care providers and specifically identifiable consumer groups who may be affected by the proposed project directly by mail and shall also give notice of the public hearing in a newspaper of general circulation in such county or city wherein a project is proposed or a contiguous county or city at least nine days prior to such public hearing. Such notification by the regional health planning agency shall include: (i) the date and location of the public hearing which shall be conducted on the application except as otherwise provided in this chapter, in the county or city wherein a project is proposed or a contiguous county or city; and (ii) the date, time and place the final recommendation of the regional health planning agency shall be made. The regional health planning agency shall maintain a verbatim record of the public hearing that includes any comments of the local governing bodies of the health planning district and all other public comments. A copy of the verbatim record shall be provided to the department. Such public hearing record shall be maintained for at least a one-year time period following the final decision on a certificate of public need application. See definition of "public hearing."~~

B. If there is no regional health planning agency for the planning district in which a project is proposed, the department shall:

1. Post notice of an application and a summary of the proposed project on the department's website, which shall include:

a. Information about how comments may be submitted; and

b. The date the public comment period expires;

2. Notify by mail the local governing bodies in the planning district that may be affected by the proposed project;

3. Give notice of the public hearing, at least nine days before the public hearing, in a newspaper of general circulation in the county or city in which a project is proposed or a contiguous county or city that shall include:

a. The date, time, and location of the public hearing; and

b. The date, time, and location of the meeting where the department shall make the final recommendation on an application; and

4. Conduct a public hearing in the case of competing applications or in response to a written request by an elected local government representative, a member of the General Assembly, the commissioner, the applicant, or a member of the public;

5. Create a verbatim record of the public hearing that includes any comments of the local governing bodies of the planning district and all other public comments.

Statutory Authority

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

Historical Notes

Derived from Virginia Register Volume 13, Issue 7, eff. January 24, 1997; amended, Virginia Register Volume 14, Issue 12, eff. April 2, 1998; Volume 19, Issue 8, eff. February 3, 2003; Volume 20, Issue 26, eff. September 27, 2004.

12VAC5-220-388. Review of completed application by the department.

A. The review period shall begin on the first day of the applicable review cycle within which an application is determined to be complete, in accordance with scheduled review cycles. If the department determines an application for the applicable review cycle to not be complete within

30 calendar days from the date of submission, the application may be refiled in the next applicable review cycle.

B. The department shall:

1. Provide written notification to the applicant no later than 5 p.m. on the first day of the review cycle that specifies:

a. The acceptance date of the completed application;

b. The review schedule of completed applications; and

c. The date for any informal fact-finding conference, which shall be held between the 80th and 90th day of the review cycle;

2. Complete the review and recommendation of a completed application by the 70th day of the review cycle that ensures:

a. All applicable requirements of subsection B of §32.1-102.3 of the Code of Virginia are considered; and

b. The recommendation is consistent with the most recent applicable provisions of the State Health Services Plan;

3. Notify the applicant and other appropriate persons of the recommendation by the 70th day of the review cycle;

4. Proceed as if the regional health planning agency has recommended approval of a project by the 71st day of the review cycle if the regional health planning agency has not:

a. Completed its review by the 60th day of the review cycle;

b. Completed its review in accordance with an applicant's request for extension, if applicable; or

c. Submitted its recommendation within 10 days after the completion of its review; and

5. By the 75th day of the review cycle, notify the applicant and other appropriate persons of the determination whether an informal fact-finding conference is necessary.

C. The department shall hold an informal fact-finding conference if the department determines it to be necessary or if requested by any person seeking to be made a party to the case for good cause.

D. Any person seeking to be made a party to the case for good cause shall provide written notification stating the grounds and factual basis for good cause:

1. No later than four days after the department has completed its review and recommendation of an application has transmitted the same to the applicant and to other appropriate persons who have prior to the issuance of the report requested a copy; and

2. To the commissioner, applicants and other competing applicants, and regional health planning agency.

E. If an informal fact-finding conference is not held, the project record shall be closed on the earlier of the date:

1. Established for holding the informal fact-finding conference; or

2. That the department determines that an informal fact-finding conference is not necessary.

F. In any case in which an informal fact-finding conference is held, the presiding officer shall establish a date for closing of the project record that shall not be more than 30 calendar days after the date of the informal fact-finding conference.

Statutory Authority

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

12VAC5-220-392. Review of completed application by the commissioner.

A. After commencement of a public hearing and before a final decision is made, there shall be no ex parte contacts between the commissioner and any person acting on behalf of the applicant or holder of a certificate or any person opposed to the issuance or in favor of revocation of a certificate of public need, unless written notification has been provided pursuant to § 32.1-102.6 C of the Code of Virginia.

B. In determining whether a public need exists for a proposed project, the commissioner shall:

1. Consider all applicable requirements of subsection B of § 32.1-102.3 of the Code of Virginia; and

2. Ensure the determination is consistent with the most recent applicable provisions of the State Health Services Plan, except as provided in subsections C and D of this section.

C. Upon presentation of appropriate evidence, the commissioner may find that the provisions of the State Health Services Plan are:

1. Not relevant to a rural locality's needs;

2. Inaccurate;

3. Outdated;

4. Inadequate; or

5. Otherwise inapplicable.

D. If the commissioner makes a finding pursuant to subsection C of this section, the commissioner:

1. May make a determination whether a public need exists for a project consistent with that finding; and

2. Shall initiate procedures to make appropriate amendments to the State Health Services Plan.

E. The commissioner shall:

1. Provide written notice of the determination to the applicant and the regional health planning agency;

2. Issue the approved schedule and maximum capital expenditure for a project with the certificate of public need, if applicable; and

3. Include the following in the written determination:

a. The reasons for the determination;

b. The factors and bases considered in making the determination;

c. The remedies available for appeal of the determination; and

d. The progress reporting requirements, if applicable.

F. With the consent of the applicant, the commissioner may determine a public need exists for a portion of a project. The commissioner shall consult with the applicant prior to making the determination. The consultation may be subject to the ex parte provision of this section.

G. Except as provided in subdivision G 2 of this subsection, the commissioner shall make a determination whether a public need exists for a project no later than 45 days after the closing of the project record.

1. The commissioner shall notify in writing the applicants or any other persons seeking to show good cause that the application, or application of each, shall be deemed approved 25 days after the expiration of the 45-day period.

2. If the receipt of recommendations from the presiding officer does not permit the commissioner to make the determination by the 45th day after the closing of the project record but does permit the commissioner to make a determination by the 70th day after the closing of the project record, the commissioner shall notify in writing the applicants or any other persons seeking to show good cause.

3. The commissioner may combine the notices prescribed in subdivisions G 1 and G 2 of this section into a single notice, if applicable.

4. The validity or timeliness of any notice prescribed by this subsection may not, in any event, prevent, delay, or otherwise impact the effectiveness of this section.

H. If the commissioner has not made a determination whether a public need for a project exists by the 45th day of the closing of the project record, any person who has filed an application competing in the relevant review cycle or who has filed an application in response to the relevant RFA may, prior to the application being deemed approved, petition for immediate injunctive relief pursuant to § 2.2-4030 of the Code of Virginia.

1. The person petitioning for immediate injunctive relief shall name as respondents the commissioner and all parties to the case.

2. During the pendency of proceeding, no applications shall be deemed to be approved.

3. The provisions of § 2.2-4030 of the Code of Virginia shall apply to the proceeding.

I. An application shall be deemed approved and a certificate shall be granted if the commissioner does not make a determination whether a public need exists for a project by the 70th day after the closing of the project record.

Statutory Authority

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

12VAC5-220-394. Review period extensions.

A. An applicant may extend any of the time periods for review of the application prescribed in 12VAC5-220-385, 12VAC5-220-388, and 12VAC5-220-392. If there are competing applications, the applicants may extend any of the time periods of review of the applications only by mutual consent of all applicants.

B. If a time period for the review of an application has been extended pursuant to subsection A of this section, the commissioner shall establish a new schedule for the remaining time periods.

Statutory Authority

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

12VAC5-220-420. ~~Action on an application.~~ (Repealed.)

~~A. Commission's responsibility. Decisions as to approval or disapproval of applications or a portion thereof for certificates of public need shall be rendered by the commissioner. Any decision to issue or approve the issuance of a certificate shall be consistent with the most recent applicable provisions of the State Medical Facilities Plan. However, if the commissioner finds, upon presentation of appropriate evidence, that the provisions of such plan are not relevant to a rural locality's needs, inaccurate, outdated, inadequate or otherwise inapplicable, the commissioner, consistent with such finding, may issue or approve the issuance of a certificate and shall initiate procedures to make appropriate amendments to such plan.~~

~~The commissioner may condition the approval of an application for a project (i) on the agreement by the applicant to provide an acceptable level of care at a reduced rate to indigents or, (ii) on the agreement of the applicant to provide care to persons with special needs, or (iii) upon the agreement of the applicant to facilitate the development and operation of primary medical care services in designated medically underserved areas of the applicant's service area. The terms of such agreements shall be specified in writing prior to the commissioner's decision~~

~~to approve a project. Any person willfully refusing, failing or neglecting to honor such agreements shall be subject to a civil penalty of $100 per violation per day from the date of receipt from the department of written notice of noncompliance until the date of compliance. Upon information and belief that a person has failed to honor such agreement in accordance with this provision, the department shall notify the person in writing and 15 days shall be provided for a response in writing including a plan for immediate correction. In the absence of an adequate response or necessary compliance or both, a judicial action shall be initiated in accordance with the provisions of § 32.1-27 of the Code of Virginia.~~

~~B. Notification process -- extension of review time. The commissioner shall make a final determination on an application for a certificate of public need and provide written notification detailing the reasons for such determination to the applicant with a copy to the regional health planning agency within the time frames specified in 12VAC5-220-385 B unless an authorization is given by the applicants to extend the time period. Such written notification shall also reference the factors and bases considered in making a decision on the application and, if applicable, the remedies available for appeal of such decision and the progress reporting requirements. The commissioner may approve a portion of a project provided the portion to be approved is agreed to by the applicant following consultation, which may be subject to the ex parte provision of this chapter, between the commissioner and the applicant.~~

~~**Statutory Authority**~~

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

Historical Notes

Derived from Virginia Register Volume 13, Issue 7, eff. January 24, 1997; amended, Virginia Register Volume 19, Issue 8, eff. February 3, 2003.

12VAC5-220-425. Conditions of approval.

The commissioner may condition the approval of an application for a project on the agreement of the applicant to:

1. Comply with a schedule for completion; or

2. Comply with a maximum expenditure amount.

Statutory Authority

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

Part VI

Duration, Extension, and Revocation of Certificates

12VAC5-220-460. Revocation of certificate.

A. ~~Lack of progress. Failure of any~~ The commissioner shall revoke a certificate of public need for:

1. Failure to comply with the requirements of subsection A of § 32.1-102.4; or

2. Willfully or recklessly misrepresenting intentions or facts on obtaining a certificate of public need.

B. The commissioner may revoke a certificate of public need if:

1. A project fails to meet the progress requirements ~~stated in 12VAC5-220-450 shall be cause for certificate revocation~~, unless the commissioner determines sufficient justification exists to permit variance ~~, considering factors enumerated in 12VAC5-220-450.~~ ;

~~B. Failure to report progress. Failure of an~~ 2. An applicant fails to file progress reports on an approved project ~~in accordance with 12VAC5-220-450 shall be cause for revocation,~~

unless, ~~due to extenuating circumstances,~~ the commissioner ~~, in his sole discretion,~~ extends the certificate ~~, in accordance with subsection B of 12VAC5-220-440.~~ ;

~~C. Unapproved changes. Exceeding a capital expenditure amount not authorized by the commissioner or not consistent with the schedule of completion shall be cause for revocation. See definition of "significant change" and "schedule of completion."~~

~~D. Failure to initiate construction. Failure~~ 3. An applicant fails to initiate construction of the project within two years following the date of issuance of the certificate of public need ~~shall be cause for revocation~~, unless ~~due to extenuating circumstances~~ the commissioner extends the certificate~~, in accordance with subsection B of 12VAC5-220-440.~~ ; or

~~E. Misrepresentation. Upon determination that an applicant has knowingly misrepresented or knowingly withheld relevant data or information prior to issuance of a certificate of public need, the commissioner may revoke said certificate.~~

~~F. Noncompliance with assurances. Failure~~ 4. An applicant fails to comply with the assurances or intentions set forth in the application or written assurances provided at the time of issuance of a certificate of public need ~~shall be cause for revocation~~.

Statutory Authority

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

Historical Notes

Derived from VR355-30-000 § 7.4, eff. June 30, 1993; amended, Virginia Register Volume 10, Issue 17, eff. June 15, 1994; recodified, Virginia Register Volume 13, Issue 7, eff. January 24, 1997.

Part VII

Appeals

~~Part IX~~

~~Appeals~~

12VAC5-220-470. Judicial review.

A. Appeals to a circuit court shall be governed ~~by~~ pursuant to ~~the Virginia Administrative Process Act, (§ 2.2-4000 et seq. of the Code of Virginia,)~~ Article 5 (§ 2.2-4025 et seq.) of Chapter 40 of Title 2.2 of the Code of Virginia and Part Two A of the Rules of the Supreme Court of Virginia.

B. Deemed approvals shall be:

1. Construed as the commissioner's case decision on the application pursuant to the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia); and

2. Subject to judicial review on appeal as the commissioner's case decision in accordance with the act.

C. A person who sought to participate as a person showing good cause in the department's review of an application that was deemed approved and who did not receive a final determination from the commissioner concerning their alleged good cause shall be deemed to be a person showing good cause for purposes of an appeal of the deemed approval.

D. In an appeal of the commissioner's case decision granting a certificate of public need pursuant to an RFA issued pursuant to § 32.1-102.3:2 of the Code of Virginia, the court may require the appellant to file a bond pursuant to § 8.01-676.1 of the Code of Virginia:

1. In a sum fixed by the court for protection of all parties interested in the case decision; and

2. Conditioned on the payment of all damages and costs incurred in consequence of such appeal.

Statutory Authority

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

Historical Notes

Derived from VR355-30-000 § 8.1, eff. June 30, 1993; amended, Virginia Register Volume 10, Issue 17, eff. June 15, 1994; recodified, Virginia Register Volume 13, Issue 7, eff. January 24, 1997; amended, Virginia Register Volume 19, Issue 8, eff. February 3, 2003.

Part VIII

Sanctions

~~Part X~~

~~Sanctions~~

12VAC5-220-480. Violation of rules and regulations.

Commencing any project without a certificate or a registration required by this chapter shall constitute grounds for refusing to issue a license for ~~such~~ the project.

Statutory Authority

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

Historical Notes

Derived from VR355-30-000 § 9.1, eff. June 30, 1993; amended, Virginia Register Volume 10, Issue 17, eff. June 15, 1994; recodified, Virginia Register Volume 13, Issue 7, eff. January 24, 1997.

12VAC5-220-490. Injunctive relief.

On petition of the commissioner, the ~~Board of Health or~~ board, the Attorney General, or the circuit court of the county or city where a project is under construction or is intended to be constructed, located, or undertaken shall have jurisdiction to enjoin:

1. ~~any~~ Any project ~~which~~ that is constructed, undertaken, or commenced without a certificate or registration; ~~or to enjoin~~

2. ~~the~~ The admission of patients to the project; or ~~or to enjoin~~

3. ~~the~~ The provision of services through the project.

Statutory Authority

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

Historical Notes

Derived from VR355-30-000 § 9.2, eff. June 30, 1993; amended, Virginia Register Volume 10, Issue 17, eff. June 15, 1994; recodified, Virginia Register Volume 13, Issue 7, eff. January 24, 1997.

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

Laura Forlano, DO MPH
State Epidemiologist and Director
Office of Epidemiology

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: August 2, 2023

TO: Virginia State Board of Health

FROM: Laurie Forlano, DO, MPH – State Epidemiologist and Director of Epidemiology

SUBJECT: Final Stage for Disease Reporting Regulations (12VAC5-90): Amendment to comply with changes in public health practice

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The Regulations for Disease Reporting and Control provide information about the process and procedures for reporting diseases to the Virginia Department of Health (VDH), including what diseases must be reported, who must report them, and other details related to reporting and disease control. VDH received no public comments during the 60-day public comment period following the publication of the Proposed stage.

This Final stage amendment removes, edits, and adds definitions as necessary to reflect current public health definitions and needs; removes the requirement to report weekly counts of influenza diagnoses; modifies the timelines for laboratories to submit isolates or specimens for further public health laboratory testing to improve the viability of material available for testing; and replaces reporting by use of the Epi-1 form with reporting via an online web portal. The list of isolates or specimens that must be forwarded for further public health testing has been removed from 12VAC5-90-90 in this action because it is being added to 12VAC5-90-80 in a separate exempt regulatory action. The section on select agent reporting has been modified to clarify that VDH requires an annual report and an immediate report of a loss, theft, or release. Other, minor changes are listed in the Detail of Changes. This Final stage amendments also require ethnicity to be reported for all reportable diseases and updates the names of some reportable diseases. The final stage includes additional clarification to the flu reporting amendments. Additionally, the final stage includes adding the group of Orthopoxviruses together instead of listing them separately, and adding Monkeypox Virus to the group of Orthopoxviruses. The updates also include the requirement for those reporting outbreaks to provide identifying information including a person's name and phone number in the case of an outbreak.

Upon approval by the Board, it will be submitted for Executive Branch Review, publication in the Register of Regulations, and final adoption.

townhall.virginia.gov

Final Regulation
Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-90
VAC Chapter title(s)	Disease Reporting and Control Regulations
Action title	Amendment to comply with changes in public health practice
Date this document prepared	8/1/2023

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 Regulations for Disease Reporting and Control provide information about the process and procedures for reporting diseases to the Virginia Department of Health (VDH), including what diseases must be reported, who must report them and other details related to reporting and disease control. VDH is proposing an amendment to the regulations to bring them 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 amendment removes, edits, and adds definitions as necessary to reflect current public health definitions and needs; removes the requirement to report weekly counts of influenza diagnoses; modifies the timelines for laboratories to submit isolates or specimens for further public health laboratory testing to improve the viability of material available for testing; and replaces reporting by use of the Epi-1 form with reporting via an online web portal. The list of isolates or specimens that must be forwarded for further

public health testing has been removed from 12VAC5-90-90 in this action because it was added to 12VAC5-90-80 in a separate exempt regulatory action. The section on select agent reporting has been modified to clarify that VDH requires an annual report and an immediate report of a loss, theft, or release. Other, minor changes are listed in the Detail of Changes section.

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.

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 are used that are not defined in context.

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.

The impetus for this regulatory action is a board decision to bring the regulations into compliance with recent changes in the field of communicable disease detection and control, and to provide greater flexibility with respect to reporting requirements. The proposed changes will assure timelier reporting of diseases while at the same time reducing the overall burden of disease reporting.

Several changes were made since the Proposed stage to clarify reporting requirements for influenza for healthcare providers; to require persons in charge of certain programs to report additional information to facilitate public health investigation of reported outbreaks; to add Monkeypox Virus to the group of Orthopoxviruses that are required to be reported; and to maintain and amend the definition of "Lead, reportable levels," which had been stricken in the Proposed stage.

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.

Chapter 2 of Title 32.1 of the Code of Virginia, §§ 32.1-12 and 32.1-35 through 32.1-73, contains language authorizing the State Board of Health to promulgate the proposed regulations. Specifically, § 32.1-35 directs the Board of Health to promulgate regulations specifying which diseases occurring in the Commonwealth are to be reportable and the method by which they are to be reported.

Further, § 32.1-42 of the Code of Virginia authorizes the Board of Health to promulgate regulations and orders to prevent a potential emergency caused by a disease dangerous to public health. The Board of Health is empowered to adopt such regulations as are necessary to carry out provisions of laws of the Commonwealth administered by the state health commissioner by § 32.1-12 of the Code of Virginia.

Chapter 293 of the 2019 Acts of Assembly expanded the reporting of health care-associated infections beyond just those that originate in a hospital to include other healthcare facilities. This action incorporates that change.

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 proposed changes are essential to protect the health and safety of citizens because they will improve the ability of VDH to conduct disease surveillance and implement disease control for conditions of public health concern. The changes will position the agency to better detect and respond to these illnesses to protect the health of the public. The changes also clarify and reduce the burden of influenza reporting for healthcare providers

Substance

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

The amendments will:

- Add, remove, and update definitions to enhance clarity;
- Specify new timelines for submission of isolates or specimens for state public health laboratory testing;
- Remove the list of isolates or specimens that must be forwarded for public health laboratory testing from 12VAC5-90-90 in this action because the list was added to 12VAC5-90-80 in another regulatory action;
- Remove the requirement that physicians and directors of medical care facilities submit weekly counts of cases of influenza and clarify that only confirmed cases of influenza are required to be reported;
- Replace reporting by way of the Epi-1 form with reporting through the VDH's online morbidity reporting portal;

- Add language that states that if a laboratory ascertains that the reference laboratory that tests a specimen reports to VDH electronically, then those reference laboratory findings do not need to be reported by the laboratory of origin;
- Add language that clarifies that if a facility director reports on behalf of the laboratory, the laboratory is still responsible for submitting isolates or specimens for public health testing "unless the laboratory has submitted an exemption request that has been approved by the department", thereby providing a process for opting out of the specimen forwarding requirement;
- Clarify the requirement for a laboratory to report the type of influenza virus isolated, if that is available, by changing the term "should" to "shall."
- Remove language referencing the commissioner's role in enforcement of isolation and quarantine because it has been removed from the Code of Virginia;
- Modify language to refer only to medications that are available in the United States for the treatment of ophthalmia neonatorum;
- Clarify that confirmatory testing is not required for blood lead levels that are below the CDC reference range on screening test;
- Limit the reporting of select agents to only an annual report and those scenarios in which such agents are released, lost, or stolen;
- Require that health care facilities share with VDH any data they supply to CDC as a result of a requirement of the Centers for Medicare and Medicaid Services and not limited to the Hospital Inpatient Quality Reporting Program of that agency
- Refine language related to Orthopoxviruses, by grouping the Orthopoxviruses together (adding Monkeypox Virus) and removing the separate listing of Variola (smallpox) and Vaccinia.
- Require outbreak reporting to include patient information allowing for improved surveillance and investigation.
- Require disease reporting to include patient ethnicity and phone number.

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 the improved ability of the agency to control the risk of disease in the community based on timelier reporting through VDHs online morbidity reporting portal as well as removing the requirement to report weekly influenza counts or to report routine, non-emergency changes in select agent inventory. No disadvantages have been identified. The primary advantage to the agency is that the proposed changes improve the focus of disease surveillance and ability of VDH to conduct surveillance and implement disease control for conditions of public health concern in a timely manner. The changes will position the agency to better detect and respond to these illnesses to protect the health of the public. No disadvantages have been identified.

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.

None of these requirements is more restrictive than 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.

Other State Agencies Particularly Affected

The Division of Consolidated Laboratory Services (DCLS) will receive isolates or specimens from other laboratories in a more timely fashion.

Localities Particularly Affected

Any impact of these changes is anticipated to be the same for all localities.

Other Entities Particularly Affected

All healthcare providers and medical care facilities who are subject to these regulations would be equally impacted by these amendments.

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.

There were no public comments received during the Proposed Stage of this Action.

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

***12VAC 5-90-10		Definitions	Add definition of “Influenza, laboratory-confirmed”	**Change:** A laboratory-confirmed influenza test was not previously defined, but is included here. **Intent:** To reduce confusion for healthcare providers about which tests they should report. **Rationale:** Previous feedback indicates that there is a need for improved clarity regarding which influenza tests need to be reported. **Likely Impact:** Only laboratory-confirmed tests should be reported. Rapid antigen tests will not be reported, reducing the burden to physicians.
12VAC5-90-10			Retain definition of “Lead, reportable levels” and add “blood”	**Change:** Retain and add “blood” to “Lead, reportable blood levels” where it previously said “Lead, reportable levels” **Intent:** To clarify what should be reported **Rationale:** The phrase, “Lead, reportable levels” was not previously found in the regulations **Likely Impact:** reportable blood levels is more clearly defined for physicians
12VAC5-90-80		In subsections B and C, update: “Influenza, laboratory-confirmed"		**Change:** add “laboratory” to the reportable disease list, where it previously said “Influenza, confirmed” **Intent:** Clarify which tests are reportable for healthcare providers and laboratories, consistent with the updated definition **Rationale:** Previous feedback indicates that which influenza tests need to be reported was not clear. **Likely Impact:** Only laboratory-confirmed tests should be reported, reducing the burden to Physicians
12VAC5-90-80		Rename Lead, reportable levels		**Change:** “Lead, blood levels” to “Lead, reportable blood levels” **Intent:** ensure language is consistent with definition section

				Rationale: previously, the phrase in the definition was not consistent with the language in the disease list **Likely Impact:** Ensure clarity for healthcare providers
***12VAC 5-90-80**		Group the Orthopoxviruses together in one category, and remove their separate listing. Include Monkeypox virus to the list of Orthopoxviruses to report.		**Change:** Orthopoxviruses are now just one category (including 4 individual viruses), and Monkeypox Virus has been added to that category. **Intent:** Grouping Orthopoxviruses together streamlines the reportable disease list. Adding Monkeypox virus improves VDH's ability to respond to the present mpox epidemic and future Orthopoxvirus outbreaks. **Rationale:** Monkeypox virus was a previously reportable disease that was removed when it was no longer a threat to the United States. The current global outbreak indicates the need to add it back to the list. **Likely Impact:** VDH can more efficiently respond to Orthopoxvirus outbreaks.
12VAC5-90-80		Lists of diseases that shall be reported	In subsections E, I, J update disease reporting website URL	**Change:** Insert updated url: https://www.vdh.virginia.gov/clinicians/disease-reporting-and-control-regulations/ **Intent:** The intent is to provide a link with quicker, more direct access to the referenced portal. **Rationale:** This will reduce confusion for reporters by linking the more specific URL. **Likely Impact:** Reporters will find the portal quicker and with less confusion.
***12VAC 5-90-90**		In subsection A, add telephone number to the list of identifying information for Physicians to report		**Change:** Add telephone number to the list of patient information that physicians report **Intent:** The intent is to allow for more efficient patient follow-up and to standardize the information provided to VDH about patients in an outbreak, under VDH's current authority. **Rationale:** This information is reported for coronavirus disease 2019 in section 90-80-

				l and improves consistency in reporting requirements. **Likely Impact:** VDH will have more efficient access to patients and will be able to conduct quicker and more robust contact tracing and case investigation in the case of outbreaks or other communicable disease threat of public health interest.
12VAC5-90-90		Those required to report	In subsection A, simplify the language about how to submit reports to VDH and in subsections A and F, update URL	**Change:** Add updated URL and made language more concise. **Intent:** The intent is to show the best URL to find all reporting options for diseases and remove additional confusing language. **Rationale:** Removing the last sentence will reduce confusion, in line with the intent of the original changes to this section. **Likely Impact:** Reduce confusion and simplify electronic reporting requirements for physicians.
***12VAC 5-90-90**		Those required to report	In subsection H, formalize the patient information reporting requirement for outbreaks by changing “may report” to “shall report” and clarifying which information should be reported	**Change:** Replace “may” with “shall” in the current language and clarify that the identifying information must include the names and telephone numbers of the individuals involved in the outbreak. **Intent:** The intent is to allow for more efficient patient follow-up during an outbreak and to standardize the information provided to public health **Rationale:** This information is often requested as a follow-up to a reported outbreak and requiring it with the report would improve efficiency in outbreak investigation. **Likely Impact:** There will be more efficient follow-up with affected individuals in the case of an outbreak or suspected outbreak.
12VAC5-90-140			Style and form changes	**Change:** The term “newborn baby” is changed to “infant” for the purposes of consistency of terminology, and a sentence is consolidated to be more concise.

				Intent: The intent is to conform the language to the Registrar of Regulations' style and form requirements. **Rationale:** Following the style and form requirements ensures that statewide regulatory language is consistent, concise, and clear. **Likely Impact:** The language will be more concise and readable.
12VAC5-90-80, -90, -103, -107, -140, -215, 225, -280, -370		Style and Form changes		**Change:** A number of other non-substantive changes were made to the style and form of the language. **Intent:** The intent is to conform the language to the Registrar of Regulations' style and form requirements. **Rationale:** Following the style and form requirements ensures that statewide regulatory language is consistent, concise, and clear. **Likely Impact:** The language will be more readable.

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
12VAC5-90-10		Definitions	• *Healthcare-associated infection (also known as nosocomial infection) –Replaced the term "hospital" with "medical care facility" to reflect infections that may occur in hospitals or nursing homes. • Hepatitis C, acute – Remove definition. This definition was needed when this infection was

			newly defined, but now the disease is better recognized and understood. • Hepatitis C, chronic – Remove definition. The infection is well understood in the regulated community so the definition is no longer needed. • Influenza, laboratory confirmed – Add definition for what a laboratory confirmed test means, which was previously undefined. • *Influenza A, novel virus – Modify definition to indicate that genetic reassortment of human and animal influenza viruses represent novel virus. Helps more clearly define what is meant by influenza A novel virus. • Isolation (all definitions)- changed to "an individual" to simplify language and ensure consistency with registrar's previous recommendations • Lead, reportable levels – update phrasing to "Lead, reportable blood levels" • *Tubercle bacilli – Modify definition to include Mycobacterium bovis, Mycobacterium canetti, Mycobacterium microti, and Mycobacterium caprae as additional species included in the Mycobacterium tuberculosis complex. More clearly defines the tubercle bacilli of interest. • Tuberculin skin test (TST) – Remove definition. No longer needed because reporting is based on a positive result from any test. • Tuberculosis – Remove definition. This definition is not needed because more specific definitions for TB active disease and infection are already included in the regulations. • Tuberculosis, active disease – In the definition, change from "disease" to "communicable disease" to indicated that TB is spread from person to person. • *Tuberculosis infection in children age <4 years – Modify definition name to Tuberculosis infection to account for the change being made in a separate regulatory action to require reporting of tuberculosis infection among all ages, not just persons <4 years of age. Also change "tuberculin skin testing" to "positive result from a test for tuberculosis infection" to reflect a broader range of acceptable diagnostic test types.
12VAC5-90-80		Directors of laboratories	• *Change from submitting the isolate or clinical specimen within seven days to the Division of Consolidated Laboratory or other specified public health laboratory to submitting the

			isolate within five days and the clinical specimen within two days of a positive result.
12VAC5-90-80		Submission of initial isolate or other specimen for further public health testing.	• Change Enterobacteriaceae to Enterobacterales
12VAC5-90-80		Lists of diseases that shall be reported	• Change: add "laboratory" to the reportable disease list, where it previously said "Influenza, confirmed" • Intent: Clarify which tests are reportable for healthcare providers and laboratories, consistent with the updated definition • Rationale: Previous feedback indicates that which influenza tests need to be reported was not clear. • Impact: Only laboratory-confirmed tests should be reported, reducing the burden to physicians
12VAC5-90-80		Lists of diseases that shall be reported	• *Change: Orthopoxviruses are now just one category (including 4 individual viruses), and Monkeypox Virus has been added to that category. • Intent: Grouping Orthopoxviruses together streamlines the reportable disease list. Adding Monkeypox virus improves VDH's ability to respond to the present mpox epidemic and future Orthopoxvirus outbreaks. • Rationale: Monkeypox virus was a previously reportable disease that was removed when it was no longer a threat to the United States. The current global outbreak indicates the need to add it back to the list. • Impact: VDH can more efficiently respond to Orthopoxvirus outbreaks.
12VAC5-90-80		Lists of diseases that shall be reported	• Change: Insert updated url: https://www.vdh.virginia.gov/clinicians/disease-reporting-and-control-regulations/ in sections E, I, and J • Intent: ensure reporters get all correct information • Rationale: This will reduce confusion for reporters by showing them the more specific URL.
12VAC5-90-90		Physicians	• *Adds ethnicity and telephone number to disease reports as a required field • *Clarify that the list of elements to be reported on a case (e.g., name, address) represent the minimum reporting requirements. • *Remove language stating that influenza should be reported by number of cases only. This is no longer required under this proposal.

			• Language added to reflect morbidity reporting through VDH's online morbidity reporting portal. • Add language referring to "disease-specific" surveillance form instead of surveillance form. • Modify language to reflect that reporting timeframes are as established in 12VAC5-90-80 rather than listing them again in this subsection.
12VAC5-90-90		Physicians	• Change: Add updated URL and remove extra language • Intent: Show the best URL to find all reporting options for diseases and remove additional confusing language. • Rationale: Removing the last sentence will reduce confusion, in line with the intent of the original changes to this section. • Impact: Reduce confusion and simplify electronic reporting requirements for physicians.
12VAC5-90-90		Directors of laboratories	• *Adds ethnicity as a required field • Language added that if a laboratory ascertains that the reference laboratory that tests a specimen reports to VDH electronically, then those reference laboratory findings do not need to be reported by the laboratory of origin. • Language added to reflect morbidity reporting through VDH's online morbidity reporting portal. • Modify language to reflect that reporting timeframes are as established in 12VAC5-90-80 rather than listing them again in this subsection. • Clarify requirement to report type of influenza virus isolated when reporting an influenza case, if it is available. • Language in subsection B pertaining to the submission of an initial isolate or other initial specimen to DCLS has been stricken because it has been updated and moved to 12VAC5-90-80 in a separate exempt regulatory action. • *Add language that clarifies that if a facility director reports on behalf of the laboratory, the laboratory is still responsible for submitting isolates or specimens for public health testing "unless the laboratory has submitted an exemption request that has been approved by the department".

12VAC5-90-90		Persons in charge of a medical facility	• *Adds ethnicity as a required field • *Remove language stating that influenza should be reported by number of cases only. This is no longer required under this proposed amendment. • Modify language to reflect that reporting timeframes are as established in 12VAC5-90-80 rather than listing them again in this subsection. • Add language to reflect morbidity reporting through VDH's online morbidity reporting portal. • Add language referring to "disease-specific" surveillance forms instead of surveillance forms.
12VAC5-90-90		Persons in charge of hospitals, nursing facilities or nursing homes, assisted living facilities, and correctional facilities	• List reportable organisms next to disease names so the reportable disease lists are equally meaningful to practicing clinicians and laboratorians.
12VAC5-90-90		Those required to report	• *Change: add ethnicity and telephone number to the list of patient information • Intent: to allow for more efficient patient follow-up and to standardize the information provided to public health about patients in an outbreak (under VDH's current authority). • Rationale: This information is reported in the for coronavirus disease 2019 in section 90-80-I and improves consistency in reporting requirements. • Inmpact: Allows for more efficient follow-up with patients during outbreaks.
12VAC5-90-90		Those required to report	• *Change: Replace "may" with "shall" in the current language and clarify that the identifying information should include the name and telephone number of the individuals involved in the outbreak. • Intent: to allow for more efficient patient follow-up during an outbreak and to standardize the information provided to public health • Rationale: This information is often requested as a follow-up to a reported outbreak and requiring it with the report would improve efficiency in outbreak investigation. • Impact: Allows for more efficient follow-up with patients during outbreaks.

12VAC5-90-103		Isolation for communicable disease of public health threat.	• Remove language referencing the commissioner's role in enforcement. This is no longer contained in the Code of Virginia.
12VAC5-90-107		Quarantine	• Remove language referencing the commissioner's role in enforcement. This is no longer contained in the Code of Virginia.
12VAC5-90-140		Procedure for preventing ophthalmia neonatorum	• Modify language to refer only to medications that are available in the United States.
12VAC5-90-215		Schedule and criteria for and confirmation of blood lead testing and information to be provided	• *Change language "built before 1960" to "built before 1950". • Add language stating that confirmatory testing is not required if the result of the capillary test is below CDC's reference value. Reflects current national guidance on confirmatory testing. • Changed numbering under, "D. Confirmation of blood lead levels" to reflect the addition of language noted above.
12VAC5-90-225		Additional data to be reported related to persons with active tuberculosis	• *Replace "tuberculin skin test (TST)" with ""tests for tuberculosis infection" to reflect the availability of other test for infection. • Remove the examples provided for Mycobacterium tuberculosis complex. Not needed because this is defined earlier in the regulations. • Replaced "tubercle bacilli" with "M. tuberculosis complex" • *Add language that laboratories are required to submit results of tests for tuberculosis infection. • Changed numbering under, "B. Laboratories are required to submit the following" to reflect the addition of language noted above.
12VAC5-90-280		Reporting of dangerous microbes and pathogens	• Removed the definitions for "Biologic agent", "CDC", "Diagnosis", "Proficiency testing", "Responsible official", "Toxin", and "Verification" because they are no longer needed. • Clarified that "dangerous microbes and pathogens" are "select agents and toxins". • *Removed subsections on Administration, Reportable agents, Those required to report, and Exemption from reporting as they are no longer necessary. This section of the regulations is being streamlined to require annual reporting as specified in the Code of Virginia and reporting of instances in which agency response would be necessary. • *Section D. Items to report. Renumbered to Section B. Removed the requirement that a report shall be made on a form determined by VDH, contain information on the objectives of

			the work with the agent, location (including building and room) where each select agent is stored or used, identification information of persons with access to each agent, identification information of the person in charge of the agents, or that the laboratory has to report that it is registered with the CDC Select Agent Program. These requirements are no longer needed. Added that the name and address of the laboratory must be reported. • *Section E. Renumbered to Section C. Timing of reports. Language has been modified to define who at a laboratory submits the required reports annually and in instances involving a release, loss, or theft of a select agent of toxin, to whom at VDH and when. Language pertaining to reports that will no longer be required has been removed. • Section H. Release of reported information. Renumbered to Section D and the statement about exemptions from liability has been moved to this subsection.
12VAC5-90-370		Reporting of healthcare-associated infections	• *The term “facilities” has been replaced with the term “health care facilities” to comply with the language in the Code of Virginia. The data that health care facilities share with VDH will be any they supply to CDC as a result of a requirement of the Centers for Medicare and Medicaid Services and not limited to the Hospital Inpatient Quality Reporting Program of that agency.
12VAC5-90-9998		FORMS	• Removed reference to the following forms; Confidential Morbidity Report, Epi1 (rev. 10/2011), and the Virginia Cancer Registry Reporting Form (rev. 1/1998). These forms are no longer used by VDH.

Office of Regulatory Management

Economic Review Form

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC 5-90
VAC Chapter title(s)	Disease Reporting and Control Regulations
Action title	Amendment to comply with changes in public health practice
Date this document prepared	August 2023
Regulatory Stage (including Issuance of Guidance Documents)	Final

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)	**<u>Changes since the Proposed Stage</u>** Clarifications to the language were made as updated definitions, updating of old URLs, and amendments to style and form. • These clarifications have no direct or indirect monetized costs. • Direct monetized benefits may include reduced staff time and cost associated with the submission of tests that are not required to be reported, such as rapid antigen flu tests. • There are no indirect monetized benefits. **Add requirement to report cases of monkeypox virus.** This virus was previously required to be reported but was removed in 2016 because monkeypox virus had not been identified in Virginia up to that point. In the past year and a half (as of August 2023), 574 cases were reported to VDH pursuant to 12VAC5-90-80 (A), which requires the reporting of any outbreaks. Eight of those cases were reported in 2023. • Direct monetized costs: Because the number of cases is still relatively low and reporting has occurred in response to the outbreak, the cost to continue the same reporting is negligible. • There are no indirect monetized costs. • There are no direct monetized benefits. • The indirect monetized benefits reflect reduced morbidity and mortality associated with monkeypox virus infection in Virginia due to the public health system's ability to surveil for potential outbreaks, clusters, or epidemics, and respond by implementing appropriate infection prevention and control protocols. **Add telephone number and ethnicity to the list of patient information that physicians are required to report.** • There are no direct or indirect monetized costs. The increase in staff time to add a data element to reports that would be submitted anyway is negligible. It is already required for COVID-19 reports. They already collect other demographic data for reportable conditions, and this will be one additional variable to be added which would only affect the initial process and will be automated after that point for labs and physicians reporting electronically. • There are no direct monetized benefits. • Indirect monetized benefits include reduced VDH staff time associated with contact tracing and case investigation, as the elements reported will be more standardized. This will allow more efficient patient follow-up on reportable communicable diseases, which also contributes to the reduced burden of communicable disease mentioned in this analysis. **Formalize requirement to provide identifying information for outbreak reports by residential or day programs, services, or**

	facilities licensed or operated by any agency of the Commonwealth, or a school, child care center, or summer camp. • Direct monetized costs include increased staff time to include the additional information in reports, which are already required to be submitted. Anticipated to be negligible. • There are no indirect monetized costs. • There are no direct monetized benefits. • Indirect monetized benefits include reduced VDH staff time associated with contact tracing and case investigation, as the elements reported will be more standardized. This will allow more efficient patient follow-up on reportable communicable diseases, which also contributes to the reduced burden of communicable disease mentioned in this analysis. **<u>Overall changes in the action</u>** Direct Costs: There are no direct monetized costs associated with any of the proposed regulatory changes. Indirect Costs: There are no indirect costs associated with the proposed regulatory changes that can be quantified. Direct Benefits: Replacing the Epi-1 form with the online morbidity portal is likely to improve efficiency for transferring the data to VDH. Entering the data into the portal is not expected to take longer for physicians, directors of laboratories, and directors of medical care facilities than using paper forms and may be faster. For physicians and other entities required to report, it could be more cost effective compared to faxing or mailing paper reports because those methods cost money for postage, fax lines, and paper. VDH is not able to quantify the direct monetary benefit of this regulatory change. Indirect Benefits: There are no monetized indirect benefits associated with any of the proposed regulatory changes.

(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	$0	(b) $0
(3) Net Monetized Benefit	$0	

(4) Other Costs & Benefits (Non-Monetized)	Non-monetized benefits overall: Some of these changes could result in more efficient reporting practices and eliminate redundant reporting. **The following changes have no non-monetized cost or benefit:** • Adding ethnicity is not expected to create a cost for labs or healthcare providers. They already collect other demographic data for reportable conditions, and this will be one additional variable to be added which should only affect the initial process and will be automated after that point for labs and physicians reporting electronically. • The update regarding tuberculosis testing clarifies that other types of tests can also be submitted but does not add burden of any additional testing that is required by healthcare providers. **Non-monetized benefits** • The proposed changes to influenza reporting will reduce the burden of reporting for physicians and persons in charge of medical care facilities because they will no longer need to report results of rapid flu tests which are often conducted at the point of care in a physician's office. Only lab-confirmed influenza tests will be reportable, which will be reported by laboratories (not physicians or persons in charge of medical care facilities), mostly through existing automated electronic lab reporting processes. • Requiring lead tests for children living in houses built before 1950 rather than 1960 will result in fewer children needing to take a blood test. Not requiring confirmatory tests for values below the CDC's reference level would theoretically also result in fewer tests being done. • Adding ethnicity to the minimum required elements to report will help improve our ability to analyze disease data by this important demographic variable.
(5) Information Sources	https://www.vdh.virginia.gov/monkeypox/data-in-virginia/

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 monetary costs associated with the current regulations. Indirect Costs: There are no monetary indirect costs associated with the current regulations. Providers currently expend resources on staffing, office supplies and time associated with printing or faxing laboratory reports; if regulations are maintained as-is, they will continue to incur these costs for maintaining a less efficient and modern disease reporting requirement.

	Direct Benefits: There are no direct monetary benefits associated with the current regulations. Indirect Benefits: Indirect monetary benefits associated with the current regulations may include the decreased morbidity and mortality associated with communicable disease in the Commonwealth, due to the public health system's ability to surveil for potential outbreaks, clusters, or epidemics, and respond by implementing the appropriate infection control protocols.	
(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)	If the regulations are maintained as-is, physicians and persons in charge of medical care facilities will maintain the same level of burden associated with disease reporting and efficiencies and modernization of the disease reporting process will be thwarted. This will result in less timely data, inability to analyze data by ethnicity, and unnecessary requirements on busy healthcare providers (such as reporting rapid flu tests to public health).	
(5) Information Sources		

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

(1) Direct & Indirect Costs & Benefits (Monetized)	VDH has not considered other alternative approaches other than the ones described in the proposed action.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $0
(3) Net Monetized Benefit	$	

(4) Other Costs & Benefits (Non-Monetized)	The proposed regulatory changes serve to bring Virginia in line with CDC guidance, and current public health best practices. For this reason, there are not any other alternatives to consider for most of the individual changes.
(5) Information Sources	

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)	Direct Costs: There are no monetized costs to local partners. Direct Benefits: There are no monetized benefits to local partners.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $0
(3) Other Costs & Benefits (Non-Monetized)	Benefits include more complete and efficient reporting of diseases of public health importance to VDH so that actions can be taken to minimize the spread of diseases in Virginia's communities. A better understanding of the magnitude of these health problems in Virginia will be gained.	
(4) Assistance		
(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 costs or benefits to families.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $0
(3) Other Costs & Benefits (Non-Monetized)	The general benefits to families include more complete and timely reporting of diseases to public health. This allows VDH to take actions to minimize the spread of diseases in Virginia's communities and allows for a better understanding of the magnitude of health problems in Virginia. Regarding lead screening changes, fewer children will be required to undergo a blood lead test compared to the status quo. This will save parents the time taking children to appointments, the appointment cost, and any out-of-pocket costs not covered by private health insurance or Medicaid.	
(4) Information Sources		

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 direct or indirect monetized costs to small businesses. Direct Benefits: As described above, for physicians and other entities required to report, it could be more cost effective compared to faxing or mailing paper reports because those methods cost money for postage, fax lines, and paper. VDH is not able to quantify the direct monetary benefit of this regulatory change. Indirect Benefits: Indirect monetized benefits reduced morbidity and mortality associated with communicable disease in Virginia due to the public health system's ability to surveil for potential outbreaks, clusters, or epidemics, and respond by implementing appropriate infection prevention and control protocols.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a)	(b)

(3) Other Costs & Benefits (Non-Monetized)	There are an estimated 665 small medical laboratories, 4,637 small physician offices, 135 small hospitals, 297 small nursing homes, and 188 small assisted living facilities who may be considered small businesses and would be impacted by these changes. The indirect benefit to local businesses is a more efficient reporting mechanism for diseases required to be reported to VDH per code of Virginia 12VAC5-90. For physicians working in settings as described above and persons in charge of medical care facilities, the burden of reporting influenza lab tests will be reduced because only lab-confirmed test results will be required to be reported to VDH. Positive rapid influenza tests will no longer be reportable to public health.
(4) Alternatives	No alternatives have been identified.
(5) Information Sources	

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
12.5.90.10	**Statutory:**	0			0
	Discretionary:	0			0
12.5.90.80	**Statutory:**	1 (R/S)	0	0	0
	Discretionary:	13 (R/D)	1 (R/D)	0	+1
12.5.90.90	**Statutory:**	6 (R/S)			0
	Discretionary:	5 (G/D) 16 (R/D)		4 (R/D)	-4
12.5.90.103	**Statutory:**	8 (G/S)			0
	Discretionary:	15 (G/D)			0
12.5.90.107	**Statutory:**	11 (G/S) 2 (R/S)			0

	Discretionary:	13 (G/D)			0
12.5.90.140	**Statutory:**	0			0
	Discretionary:	2 (G/D)			0
012.5.90.215	**Statutory:**	1 (G/S) 1 (R/S)			0
	Discretionary:	6 (R/D)		1 (R/D)	-1
12.5.90.225	**Statutory:**	2 (R/S)			0
	Discretionary:	5 (R/D)			0
12.5.90.280	**Statutory:**	3 (G/S) 2 (R/S)		1 (R/S)	-1
	Discretionary:	2 (G/D) 16 (R/D)		6 (R/D)	-6
12.5.90.370	**Statutory:**	1 (G/S) 1 (R/S)			0
	Discretionary:	0			0

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**
12.5.90.80	Adds monkeypox virus to reportable disease list.	Cases part of the recent mpox outbreak were already required to be reported pursuant to the item "Outbreaks, all…" in 12VAC5-90-80 and subsection H of that section. This will only require reporting of any cases that arise that are not associated with an outbreak.

Project 5357 - Final

Department of Health

Amendment to comply with changes in public health practice

12VAC5-90-10. Definitions.

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

"Affected area" means any part or the whole of the Commonwealth, which has been identified as where persons reside~~,~~ or may be located~~,~~ who are known to have been exposed to or infected with, or who are reasonably suspected to have been exposed to or infected with, a communicable disease of public health threat. "Affected area" shall include~~, but not be limited to,~~ cities, counties, towns, and subsections of such areas, public and private property, buildings, and other structures.

"Arboviral infection" means a viral illness that is transmitted by a mosquito, tick, or other arthropod. This includes~~, but is not limited to,~~ chikungunya (CHIK), dengue, eastern equine encephalitis (EEE), LaCrosse encephalitis (LAC), also known as California encephalitis, St. Louis encephalitis (SLE), West Nile virus (WNV), and Zika virus (Zika) infection.

"Board" means the State Board of Health.

"Cancer" means all carcinomas, sarcomas, melanomas, leukemias, and lymphomas excluding localized basal and squamous cell carcinomas of the skin, except for lesions of the mucous membranes.

"CDC" means the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services.

"Child care center" means a child day center, child day program, family day home, family day system, or registered family day home as defined by § 63.2-100 of the Code of Virginia, or a similar place providing day care of children by such other name as may be applied.

"Clinic" means any facility, freestanding or associated with a hospital, that provides preventive, diagnostic, therapeutic, rehabilitative, or palliative care or services to outpatients.

"Commissioner" means the State Health Commissioner or ~~his~~ the State Health Commissioner's duly designated officer or agent, unless stated in a provision of this chapter that it applies to the State Health Commissioner in ~~his~~ the State Health Commissioner's sole discretion.

"Communicable disease" means an illness due to an infectious agent or its toxic products ~~which~~ that is transmitted, directly or indirectly, to a susceptible host from an infected person, animal, or arthropod or through the agency of an intermediate host or a vector or through the inanimate environment.

"Communicable disease of public health significance" means an illness caused by a specific or suspected infectious agent that may be transmitted directly or indirectly from one individual to another. This includes ~~but is not limited to~~ infections caused by human immunodeficiency viruses, bloodborne pathogens, and tubercle bacillus. The State Health Commissioner may determine that diseases caused by other pathogens constitute communicable diseases of public health significance.

"Communicable disease of public health threat" means an illness of public health significance, as determined by the State Health Commissioner in accordance with this chapter, caused by a specific or suspected infectious agent that may be reasonably expected or is known to be readily transmitted directly or indirectly from one individual to another and has been found to create a risk of death or significant injury or impairment; this definition shall not, however, be construed to

include human immunodeficiency viruses or the tubercle bacilli, unless used as a bioterrorism weapon.

"Companion animal" means, consistent with the provisions of § 3.2-6500 of the Code of Virginia, any domestic or feral dog, domestic or feral cat, nonhuman primate, guinea pig, hamster, rabbit not raised for human food or fiber, exotic or native animal, reptile, exotic or native bird, or any feral animal or any animal under the care, custody, or ownership of a person or any animal that is bought, sold, traded, or bartered by any person. Agricultural animals, game species, or any animals regulated under federal law as research animals shall not be considered companion animals for the purpose of this chapter.

"Condition" means any adverse health event, such as a disease, an infection, a syndrome, or as indicated by a procedure ~~(~~, including ~~but not limited to~~ the results of a physical exam, laboratory test, or imaging interpretation~~)~~, suggesting that an exposure of public health importance has occurred.

"Contact" means a person or animal known to have been in such association with an infected person or animal as to have had an opportunity of acquiring the infection.

"Contact services" means a broad array of services that are offered to persons with infectious diseases and their contacts. Contact services include contact tracing, providing information about current infections, developing risk reduction plans to reduce the chances of future infections, and connecting to appropriate medical care and other services.

"Contact tracing" means the process by which an infected person or health department employee notifies others that they may have been exposed to the infected person in a manner known to transmit the infectious agent in question.

"Coronavirus infection, severe" means suspected or confirmed infection with severe acute respiratory syndrome (SARS)-associated coronavirus (SARS-CoV), Middle East respiratory syndrome (MERS)-associated coronavirus (MERS-CoV), or another coronavirus causing a severe acute illness.

"Decontamination" means the use of physical or chemical means to remove, inactivate, or destroy hazardous substances or organisms from a person, surface, or item to the point that such substances or organisms are no longer capable of causing adverse health effects and the surface or item is rendered safe for handling, use, or disposal.

"Department" means the State Department of Health, also referred to as the Virginia Department of Health (VDH).

"Designee" or "designated officer or agent" means any person, or group of persons, designated by the State Health Commissioner, to act on behalf of the commissioner or the board.

"Ehrlichiosis/Anaplasmosis" means human infections caused by Ehrlichia chaffeensis (formerly included in the category "human monocytic ehrlichiosis" or "HME"), Ehrlichia ewingii or Anaplasma phagocytophilum (formerly included in the category "human granulocytic ehrlichiosis" or "HGE").

"Epidemic" means the occurrence in a community or region of cases of an illness clearly in excess of normal expectancy.

"Essential needs" means basic human needs for sustenance, including ~~but not limited to~~ food, water, clothing, and health care (e.g., medications, therapies, testing, and durable medical equipment).

"Exceptional circumstances" means the presence, as determined by the commissioner in ~~his~~ the commissioner's sole discretion, of one or more factors that may affect the ability of the department to effectively control a communicable disease of public health threat. Factors to be considered include ~~but are not limited to:~~ (i) characteristics or suspected characteristics of the disease-causing organism or suspected disease-causing organism such as virulence, routes of

transmission, minimum infectious dose, rapidity of disease spread, the potential for extensive disease spread, and the existence and availability of demonstrated effective treatment; (ii) known or suspected risk factors for infection; (iii) the potential magnitude of the effect of the disease on the health and welfare of the public; and (iv) the extent of voluntary compliance with public health recommendations. The determination of exceptional circumstances by the commissioner may take into account the experience or results of investigation in Virginia, another state, or another country.

"Foodborne outbreak" means two or more cases of a similar illness acquired through the consumption of food contaminated with chemicals or an infectious agent or its toxic products. Such illnesses include ~~but are not limited to~~ heavy metal intoxication, staphylococcal food poisoning, botulism, salmonellosis, shigellosis, Clostridium perfringens food poisoning, hepatitis A, and Shiga toxin-producing Escherichia coli infection.

~~"Healthcare-associated~~ "Health care-associated infection" (also known as nosocomial infection) means a localized or systemic condition resulting from an adverse reaction to the presence of an infectious agent ~~or agents~~ or its toxin ~~or toxins~~ that (i) occurs in a patient in a health care ~~setting~~ facility (e.g., a ~~hospital~~ medical care facility or outpatient clinic), and (ii) was not found to be present or incubating at the time of admission unless the infection was related to a previous admission to the same setting~~, and (iii) if the setting is a hospital, meets the criteria for a specific infection site as defined by CDC~~.

~~"Hepatitis C, acute" means the following clinical characteristics are met: (i) discrete onset of symptoms indicative of viral hepatitis and (ii) jaundice or elevated serum aminotransferase levels and the following laboratory criteria are met: (a) serum alanine aminotransferase levels (ALT) greater than 200 IU/L; (b) IgM anti-HAV negative (if done); (c) IgM anti-HBc negative (if done); and (d) hepatitis C virus antibody (anti-HCV) positive, HCV antigen positive, or HCV RNA positive by nucleic acid test.~~

~~"Hepatitis C, chronic" means that the laboratory criteria specified in clauses (b), (c) and (d) listed above for an acute case are met but clinical signs or symptoms of acute viral hepatitis are not present and serum alanine aminotransferase (ALT) levels do not exceed 200 IU/L. This category will include cases that may be acutely infected but not symptomatic.~~

"Immunization" means a procedure that increases the protective response of an individual's immune system to specified pathogens.

"Independent pathology laboratory" means a nonhospital or a hospital laboratory performing surgical pathology, including fine needle aspiration biopsy and bone marrow specimen examination services, ~~which~~ that reports the results of such tests directly to physician offices, without reporting to a hospital or accessioning the information into a hospital tumor registry.

"Individual" means a person or companion animal. When the context requires it, "person ~~or persons~~" shall be deemed to include any individual.

"Infection" means the entry and multiplication or persistence of a disease-causing organism (prion, virus, bacteria, fungus, parasite, or ectoparasite) in the body of an individual. An infection may be inapparent (i.e., without recognizable signs or symptoms but identifiable by laboratory means) or manifest (clinically apparent).

["Influenza, laboratory-confirmed" means by culture, antigen detection by direct fluorescent antibody (DFA), or nucleic acid detection. Influenza rapid antigen tests are not reportable.]

"Influenza A, novel virus" means infection of a human with an influenza A virus subtype that is different from currently circulating human influenza H1 and H3 viruses. Novel subtypes include H2, H5, H7, and H9 subtypes or influenza H1 and H3 subtypes originating from a nonhuman species or from genetic reassortment of human and animal influenza viruses.

"Invasive" means the organism is affecting a normally sterile site, including ~~but not limited to~~ blood or cerebrospinal fluid.

"Investigation" means an inquiry into the incidence, prevalence, extent, source, mode of transmission, causation of, and other information pertinent to a disease occurrence.

"Isolation" means the physical separation, including confinement or restriction of movement, of ~~an individual or~~ [~~individuals who are~~ an individual who is] infected with, or [~~are~~ is] reasonably suspected to be infected with, a communicable disease in order to prevent or limit the transmission of the communicable disease to uninfected and unexposed individuals.

"Isolation, complete" means the full-time confinement or restriction of movement of an individual ~~or individuals~~ infected with, or reasonably suspected to be infected with, a communicable disease in order to prevent or limit the transmission of the communicable disease to uninfected and unexposed individuals.

"Isolation, modified" means a selective, partial limitation of freedom of movement or actions of an individual ~~or individuals~~ infected with, or reasonably suspected to be infected with, a communicable disease. Modified isolation is designed to meet particular situations and includes ~~but is not limited to~~ the exclusion of children from school, the prohibition or restriction from engaging in a particular occupation or using public or mass transportation, or requirements for the use of devices or procedures intended to limit disease transmission.

"Isolation, protective" means the physical separation of a susceptible individual ~~or individuals~~ not infected with, or not reasonably suspected to be infected with, a communicable disease from an environment where transmission is occurring, or is reasonably suspected to be occurring, in order to prevent the individual ~~or individuals~~ from acquiring the communicable disease.

"Laboratory" means a clinical laboratory that examines materials derived from the human body for the purpose of providing information on the diagnosis, prevention, or treatment of disease.

"Laboratory director" means any person in charge of supervising a laboratory conducting business in the Commonwealth of Virginia.

"Law-enforcement agency" means any sheriff's office, police department, adult or youth correctional officer, or other agency or department that employs persons who have law-enforcement authority that is under the direction and control of the Commonwealth or any local governing body. "Law-enforcement agency" shall include, by order of the Governor, the Virginia National Guard.

["Lead, reportable blood levels" means any detectable blood lead level in children 15 years of age and younger and levels greater than or equal to 5 µg/dL in a person older than 15 years of age.]

"Least restrictive" means the minimal limitation of the freedom of movement and communication of an individual while under an order of isolation or an order of quarantine that also effectively protects unexposed and susceptible individuals from disease transmission.

"Medical care facility" means any hospital or nursing home licensed in the Commonwealth~~,~~ or any hospital operated by or contracted to operate by an entity of the United States government or the Commonwealth of Virginia.

"Midwife" means any person who is licensed as a nurse midwife by the Virginia Boards of Nursing and Medicine or who is licensed by the Board of Medicine as a certified professional midwife.

"National Healthcare Safety Network" or "NHSN" means a surveillance system created by the CDC for accumulating, exchanging, and integrating relevant information on infectious adverse events associated with health care delivery.

"Nucleic acid detection" means laboratory testing of a clinical specimen to determine the presence of deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) specific for an infectious agent using any method, including hybridization, sequencing, or amplification such as polymerase chain reaction.

"Nurse" means any person licensed as a professional nurse or as a licensed practical nurse by the Virginia Board of Nursing.

"Occupational outbreak" means a cluster of illness or disease that is indicative of a work-related exposure. Such conditions include ~~but are not limited to~~ silicosis, asbestosis, byssinosis, pneumoconiosis, and tuberculosis.

"Outbreak" means the occurrence of more cases of a disease than expected.

"Period of communicability" means the time ~~or times~~ during which the etiologic agent may be transferred directly or indirectly from an infected person to another person~~,~~ or from an infected animal to a person.

"Physician" means any person licensed to practice medicine or osteopathy by the Virginia Board of Medicine.

"Quarantine" means the physical separation, including confinement or restriction of movement, of ~~an individual or~~ individuals who are present within an affected area or who are known to have been exposed, or may reasonably be suspected to have been exposed, to a communicable disease and who do not yet show signs or symptoms of infection with the communicable disease in order to prevent or limit the transmission of the communicable disease of public health threat to unexposed and uninfected individuals.

"Quarantine, complete" means the full-time confinement or restriction of movement of ~~an individual or~~ individuals who do not have signs or symptoms of infection but may have been exposed, or may reasonably be suspected to have been exposed, to a communicable disease of public health threat in order to prevent the transmission of the communicable disease of public health threat to uninfected individuals.

"Quarantine, modified" means a selective, partial limitation of freedom of movement or actions of ~~an individual or~~ individuals who do not have signs or symptoms of the infection but have been exposed to, or are reasonably suspected to have been exposed to, a communicable disease of public health threat. Modified quarantine may be designed to meet particular situations and includes ~~but is not limited to~~ limiting movement to the home, work, or one or more other locations, the prohibition or restriction from using public or mass transportation, or requirements for the use of devices or procedures intended to limit disease transmission.

"Reportable disease" means an illness due to a specific toxic substance, occupational exposure, or infectious agent, ~~which~~ that affects a susceptible individual, either directly, as from an infected animal or person, or indirectly through an intermediate host, vector, or the environment, as determined by the board.

"School" means (i) any public school from kindergarten through grade 12 operated under the authority of any locality within the Commonwealth~~,~~; (ii) any private or religious school that offers instruction at any level or grade from kindergarten through grade 12; and (iii) any private or religious nursery school or preschool, or any private or religious child care center required to be licensed by the Commonwealth.

"Serology" means the testing of blood, serum, or other body fluids for the presence of antibodies or other markers of an infection or disease process.

"Surveillance" means the ongoing systematic collection, analysis, and interpretation of outcome-specific data for use in the planning, implementation, and evaluation of public health practice. A surveillance system includes the functional capacity for data analysis as well as the

timely dissemination of these data to persons who can undertake effective prevention and control activities.

"Susceptible individual" means a person or animal who is vulnerable to or potentially able to contract a disease or condition. Factors that affect an individual's susceptibility include ~~but are not limited to~~ physical characteristics, genetics, previous or chronic exposures, chronic conditions or infections, immunization history, or use of medications.

"Toxic substance" means any substance, including any raw materials, intermediate products, catalysts, final products, or by-products of any manufacturing operation conducted in a commercial establishment, that has the capacity~~,~~ through its physical, chemical, or biological properties~~,~~ to pose a substantial risk of death or impairment either immediately or over time~~,~~ to the normal functions of humans, aquatic organisms, or any other animal but not including any pharmaceutical preparation, which deliberately or inadvertently is consumed in such a way as to result in a drug overdose.

"Tubercle bacilli" means disease-causing organisms belonging to the Mycobacterium tuberculosis complex and includes Mycobacterium tuberculosis, Mycobacterium africanum, Mycobacterium bovis, ~~and Mycobacterium africanum~~ Mycobacterium canetti, Mycobacterium microti, Mycobacterium caprae, or other members as may be established by the commissioner.

~~"Tuberculin skin test (TST)" means a test for demonstrating infection with tubercle bacilli, performed according to the Mantoux method, in which 0.1 ml of 5 TU strength tuberculin purified protein derivative (PPD) is injected intradermally on the volar surface of the arm. Any reaction is observed 48-72 hours after placement and palpable induration is measured across the diameter transverse to the long axis of the arm. The measurement of the indurated area is recorded in millimeters and the significance of the measured induration is based on existing national and department guidelines.~~

~~"Tuberculosis" means a disease caused by tubercle bacilli.~~

"Tuberculosis, active disease" (also "active tuberculosis disease" and "active TB disease"), as defined by § 32.1-49.1 of the Code of Virginia, means a communicable disease caused by an airborne microorganism and characterized by the presence of either (i) a specimen of sputum or other bodily fluid or tissue that has been found to contain tubercle bacilli as evidenced by culture or nucleic acid amplification, including preliminary identification by rapid methodologies; (ii) a specimen of sputum or other bodily fluid or tissue that is suspected to contain tubercle bacilli as evidenced by smear, and where sufficient clinical and radiographic evidence of active tuberculosis disease is present as determined by a physician licensed to practice medicine in Virginia; or (iii) sufficient clinical and radiographic evidence of active tuberculosis disease as determined by the commissioner is present, but a specimen of sputum or other bodily fluid or tissue containing, or suspected of containing, tubercle bacilli is unobtainable.

"Tuberculosis infection ~~in children age <4 years~~" means a ~~significant reaction resulting from a tuberculin skin test (TST) or other approved test for latent infection without~~ positive result from a test for tuberculosis infection without clinical or ~~radiographic~~ other evidence of active tuberculosis disease~~, in children from birth up to their fourth birthday~~.

"Vaccinia, disease or adverse event" means vaccinia infection or serious or unexpected events in persons who received the smallpox vaccine or their contacts, including ~~but not limited to~~ bacterial infections, eczema vaccinatum, erythema multiforme, generalized vaccinia, progressive vaccinia, inadvertent inoculation, post-vaccinial encephalopathy or encephalomyelitis, ocular vaccinia, and fetal vaccinia.

"Waterborne outbreak" means two or more cases of a similar illness acquired through the ingestion of or other exposure to water contaminated with chemicals or an infectious agent or its toxic products. Such illnesses include ~~but are not limited to~~ giardiasis, viral gastroenteritis, cryptosporidiosis, hepatitis A, cholera, and shigellosis. A single case of laboratory-confirmed

primary amebic meningoencephalitis or of waterborne chemical poisoning is considered an outbreak.

Statutory Authority

§§ 32.1-12, 32.1-35, and 32.1-42 of the Code of Virginia.

Historical Notes

Derived from VR355-28-100 § 1.1, eff. July 1, 1993; amended, Virginia Register Volume 15, Issue 6, eff. January 6, 1999; Errata, 15:8 VA.R. 1099 January 4, 1999; amended, Virginia Register Volume 20, Issue 21, eff. July 28, 2004; Volume 23, Issue 15, eff. May 2, 2007; Volume 27, Issue 13, eff. March 28, 2011; Volume 33, Issue 2, eff. October 20, 2016; Volume 36, Issue 6, eff. December 26, 2019.

12VAC5-90-80. Lists of diseases that shall be reported.

A. [~~Reportable disease list. The board declares suspected or confirmed cases of the following named diseases, toxic effects, and conditions to be reportable by the~~ The] persons enumerated in 12VAC5-90-90 [~~. Conditions~~ shall report the following named diseases, toxic effects, and conditions pursuant to this chapter. A condition] identified by an asterisk (*) [~~require~~ requires] immediate communication to the local health department by the most rapid means available upon suspicion or confirmation, as defined in subsection C of this section. Other conditions [~~should~~ shall] be reported within three days of suspected or confirmed diagnosis, unless otherwise specified in this section. Neonatal Abstinence Syndrome shall be reported as specified in subsection E of this section. Coronavirus disease 2019 (SARS-CoV-2) shall be reported as specified in subsection I of the section.

Amebiasis (Entamoeba histolytica)
*Anthrax (Bacillus anthracis)
Arboviral infections (e.g., CHIK, dengue, EEE, LAC, SLE, WNV, Zika)
Babesiosis (Babesia spp.)
*Botulism (Clostridium botulinum)
*Brucellosis (Brucella spp.)
Campylobacteriosis (Campylobacter spp.)
Candida auris, infection or colonization
Carbapenemase-producing organism, infection or colonization
Chancroid (Haemophilus ducreyi)
Chickenpox (Varicella virus)
Chlamydia trachomatis infection
*Cholera (Vibrio cholerae O1 or O139)
*Coronavirus infection, severe (e.g., SARS-CoV, MERS-CoV)
Coronavirus disease 2019 (COVID-19 or SARS-CoV-2)
Cryptosporidiosis (Cryptosporidium spp.)
Cyclosporiasis (Cyclospora spp.)
*Diphtheria (Corynebacterium diphtheriae)
*Disease caused by an agent that may have been used as a weapon
Ehrlichiosis/Anaplasmosis (Ehrlichia spp., Anaplasma phagocytophilum)
Giardiasis (Giardia spp.)
Gonorrhea (Neisseria gonorrhoeae)
Granuloma inguinale (Calymmatobacterium granulomatis)

*Haemophilus influenzae infection, invasive
Hantavirus pulmonary syndrome
Hemolytic uremic syndrome (HUS)
*Hepatitis A
Hepatitis B (acute and chronic)
Hepatitis C (acute and chronic)
Hepatitis, other acute viral
Human immunodeficiency virus (HIV) infection
Influenza, [laboratory-] confirmed
*Influenza-associated deaths if younger than 18 years of age
Lead, [reportable] blood levels
Legionellosis (Legionella spp.)
Leprosy (Hansen's disease) (Mycobacterium leprae)
Leptospirosis (Leptospira interrogans)
Listeriosis (Listeria monocytogenes)
Lyme disease (Borrelia spp.)
Lymphogranuloma venereum (Chlamydia trachomatis)
Malaria (Plasmodium spp.)
*Measles (Rubeola)
*Meningococcal disease (Neisseria meningitidis)
Mumps
Neonatal abstinence syndrome (NAS)
Ophthalmia neonatorum
[*Orthopoxviruses (e.g., Monkeypox virus, Variola virus, Vaccinia disease or adverse event)]
*Outbreaks, all (including foodborne, health care-associated, occupational, toxic substance-related, waterborne, and any other outbreak)
*Pertussis (Bordetella pertussis)
*Plague (Yersinia pestis)
*Poliovirus infection, including poliomyelitis
*Psittacosis (Chlamydophila psittaci)
*Q fever (Coxiella burnetii)
*Rabies, human and animal
Rabies treatment, post-exposure
*Rubella, including congenital rubella syndrome
Salmonellosis (Salmonella spp.)
Shiga toxin-producing Escherichia coli infection
Shigellosis (Shigella spp.)
[~~*Smallpox (Variola virus)~~]
Spotted fever rickettsiosis (Rickettsia spp.)
Streptococcal disease, Group A, invasive or toxic shock

Streptococcus pneumoniae infection, invasive if younger than five years of age
Syphilis (Treponema pallidum) report *congenital, *primary, *secondary, and other
Tetanus (Clostridium tetani)
Toxic substance-related illness
Trichinosis (Trichinellosis) (Trichinella spiralis)
*Tuberculosis, active disease (Mycobacterium tuberculosis complex)
Tuberculosis infection
*Tularemia (Francisella tularensis)
*Typhoid/Paratyphoid infection (Salmonella Typhi, Salmonella Paratyphi)
*Unusual occurrence of disease of public health concern
[~~*Vaccinia, disease or adverse event~~]
Vancomycin-intermediate or vancomycin-resistant Staphylococcus aureus infection
*Vibriosis (Vibrio spp.)
*Viral hemorrhagic fever
*Yellow fever
Yersiniosis (Yersinia spp.)

B. [~~Conditions reportable by directors of laboratories. Laboratories~~ A laboratory director] shall report [~~all~~] test results indicative of and specific for the diseases, infections, microorganisms, conditions, and toxic effects specified in this subsection for humans. [~~Such tests~~ Tests] include microbiological culture, isolation, or identification; assays for specific antibodies; and identification of specific antigens, toxins, or nucleic acid sequences. Additional condition-specific requirements are noted in this subsection and subsection D of this section. [~~Conditions~~ A condition] identified by an asterisk (*) [~~require~~ requires] immediate communication to the local health department by the most rapid means available upon suspicion or confirmation, as defined in subsection C of this section. Other conditions [~~should~~ shall] be reported within three days of suspected or confirmed diagnosis.

Amebiasis (Entamoeba histolytica)
*Anthrax (Bacillus anthracis)
Arboviral infection, for example, CHIK, dengue, EEE, LAC, SLE, WNV, or Zika
Babesiosis (Babesia spp.)
*Botulism (Clostridium botulinum)
*Brucellosis (Brucella spp.)
Campylobacteriosis (Campylobacter spp.)
Candida auris - Include available antimicrobial susceptibility findings in report.
Carbapenemase-producing organism - Include available antimicrobial susceptibility findings in report.
Chancroid (Haemophilus ducreyi)
Chickenpox (Varicella virus)
Chlamydia trachomatis infection
*Cholera (Vibrio cholerae O1 or O139)
*Coronavirus infection, severe (e.g., SARS-CoV, MERS-CoV)
Coronavirus disease 2019 (COVID-19 or SARS-CoV-2)
Cryptosporidiosis (Cryptosporidium spp.)

Cyclosporiasis (Cyclospora spp.)

*Diphtheria (Corynebacterium diphtheriae)

Ehrlichiosis/Anaplasmosis (Ehrlichia spp., Anaplasma phagocytophilum)

Giardiasis (Giardia spp.)

Gonorrhea (Neisseria gonorrhoeae) - Include available antimicrobial susceptibility findings in report.

*Haemophilus influenzae infection, invasive

Hantavirus pulmonary syndrome

*Hepatitis A

Hepatitis B (acute and chronic) - For All hepatitis B patients, also report available results of serum alanine aminotransferase (ALT) and all available results from the hepatitis panel.

Hepatitis C (acute and chronic) - For all patients with any positive HCV test, also report all results of HCV viral load tests, including undetectable viral loads and report available results of serum alanine aminotransferase (ALT) and all available results from the hepatitis panel.

Hepatitis, other acute viral - Any finding indicative of acute infection with hepatitis D, E, or other cause of viral hepatitis. For any reportable hepatitis finding, submit all available results from the hepatitis panel.

Human immunodeficiency virus (HIV) infection - For HIV-infected patients, report all results of CD4 and HIV viral load tests, including undetectable viral loads. For HIV-infected patients, report all HIV genetic nucleotide sequence data associated with HIV drug resistance tests by electronic submission. For children younger than three years of age, report all tests regardless of the test findings (e.g., negative or positive).

Influenza, [laboratory-] confirmed- By culture, antigen detection by direct fluorescent antibody (DFA), or nucleic acid detection.

Lead, [reportable] blood levels - All lead results from tests of venous or capillary blood performed by a laboratory certified by the Centers for Medicare and Medicaid Services in accordance with 42 USC § 263a, the Clinical Laboratory Improvement Amendment of 1988 (CLIA-certified).

Legionellosis (Legionella spp.)

Leptospirosis (Leptospira interrogans)

Listeriosis (Listeria monocytogenes), invasive or if associated with miscarriage or stillbirth from placental or fetal tissue

Lyme disease (Borrelia spp.)

Malaria (Plasmodium spp.)

*Measles (Rubeola)

*Meningococcal disease (Neisseria meningitidis), invasive - Include identification of gram-negative diplococci.

Mumps

*Mycobacterial diseases - (See 12VAC5-90-225 [~~B~~]) Report any of the following:

1. Acid fast bacilli;
2. M. tuberculosis complex or any other mycobacteria; or
3. Antimicrobial susceptibility results for M. tuberculosis complex.

[*Orthopoxviruses (e.g., Monkeypox virus, Variola virus, Vaccinia disease or adverse event]

*Pertussis (Bordetella pertussis)
*Plague (Yersinia pestis)
*Poliovirus infection
*Psittacosis (Chlamydophila psittaci)
*Q fever (Coxiella burnetii)
*Rabies, human and animal
*Rubella
Salmonellosis (Salmonella spp.)
Shiga toxin-producing Escherichia coli infection
Shigellosis (Shigella spp.)
[~~*Smallpox (Variola virus)~~]
Spotted fever rickettsiosis (Rickettsia spp.)
Streptococcal disease, Group A, invasive or toxic shock
Streptococcus pneumoniae infection, invasive if younger than five years of age
*Syphilis (Treponema pallidum)
Toxic substance-related illness - By blood or urine laboratory findings above the normal range, including heavy metals, pesticides, and industrial-type solvents and gases. When applicable and available, report speciation of metals when blood or urine levels are elevated in order to differentiate the chemical species (elemental, organic, or inorganic).
Trichinosis (Trichinellosis) (Trichinella spiralis)
Tuberculosis infection
*Tularemia (Francisella tularensis)
*Typhoid/Paratyphoid infection (Salmonella Typhi, Salmonella Paratyphi A, Salmonella Paratyphi B, Salmonella Paratyphi C)
[~~*Vaccinia, disease or adverse event~~]
Vancomycin-intermediate or vancomycin-resistant Staphylococcus aureus infection - Include available antimicrobial susceptibility findings in report.
*Vibriosis (Vibrio spp., Photobacterium damselae, Grimontia hollisae), other than toxigenic Vibrio cholera O1 or O139, which are reportable as cholera
*Viral hemorrhagic fever
*Yellow fever
Yersiniosis (Yersinia spp.)

C. [~~Reportable diseases requiring rapid communication.~~] Certain of the diseases in the list of reportable diseases because of their extremely contagious nature, potential for greater harm, or availability of a specific intervention that must be administered in a timely manner require immediate identification and control. Reporting of persons confirmed or suspected of having these diseases, listed in this subsection, shall be made immediately by the most rapid means available, preferably by telephone to the local health department. (These same diseases are also identified by an asterisk (*) in subsections A and B, where applicable, of this section.)

Anthrax (Bacillus anthracis)
Botulism (Clostridium botulinum)
Brucellosis (Brucella spp.)
Cholera (Vibrio cholerae O1 or O139)

Coronavirus infection, severe (e.g., SARS-CoV, MERS-CoV)

Diphtheria (Corynebacterium diphtheriae)

Disease caused by an agent that may have been used as a weapon

Haemophilus influenzae infection, invasive

Hepatitis A

Influenza-associated deaths if younger than 18 years of age

Influenza A, novel virus

Measles (Rubeola virus)

Meningococcal disease (Neisseria meningitidis)

Outbreaks, all

[Orthopoxviruses (e.g., Monkeypox virus, Variola virus, Vaccinia disease or adverse event)]

Pertussis (Bordetella pertussis)

Plague (Yersinia pestis)

Poliovirus infection, including poliomyelitis

Psittacosis (Chlamydophila psittaci)

Q fever (Coxiella burnetii)

Rabies, human and animal

Rubella, including congenital rubella syndrome

[~~Smallpox (Variola virus)~~]

Syphilis, congenital, primary, and secondary (Treponema pallidum)

Tuberculosis, active disease (Mycobacterium tuberculosis complex)

Tularemia (Francisella tularensis)

Typhoid/Paratyphoid infection (Salmonella Typhi, Salmonella Paratyphi (all types))

Unusual occurrence of disease of public health concern

[~~Vaccinia, disease or adverse event~~]

Vibriosis (Vibrio spp., Photobacterium damselae, Grimontia hollisae), other than toxigenic Vibrio cholerae O1 or O139, which are reportable as cholera

Viral hemorrhagic fever

Yellow fever

D. [~~Submission of initial isolate or other specimen for further public health testing.~~] A laboratory identifying evidence of any of the conditions in this subsection shall notify the local health department of the positive culture or other positive test result within the timeframes specified in subsection B of this section and submit the initial isolate (preferred) ~~or other initial specimen~~ within five days or the clinical specimen within two days of a positive result to the Division of Consolidated Laboratory Services or other public health laboratory where specified in this subsection ~~within seven days of identification~~. [~~All specimens~~ A specimen or isolate] must be identified with the patient and physician information required in 12VAC5-90-90 [~~B~~ C] .

Anthrax (Bacillus anthracis)

Botulism (Clostridium botulinum)

Brucellosis (Brucella sp.)

Candida auris

Candida haemulonii

Carbapenem-resistant ~~Enterobacteriaceae~~Enterobacterales

Carbapenem-resistant Pseudomonas aeruginosa

Cholera (Vibrio cholerae O1 or O139)

Coronavirus infection, severe (e.g., SARS-CoV, MERS-CoV)

Diphtheria (Corynebacterium diphtheriae)

Haemophilus influenzae infection, invasive

Influenza, unsubtypeable

Listeriosis (Listeria monocytogenes)

Meningococcal disease (Neisseria meningitidis)

Plague (Yersinia pestis)

Poliovirus infection

Q fever (Coxiella burnetii)

Salmonellosis (Salmonella spp.)

Shiga toxin-producing E. coli infection [~~(Laboratories that identify~~ . A laboratory that identifies] a Shiga toxin but [~~do~~ does] not perform simultaneous culture for Shiga toxin-producing E. coli should forward all positive stool specimens or positive enrichment broths to the Division of Consolidated Laboratory Services for confirmation and further characterization. [~~)~~]

Shigellosis (Shigella spp.)

Streptococcal disease, Group A, invasive

Tuberculosis [~~(~~ .] A laboratory identifying Mycobacterium tuberculosis complex (see 12VAC5-90-225) shall submit a representative and viable sample of the initial culture to the Division of Consolidated Laboratory Services or other laboratory designated by the board to receive [~~such~~ the] specimen. [~~)~~]

Tularemia (Francisella tularensis)

Typhoid/Paratyphoid infection (Salmonella Typhi, Salmonella Paratyphi (all types))

Vancomycin-intermediate or vancomycin-resistant Staphylococcus aureus infection

Vibriosis (Vibrio spp., Photobacterium damselae, Grimontia hollisae)

Yersiniosis (Yersinia spp.)

Other diseases as may be requested by the health department.

E. [~~Neonatal abstinence syndrome. Neonatal~~ A physician or director of a medical care facility shall report neonatal] abstinence syndrome [~~shall be reported by physicians and directors of medical care facilities when~~ if] a newborn has been diagnosed with neonatal abstinence syndrome, a condition characterized by clinical signs of withdrawal from exposure to prescribed or illicit drugs. [~~Reports~~ A report] shall be submitted within one month of diagnosis by entering the information into the Department of Health's online Confidential Morbidity Report portal ([~~http://www.vdh.virginia.gov/clinicians~~ https://www.vdh.virginia.gov/clinicians/disease-reporting-and-control-regulations/]).

F. [~~Outbreaks.~~] The occurrence of [~~outbreaks or clusters~~ an outbreak or cluster] of any illness that may represent a group expression of an illness that may be of public health concern shall be reported to the local health department immediately by the most rapid means available, preferably by telephone.

G. Toxic [~~substance-related illnesses. All toxic~~] substance-related illnesses, including pesticide and heavy metal poisoning or illness resulting from exposure to an occupational dust or fiber or radioactive substance, shall be reported.

If [~~such~~ the] illness is verified or suspected and presents an emergency or a serious threat to public health or safety, the report of such illness shall be made immediately by the most rapid means available, preferably by telephone.

H. [~~Unusual occurrence of disease of public health concern. Unusual~~ An unusual] or emerging [~~conditions~~ condition] of public health concern shall be reported to the local health department immediately by the most rapid means available, preferably by telephone. In addition, the commissioner or the commissioner's designee may establish surveillance systems for diseases or conditions that are not on the list of reportable diseases [~~. Such surveillance may be established~~] to identify cases (delineate the magnitude of the situation), to identify the mode of transmission and risk factors for the disease, and to identify and implement appropriate action to protect public health. [~~Any~~ A] person reporting information at the request of the department for special surveillance or other epidemiological studies shall be immune from liability as provided by § 32.1-38 of the Code of Virginia.

I. [~~Coronavirus~~ A physician or medical care facility director shall report coronavirus] disease 2019 (SARS-CoV-2) [~~.~~ , also known as "] COVID-19 [~~shall be reported by physicians and directors of medical care facilities when~~ ," if] a person who is infected with or who is suspected of having COVID-19 is treated or examined, hospitalized, or admitted into the intensive care unit. [~~Physicians and directors of medical care facilities~~ A physician or medical care facility director] shall report [~~that~~ the] person's name, telephone number, address, age, date of birth, race, ethnicity, sex, and pregnancy status; name of disease diagnosed or suspected; the medical record number (if applicable); the date of onset of illness; available laboratory tests and results; and the name, address, and telephone number of the physician and medical facility where the examination was made. [~~Case reports~~ A case report] shall be submitted within three days of the suspicion or confirmation of disease by entering the information into the Department of Health online Confidential Morbidity Report portal at [~~http://www.vdh.virginia.gov/clinicians~~ https://www.vdh.virginia.gov/clinicians/disease-reporting-and-control-regulations/] or via electronic case reporting (https://www.vdh.virginia.gov/meaningful-use/meaningful-use-submissions-of-electronic-case-reports/).

J. [~~Positive SARS-CoV-2 tests shall be reported by directors of laboratories, including other entities that hold~~ A laboratory director, including a director of another entity that holds] Clinical Laboratory Improvement Amendments Certificates of Waiver [~~. Each report shall give~~ , shall report a positive SARS-CoV-2 test within three days of identification of evidence of disease. The report shall include] the source of the specimen and the laboratory method and result; the name, telephone number, email address, address, age, date of birth, race, ethnicity, sex, and pregnancy status (if known) of the person from whom the specimen was obtained; and the name, address, and telephone number of the physician at whose request and medical facility at which the examination was made. [~~Reports shall be submitted within three days of identification of evidence of disease. Reports~~ A report] shall be made by entering information into the department's available portal for laboratory reporting at [~~http://www.vdh.virginia.gov/clinicians~~ https://www.vdh.virginia.gov/clinicians/disease-reporting-and-control-regulations/] or via electronic laboratory reporting at http://www.vdh.virginia.gov/meaningful-use/submissionofreportablelabresults.

Statutory Authority

§§ 32.1-12, 32.1-35, and 32.1-42 of the Code of Virginia.

Historical Notes

Derived from VR355-28-100 § 3.1, eff. July 1, 1993; amended, Virginia Register Volume 15, Issue 6, eff. January 6, 1999; Volume 18, Issue 9, eff. December 18, 2001; Volume 20, Issue 21, eff. July 28, 2004; Volume 23, Issue 15, eff. May 2, 2007; Volume 25, Issue 11, eff. March 4, 2009; Errata, 25:12 VA.R. 2293 February 16, 2009; amended, Virginia Register Volume 27, Issue 13,

eff. March 28, 2011; Volume 33, Issue 2, eff. October 20, 2016; Volume 34, Issue 7, eff. December 27, 2017; Errata, 34:8 VA.R. 831 December 11, 2017; Volume 35, Issue 4, eff. November 14, 2018; Volume 36, Issue 6, eff. December 26, 2019; Volume 39, Issue 9, eff. January 18, 2023.

12VAC5-90-90. Those required to report.

A. [~~Physicians. Each~~ A] physician who treats or examines any person who is suffering from or who is suspected of having a reportable disease or condition shall report, at a minimum, that person's name, [telephone number,] address, age, date of birth, race, ethnicity, sex, and pregnancy status for females; name of disease diagnosed or suspected; the date of onset of illness; available laboratory tests and results; and the name, address, and telephone number of the physician and medical facility where the examination was made ~~, except that influenza should be reported by number of cases only (and type of influenza, if available)~~. [~~Reports are to be made to the local health department serving the jurisdiction where the physician practices.~~] A physician may designate someone to report on his behalf, but the physician [~~remains responsible for ensuring~~ shall ensure] that the appropriate report is made. [~~Any~~ A] physician, designee, or organization making [~~such~~ a] report as authorized ~~herein~~ in this section shall be immune from liability as provided by § 32.1-38 of the Code of Virginia. [~~Such reports shall be made~~ The physician shall send the report] ~~on a Form Epi-1, a computer generated printout containing the data items requested on Form Epi-1,~~ within the timeframes specified in 12VAC5-90-80 to the local health department serving the jurisdiction in which the facility is located [~~. Reports shall be made~~] via the Virginia Department of Health's online Confidential Morbidity Report portal at [~~http://www.vdh.virginia.gov/clinicians~~ https://www.vdh.virginia.gov/clinicians/disease-reporting-and-control-regulations/] or a CDC or VDH disease-specific surveillance form ~~that provides the same information and shall be made within three days of the suspicion or confirmation of disease except that those identified in 12VAC5-90-80 C shall be reported immediately by the most rapid means available, preferably by telephone, to the local health department serving the jurisdiction in which the facility is located~~. [~~Reporting may be done by means of secure electronic transmission upon agreement of the physician and the department.~~

~~Additional elements are required to be reported for individuals with confirmed or suspected active tuberculosis disease. Refer to Part X (12VAC5-90-225 et seq.) for details on these requirements.~~]

B. [~~Directors of laboratories. Laboratory directors~~ A laboratory director] shall report [~~any~~ a] laboratory examination of [~~any~~ a] clinical specimen~~, whether performed in-house or referred to an out-of-state laboratory, which~~ that yields evidence~~, by the laboratory method indicated or any other confirmatory test,~~ of a disease listed in 12VAC5-90-80 B. [~~Laboratory directors~~ A laboratory director] shall report results that are performed in-house or referred to a reference laboratory, with the following exception: if the laboratory director ascertains that the reference laboratory that tests a specimen reports to the department electronically, then [~~those~~ the] reference laboratory findings do not need to be reported by the laboratory of origin.

[~~Each~~ C. A] report [from a laboratory director] shall give the source of the specimen and the laboratory method and result; the name, address, age, date of birth, race, ethnicity, sex, and pregnancy status for females (if known) of the person from whom the specimen was obtained; and the name, address, and telephone number of the physician at whose request and medical facility at which the examination was made. [~~When~~ If] the influenza virus is isolated, the type [~~should~~ shall] be reported, if available. [~~Reports shall be made~~ A laboratory director shall make the report] within ~~three days of identification of evidence of disease, except that those identified in 12VAC5-90-80 C shall be reported immediately by the most rapid means available, preferably by telephone,~~ the timeframes specified in 12VAC5-90-80 to the local health department serving the jurisdiction in which the laboratory is located [~~. Reports shall be made~~] ~~on Form Epi-1~~ via the department's online Confidential Morbidity Report portal or on the laboratory's own form [, including a computer generated report] if it includes the required information. [~~Computer~~

~~generated reports containing the required information may be submitted. Reporting may be done~~ A laboratory director may make the required reports] by means of secure electronic transmission upon agreement of the laboratory director and the department. [~~Reports~~ A laboratory director shall submit a report] of HIV genetic nucleotide sequence data associated with HIV drug resistance tests [~~must be submitted~~] electronically. [~~Any~~ A] person making [~~such~~ a] report as authorized ~~herein~~ in this section shall be immune from liability as provided by § 32.1-38 of the Code of Virginia.

~~A laboratory identifying evidence of any of the following conditions shall notify the local health department of the positive culture or other positive test result within the timeframes specified in 12VAC5-90-80 and submit the initial isolate or other initial specimen to the Division of Consolidated Laboratory Services within seven days of identification. All specimens must be identified with the patient and physician information required in this subsection.~~

~~Anthrax~~

~~Botulism~~

~~Brucellosis~~

~~Cholera~~

~~Diphtheria~~

~~E. coli infection, Shiga toxin-producing. (Laboratories that use a Shiga toxin EIA methodology but do not perform simultaneous culture for Shiga toxin-producing E. coli should forward all positive stool specimens or positive enrichment broths to the Division of Consolidated Laboratory Services for confirmation and further characterization.)~~

~~Haemophilus influenzae infection, invasive~~

~~Influenza A, novel virus~~

~~Listeriosis~~

~~Meningococcal disease~~

~~Pertussis~~

~~Plague~~

~~Poliovirus infection~~

~~Q fever~~

~~Salmonellosis~~

~~Shigellosis~~

~~Streptococcal disease, Group A, invasive~~

~~Tuberculosis (A laboratory identifying Mycobacterium tuberculosis complex (see 12VAC5-90-225) shall submit a representative and viable sample of the initial culture to the Division of Consolidated Laboratory Services or other laboratory designated by the board to receive such specimen.)~~

~~Tularemia~~

~~Typhoid/Paratyphoid fever~~

~~Vancomycin-intermediate or vancomycin-resistant Staphylococcus aureus infection~~

~~Vibrio infection, including infections due to Photobacterium damselae and Grimontia hollisae~~

~~Yersiniosis~~

~~Other diseases as may be requested by the health department~~

[~~When~~ D. If] a clinical specimen yields evidence indicating the presence of a select agent or toxin as defined [~~by federal regulations~~] in 42 CFR Part 73, the [~~person in charge of the~~]

laboratory [director] shall contact the Division of Consolidated Laboratory Services and arrange to forward an isolate for confirmation. If a select agent or toxin has been confirmed in a clinical specimen, the laboratory director shall consult with Division of Consolidated Laboratory Services or CDC regarding isolate transport or destruction.

[~~Laboratories~~ E. A laboratory] operating within a medical care facility shall be considered to be in compliance with the requirement to notify the local health department [~~when~~ if] the director of [~~that~~ the] medical care facility assumes the reporting responsibility; however, [~~laboratories are still required to~~ the laboratory director shall still] submit isolates to the Division of Consolidated Laboratory Services or other designated laboratory as noted in ~~this subsection~~ 12VAC5-90-80 D unless the laboratory has submitted an exemption request that has been approved by the department.

[~~C. Persons in charge of a medical care facility. Any~~ F. A] person in charge of a medical care facility shall make a report to the local health department serving the jurisdiction where the facility is located of the occurrence in or admission to the facility of a patient with a reportable disease listed in 12VAC5-90-80 A unless ~~he~~ the person in charge of a medical care facility has evidence that the occurrence has been reported by a physician. [~~Any~~ A] person making [~~such~~ a] report as authorized ~~herein~~ in this section shall be immune from liability as provided by § 32.1-38 of the Code of Virginia. The requirement to report shall include all inpatient, outpatient, and emergency care departments within the medical care facility. [~~Such~~ A] report shall contain the patient's name, address, age, date of birth, race, ethnicity, sex, and [, if the patient is female,] pregnancy status [~~for females~~] ; name of disease being reported; available laboratory tests and results; the date of admission; medical record number; date expired ([~~when~~ if] applicable); and attending physician. ~~Influenza should be reported by number of cases only (and type of influenza, if available).~~ [~~Reports~~ A] shall be made within ~~three days of the suspicion or confirmation of disease except that those identified in 12VAC5-90-80 C shall be reported immediately by the most rapid means available, preferably by telephone,~~ the timeframes specified in 12VAC5-90-80 to the local health department serving the jurisdiction in which the facility is located [~~. Reports shall be made~~] ~~on Form Epi-1, a computer generated printout containing the data items requested on Form Epi-1,~~ via the Virginia Department of Health's online Confidential Morbidity Report portal at ___ [~~http://www.vdh.virginia.gov/clinicians~~ https://www.vdh.virginia.gov/clinicians/disease-reporting-and-control-regulations/] or a CDC or VDH disease-specific surveillance form ~~that provides the same information~~. [~~Reporting may be done~~ The person in charge of the medical facility may make the reports] by means of secure electronic transmission upon agreement of the medical care facility and the department.

[G.] A person in charge of a medical care facility may assume the reporting responsibility on behalf of the director of the laboratory operating within the facility.

[~~D. Persons in charge of a residential or day program, service, or facility licensed or operated by any agency of the Commonwealth, or a school, child care center, or summer camp. Any~~ H. The] person in charge of a residential or day program, service, or facility licensed or operated by any agency of the Commonwealth, or a school, child care center, or summer camp as defined in § 35.1-1 of the Code of Virginia shall report immediately to the local health department the presence or suspected presence in ~~his~~ the person in charge's program, service, facility, school, child care center, or summer camp of persons who have common symptoms suggesting an outbreak situation. [~~Such~~ The] ~~persons~~ person in charge [~~may~~ shall] report additional information, including identifying and contact information for individuals with communicable diseases of public health concern or individuals who are involved in outbreaks that occur in ~~their~~ the person in charge's facilities, as necessary to facilitate public health investigation and disease control. [~~Any person so reporting~~ Identifying and contact information, at minimum, shall include a name and phone number. A person making a report pursuant to this section] shall be immune from liability as provided by § 32.1-38 of the Code of Virginia.

[~~E. Local health directors.~~ H.] The local health director shall forward [~~any~~ a] report of a disease or report of evidence of a disease ~~which~~ that has been made on a resident of ~~his~~ the local health director's jurisdiction to the Office of Epidemiology within three days of receipt. [~~This~~ The] report shall be submitted immediately by the most rapid means available if the disease is one requiring rapid communication, as required in 12VAC5-90-80 C. [~~All such rapid~~ Rapid] reporting shall be confirmed in writing and submitted to the Office of Epidemiology, by either a paper report or entry into a shared secure electronic disease surveillance system, within three days. [~~Furthermore, the~~ A] local health director shall immediately forward to the appropriate local health director [~~any disease reports on individuals~~ a disease report on an individual] residing in ~~the latter's~~ the appropriate local health director's jurisdiction or to the Office of Epidemiology [~~on individuals residing~~ if the individual resides] outside Virginia. The Office of Epidemiology shall [~~be responsible for notifying~~ notify] other state health departments of reported illnesses in ~~their~~ residents of [the] other state [~~health departments~~] and [~~for notifying~~ shall notify] CDC as necessary and appropriate.

[~~F. Persons in charge of hospitals, nursing facilities or nursing homes, assisted living facilities, and correctional facilities.~~ I.] In accordance with § 32.1-37.1 of the Code of Virginia, [~~any~~ a] person in charge of a hospital, nursing facility or nursing home, assisted living facility, or correctional facility shall, at the time of transferring custody of [~~any~~ a] dead body to [~~any~~ a] person practicing funeral services, notify the person practicing funeral services or ~~his~~ the person practicing funeral services's agent if the dead person was known to have had, immediately prior to death, an infectious disease which may be transmitted through exposure to any bodily fluids. These include any of the following infectious diseases:

Coronavirus, severe (e.g., SARS-CoV, MERS-CoV)

Creutzfeldt-Jakob disease

Human immunodeficiency virus (HIV) infection

Hepatitis B (acute and chronic)

Hepatitis C (acute and chronic)

Rabies

Smallpox (Variola virus)

Syphilis, infectious (Treponema pallidum)

Tuberculosis, active disease (Mycobacterium tuberculosis complex)

Vaccinia, disease or adverse event

Viral hemorrhagic fever

[~~G. Employees, conditional employees, and persons in charge of food establishments.~~ J. Pursuant to] 12VAC5-421-80 ~~of the Food Regulations~~ [~~requires~~] a food employee or conditional employee [~~to~~ shall] notify the person in charge of the food establishment when diagnosed with certain diseases that are transmissible through food and [~~requires~~] the person in charge of the food establishment [~~to~~ shall] notify the [~~regulatory authority. Refer to 12VAC5-421-80 for further guidance and clarification regarding these reporting requirements.~~ department.]

Statutory Authority

§§ 32.1-12, 32.1-35, and 32.1-42 of the Code of Virginia.

Historical Notes

Derived from VR355-28-100 § 3.2, eff. July 1, 1993; amended, Virginia Register Volume 15, Issue 6, eff. January 6, 1999; Errata, 15:8 VA.R. 1099 January 4, 1999; amended, Virginia Register Volume 20, Issue 21, eff. July 28, 2004; Volume 23, Issue 15, eff. May 2, 2007; Volume 27, Issue 13, eff. March 28, 2011; Volume 33, Issue 2, eff. October 20, 2016; Volume 36, Issue 6, eff. December 26, 2019; Volume 39, Issue 9, eff. January 18, 2023.

12VAC5-90-103. Isolation for communicable disease of public health threat.

A. [~~Application.~~] The commissioner, in ~~his~~ the commissioner's sole discretion, may invoke the provisions of Article 3.02 (§ 32.1-48.05 et seq.) of Chapter 2 of Title 32.1 of the Code of Virginia and may declare the isolation of any individual ~~or individuals~~ upon a determination that:

1. [~~Such~~ The] individual ~~or individuals are~~ is known to have been infected with or ~~are~~ is reasonably suspected to have been infected with a communicable disease of public health threat;

2. Exceptional circumstances render the procedures of Article 3.01 (§ 32.1-48.01 et seq.) of Chapter 2 of Title 32.1 of the Code of Virginia to be insufficient, or the individual ~~or individuals have~~ has failed or refused to comply voluntarily with the control measures directed by the commissioner in response to a communicable disease of public health threat; and

3. Isolation is the necessary means to contain a communicable disease of public health threat, to ensure that [~~such~~ the] isolated individual ~~or individuals receive~~ receives appropriate medical treatment subject to the provisions of § 32.1-44 of the Code of Virginia, or to protect health care providers and others who may come into contact with [~~such~~ the] infected individual ~~or individuals~~.

The commissioner, in ~~his~~ the commissioner's sole discretion, may also order the isolation of an affected area if, in addition to the ~~above~~ the provisions of [~~this~~] subsection [A of this section] , the Governor has declared a state of emergency for such affected area of the Commonwealth.

B. [~~Documentation.~~] For isolation for a communicable disease of public health threat, [the local health department shall record] information about the infection or suspected infection, the individual~~, individuals, and/or~~ or affected area, and the nature or suspected nature of the exposure [~~shall be duly recorded by the local health department~~] in consultation with the Office of Epidemiology. This information shall be sufficient to enable documenting a record of findings and to enable the commissioner to prepare the order of isolation, including the information required in § 32.1-48.12 of the Code of Virginia. In addition, [the local health department shall maintain] sufficient information on individuals [~~shall be maintained by the local health department~~] to enable appropriate follow-up of individuals for health status evaluation and treatment as well as compliance with the order of isolation. The commissioner shall ensure that the protected health information of [~~any~~ an] individual ~~or individuals~~ subject to the order of isolation is disclosed only in compliance with state and federal law.

C. [~~Means of isolation.~~] The local health department shall assess the situation, and in consultation with the Office of Epidemiology, identify the least restrictive means of isolation that effectively protects unexposed and susceptible individuals. The place of isolation selected shall allow the most freedom of movement and communication with family members and other contacts without allowing disease transmission to other individuals and shall allow the appropriate level of medical care needed by isolated individuals to the extent practicable. The commissioner, in ~~his~~ the commissioner's sole discretion, may order [~~the~~ an] isolated [individual] ~~or~~ [~~individuals~~] to remain in [~~their residences,~~ the individual's residence,] to remain in another place where [~~they are~~ the individual is] present, or to report to a place ~~or places~~ designated by the commissioner for the duration of [~~their~~ the] isolation.

[D.] The commissioner's order of isolation shall be for a duration consistent with the known period of communicability of the communicable disease of public health threat or, if the course of the disease is unknown or uncertain, for a period anticipated as being consistent with the period of communicability of other similar infectious agents. In the situation where an area is under isolation, the duration of isolation shall take into account the transmission characteristics and known or suspected period of communicability.

[~~D. Delivery.~~ E.] The local health department shall deliver the order of isolation, or ensure its delivery by an appropriate party such as a law-enforcement officer or health department employee, to the affected individual ~~or individuals~~ in person to the extent practicable. If, in the opinion of the commissioner, the scope of the notification would exceed the capacity of the local health department to ensure individual notification in a timely manner, then print, radio, television, Internet, ~~and/or~~ or other available means shall be used to inform those affected.

[~~E. Enforcement.~~ F.] ~~Upon finding that there is probable cause to believe that any individual or individuals who are subject to an order of isolation may fail or refuse to comply with such order, the commissioner in his sole discretion may include in the order a requirement that such individual or individuals are to be taken immediately into custody by law-enforcement agencies and detained for the duration of the order of isolation or until the commissioner determines that the risk of noncompliance is no longer present.~~ For [~~any~~ an] individual ~~or individuals~~ identified as, or for whom probable cause exists that ~~he~~ the individual may be, in violation of [~~any~~ an] order of isolation, or for whom probable cause exists that ~~he~~ the individual may fail or refuse to comply with [~~any such~~ the] order, the enforcement authority directed by the commissioner to law-enforcement agencies shall include ~~but need not be limited to~~ the power to detain or arrest.

[~~Any~~ An] individual ~~or individuals~~ so detained shall be held in the least restrictive environment that can provide any required health care or other services for such individual. The commissioner shall ensure that law-enforcement personnel responsible for enforcing an order ~~or orders~~ of isolation are informed of appropriate measures to take to protect themselves from contracting the disease of public health threat.

[~~F. Health status monitoring.~~ G.] The local health department shall monitor the health of those under isolation either by regular telephone calls, visits, self-reports, or by reports of caregivers or ~~healthcare~~ health care providers or by other means.

[~~G. Essential needs.~~ H.] Upon issuance of an order of isolation to an individual ~~or individuals~~ by the commissioner, the local health department shall manage the isolation, in conjunction with local emergency management resources, such that ~~individual~~ the individual's essential needs can be met to the extent practicable. Upon issuance of an order of isolation by the commissioner for an affected area, existing emergency protocols pursuant to Chapter 3.2 (§ 44-146.13 et seq.) of Title 44 of the Code of Virginia shall be utilized for mobilizing appropriate resources to ensure essential needs are met.

[~~H. Appeals. Any~~ I. An] individual ~~or individuals~~ subject to an order of isolation or a court-ordered confirmation or extension of [~~any such~~ the] order may file an appeal of the order of isolation in accordance with the provisions of § 32.1-48.13 of the Code of Virginia. An appeal shall not stay any order of isolation.

[~~I. Release from isolation.~~ J.] Once the commissioner determines that ~~an individual or~~ individuals no longer pose a threat to the public health, the order of isolation has expired, or the order of isolation has been vacated by the court, the ~~individual or~~ individuals under the order of isolation shall be released immediately. If the risk of an infected individual transmitting the communicable disease of public health threat to other individuals continues to exist, an order of isolation may be developed to extend the restriction prior to release from isolation.

[~~J. Affected area.~~ K.] If the criteria in subsection A of this section are met and an area is known or suspected to have been affected, then the commissioner shall notify the Governor of the situation and the need to order isolation for the affected area during the known or suspected time of exposure. In order for an affected area to be isolated, the Governor must declare a state of emergency for the affected area.

[L.] If an order of isolation is issued for an affected area during the known or suspected time of exposure, the commissioner shall cause the order of isolation to be communicated to the individuals residing or located in the affected area. The use of multiple forms of communication,

including ~~but not limited to~~ radio, television, ~~internet~~ Internet, ~~and/or~~ or other available means~~,~~ may be required in order to reach the individuals who were in the affected area during the known or suspected time of exposure.

[M.] The provisions for documentation, means of isolation, enforcement, health status monitoring, essential needs, and release from isolation as described ~~above~~ in this section [~~will~~] apply to the isolation of affected areas. Appropriate management of a disease of public health threat for an affected area may require the coordinated use of local, regional, state, and national resources. In specifying one or more affected areas to be placed under isolation, [the commissioner shall maintain] the objective [~~will be~~] to protect as many people as possible using the least restrictive means. As a result, defining the precise boundaries and ~~time frame~~ timeframe of the exposure may not be possible~~,~~ or may change as additional information becomes available. [~~When~~ If] this occurs, the commissioner shall ensure that the description of the affected area is in congruence with the Governor's declaration of emergency and shall ensure that the latest information is communicated to those in or exposed to the affected area.

Statutory Authority

§§ 32.1-12, 32.1-35, and 32.1-42 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 23, Issue 15, eff. May 2, 2007; amended, Virginia Register Volume 27, Issue 13, eff. March 28, 2011; Volume 36, Issue 6, eff. December 26, 2019.

12VAC5-90-107. Quarantine.

A. [~~Application.~~] The commissioner, in ~~his~~ the commissioner's sole discretion, may invoke the provisions of Article 3.02 (§ 32.1-48.05 et seq.) of Chapter 2 of Title 32.1 of the Code of Virginia and may order a complete or modified quarantine of [~~any~~ an] individual ~~or individuals~~ upon a determination that:

1. [~~Such~~ The] individual ~~or individuals are~~ is known to have been exposed to or ~~are~~ is reasonably suspected to have been exposed to a communicable disease of public health threat;

2. Exceptional circumstances render the procedures of Article 3.01 (§ 32.1-48.01 et seq.) of Chapter 2 of Title 32.1 of the Code of Virginia to be insufficient, or the individual ~~or individuals have~~ has failed or refused to comply voluntarily with the control measures directed by the commissioner in response to a communicable disease of public health threat; and

3. Quarantine is the necessary means to contain a communicable disease of public health threat to which an individual ~~or individuals have~~ has been or may have been exposed and thus may become infected.

The commissioner, in ~~his~~ the commissioner's sole discretion, may also order the quarantine of an affected area if, in addition to the ~~above~~ the provisions of this subsection, the Governor has declared a state of emergency for such affected area of the Commonwealth.

B. [~~Documentation.~~] For quarantine for a communicable disease of public health threat, [the local health department shall record] information about the infection or suspected infection; the individual~~, individuals, and/or~~ or affected area; and the nature or suspected nature of the exposure [~~shall be duly recorded by the local health department,~~] in consultation with the Office of Epidemiology. This information shall be sufficient to enable documenting a record of findings and enable the commissioner to prepare a written order of quarantine, including the information required in § 32.1-48.09 of the Code of Virginia. In addition, [the local health department shall maintain] sufficient information on individuals [~~shall be maintained by the local health department~~] to enable appropriate follow-up of individuals for health status evaluation and treatment as well as compliance with the order of quarantine. The commissioner shall ensure that the protected

health information of any individual ~~or individuals~~ subject to the order of quarantine is disclosed only in compliance with state and federal law.

C. [~~Means of quarantine.~~] The local health department shall assess the situation, and in consultation with the Office of Epidemiology, shall recommend to the commissioner the least restrictive means of quarantine that effectively protects unexposed and susceptible individuals. The place of quarantine selected shall allow the most freedom of movement and communication with family members and other contacts without allowing disease transmission to others. The commissioner, in ~~his~~ the commissioner's sole discretion, may order the quarantined ~~individual or~~ individuals to remain in their residences, to remain in another place where they are present, or to report to a place ~~or places~~ designated by the commissioner for the duration of their quarantine.

[D.] The commissioner's order of quarantine shall be for a duration consistent with the known incubation period of the communicable disease of public health threat or, if the incubation period is unknown or uncertain, for a period anticipated as being consistent with the incubation period for other similar infectious agents. [~~In the situation where~~ If] an area is under quarantine, the duration of quarantine shall take into account the transmission characteristics and known or suspected incubation period.

[~~D. Delivery.~~ E.] The local health department shall deliver the order of quarantine, or ensure its delivery by an appropriate party such as a law-enforcement officer or health department employee, to the affected individual ~~or individuals~~ in person to the extent practicable. If, in the opinion of the commissioner, the scope of the notification would exceed the capacity of the local health department to ensure notification in a timely manner, then print, radio, television, Internet, ~~and/or~~ or other available means shall be used to inform those affected.

[~~E. Enforcement.~~ F.] ~~Upon finding that there is probable cause to believe that any individual or individuals who are subject to an order of quarantine may fail or refuse to comply with such order, the commissioner in his sole discretion may include in the order a requirement that such individual or individuals are to be taken immediately into custody by law-enforcement agencies and detained for the duration of the order of quarantine or until the commissioner determines that the risk of and from noncompliance is no longer present.~~ For [~~any~~ an] individual ~~or individuals~~ identified as, or for whom probable cause exists that ~~he~~ the individual may be, in violation of [~~any~~ an] order of quarantine, or for whom probable cause exists that ~~he~~ the individual may fail or refuse to comply with [~~any such~~ an] order, the enforcement authority directed by the commissioner to law-enforcement agencies shall include ~~but need not be limited to~~ the power to detain or arrest.

[~~Any~~ An] individual ~~or individuals~~ so detained shall be held in the least restrictive environment that can provide any required health care or other services for such individual. The commissioner shall ensure that law-enforcement personnel responsible for enforcing an order ~~or orders~~ of quarantine are informed of appropriate measures to take to protect themselves from contracting the disease of public health threat.

[~~F. Health status monitoring.~~ G.] The local health department shall monitor the health of those under quarantine either by regular telephone calls, visits, self-reports, or by reports of caregivers or ~~healthcare~~ health care providers or by other means. If ~~an individual or~~ individuals develop symptoms compatible with the communicable disease of public health threat, then 12VAC5-90-103 would apply to the ~~individual or~~ individuals.

[~~G. Essential needs.~~ H.] Upon issuance of an order of quarantine to an individual ~~or individuals~~ by the commissioner, the local health department shall manage the quarantine, in conjunction with local emergency management resources, such that ~~individual~~ the individual's essential needs can be met to the extent practicable. Upon issuance of an order of quarantine by the commissioner for an affected area, existing emergency protocols pursuant to Chapter 3.2 (§ 44-146.13 et seq.) of Title 44 of the Code of Virginia shall be utilized for mobilizing appropriate resources to ensure essential needs are met.

[~~H. Appeals. Any~~ I. An] individual ~~or individuals~~ subject to an order of quarantine or a court-ordered confirmation or extension of [~~any such~~ an] order may file an appeal of the order of quarantine in accordance with the provisions of § 32.1-48.10 of the Code of Virginia. An appeal shall not stay any order of quarantine.

[~~I. Release from quarantine.~~ J.] Once the commissioner determines that ~~an individual or~~ individuals are no longer at risk of becoming infected and pose no risk of transmitting the communicable disease of public health threat to other individuals, the order of quarantine has expired, or the order of quarantine has been vacated by the court, the individuals under the order of quarantine shall be released immediately. If the risk of an individual becoming infected and transmitting the communicable disease of public health threat to other individuals continues to exist, an order of quarantine may be developed to extend the restriction prior to release from quarantine.

[~~J. Affected area.~~ K.] If the criteria in subsection A of this section are met and an area is known or suspected to have been affected, then the commissioner shall notify the Governor of the situation and the need to order quarantine for the affected area. In order for an affected area to be quarantined, the Governor must declare a state of emergency for the affected area.

[L.] If an order of quarantine is issued for an affected area, the commissioner shall cause the order of quarantine to be communicated to the individuals residing or located in the affected area. The use of multiple forms of communication, including ~~but not limited to~~ radio, television, Internet, ~~and/or~~ or other available means~~,~~ may be required in order to reach the individuals who were in the affected area during the known or suspected time of exposure.

[M.] The provisions for documentation, means of quarantine, enforcement, health status monitoring, essential needs, and release from quarantine as described ~~above~~ in this section [~~will~~] apply to the quarantine of affected areas. Appropriate management of a disease of public health threat for an affected area may require the coordinated use of local, regional, state, and national resources. In specifying one or more affected areas to be placed under quarantine, [the commissioner shall maintain] the objective [~~will be~~] to protect as many people as possible using the least restrictive means. As a result, defining the precise boundaries and ~~time frame~~ timeframe of the exposure may not be possible~~,~~ or may change as additional information becomes available. [~~When~~ If] this occurs, the commissioner shall ensure that the description of the affected area is in congruence with the Governor's declaration of emergency and shall ensure that the latest information is communicated to those in or exposed to the affected area.

Statutory Authority

§§ 32.1-12, 32.1-35, and 32.1-42 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 23, Issue 15, eff. May 2, 2007; amended, Virginia Register Volume 27, Issue 13, eff. March 28, 2011; Volume 36, Issue 6, eff. December 26, 2019.

12VAC5-90-140. Procedure for preventing ophthalmia neonatorum.

The physician, nurse, or midwife in charge of the infant's care after delivery of a baby shall ensure that ~~one of the following is administered in each eye of that newborn baby as soon as possible after birth: (i) two drops of a 1.0% silver nitrate solution; (ii) a 1-cm ribbon of 1.0% tetracycline ophthalmic ointment; or (iii)~~ a 1-cm ribbon of 0.5% erythromycin ophthalmic ointment is administered in each eye of [~~that newborn baby~~ the infant] as soon as possible [~~. This~~ after birth and shall record the] treatment [~~shall be recorded~~] in the medical record of the infant.

Statutory Authority

§§ 32.1-12, 32.1-35, and 32.1-42 of the Code of Virginia.

Historical Notes

Derived from VR355-28-100 § 7.1, eff. July 1, 1993; amended, Virginia Register Volume 27, Issue 13, eff. March 28, 2011; Volume 36, Issue 6, eff. December 26, 2019.

12VAC5-90-215. Schedule and criteria for and confirmation of blood lead testing and information to be provided.

A. [~~Schedule for testing. Every~~ A] child shall be tested to determine the blood lead level at 12 months and 24 months of age if the health care provider determines that the child meets any of the criteria listed in subsection B of this section. [~~Children~~ A child] 25 months through 72 months of age who [~~present~~ presents] for medical care and [~~meet~~ meets] any of [the] criteria of subsection B of this section shall also be tested if [~~they have~~ the child has] either not previously been tested for blood lead level or [~~were~~ was] previously tested but experienced a change since testing that has resulted in an increased risk of lead exposure based on the criteria listed in subsection B of this section.

B. [~~Criteria for testing.~~ The criteria for blood lead testing are as follows:]

1. The child is eligible for or receiving benefits from Medicaid or the Special Supplemental Nutrition Program for Women, Infants and Children (WIC);

2. The child is living in or regularly visiting a house, apartment, dwelling, structure, or child care facility built before ~~1960~~ 1950;

3. The child is living in or regularly visiting a house, apartment, dwelling, structure, or child care facility built before 1978 that has (i) peeling or chipping paint or (ii) recent (within the last six months) ongoing or planned renovations;

4. The child is living in or regularly visiting a house, apartment, dwelling, or other structure in which one or more persons have blood lead testing yielding evidence of lead exposure;

5. The child is living with an adult whose job, hobby, or other activity involves exposure to lead;

6. The child is living near an active lead smelter, battery recycling plant, or other industry likely to release lead;

7. The child's parent, guardian, or other person standing in loco parentis requests the child's blood be tested due to any suspected exposure; or

8. The child is a recent refugee or immigrant or is adopted from outside of the United States.

C. [~~Exceptions.~~] A child who does not meet any of the schedule or criteria provided in subsection A or B of this section is considered to be at low risk, and testing is not required but may be conducted at the discretion of the health care provider. The testing requirement shall be waived if the parent, guardian, or other person standing in loco parentis of a child objects to the testing on the basis that the procedure conflicts with his religious tenets or practices.

D. [~~Confirmation of blood lead levels.~~] Blood lead level testing shall be performed on venous or capillary blood. Tests of venous blood performed by a laboratory certified by the federal Centers for Medicare & Medicaid Services in accordance with 42 USC § 263a, the Clinical Laboratory Improvement Amendment of 1988 (CLIA-certified), are considered confirmatory. Tests of venous blood performed by any other laboratory and tests of capillary blood shall be confirmed by a repeat blood test, preferably venous, performed by a CLIA-certified laboratory. [~~Such confirmatory~~ Confirmatory testing is not required if the result of the capillary test is below CDC's reference value. Confirmatory] testing shall be performed [~~in accordance with the following schedule~~] :

1. [~~Confirmatory testing is not required if the result of the capillary test is below CDC's reference value.~~

~~2.~~] Within one to three months if the result of the capillary test is at or above the CDC's reference value and up to ~~9~~ nine micrograms of lead per deciliter of whole blood (µg/dL) [~~.~~ ;]

[2. ~~3.~~] Within one week to one month if the result of the capillary test is 10-44 µg/dL. The higher this test result, the more urgent the need for a confirmatory test [~~.~~ is:]

[3. ~~4.~~] Within 48 hours if the result of the capillary test is 45-59 µg/dL [~~.~~ ;]

[4. ~~5.~~] Within 24 hours if the result of the capillary test is 60-69 µg/dL [~~.~~ and]

[5. ~~6.~~] Immediately as an emergency laboratory test if the result of the capillary test is 70 µg/dL or higher.

E. [~~Information to be provided.~~] As part of regular well-check visits for all children, the health care provider shall make available to parents, guardians, or other persons standing in loco parentis information on the dangers of lead poisoning, potential sources of lead and ways to prevent exposure, and a list of available lead-related resources. When blood lead level testing is performed, the health care provider shall share the child's blood lead level test result with the child's parent, guardian, or other person standing in loco parentis and [shall] report to the local health department in accordance with the requirements of 12VAC5-90-80.

Statutory Authority

§§ 32.1-12, 32.1-35, and ~~32.1-46.1~~ 32.1-42 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 32, Issue 12, eff. March 11, 2016; amended, Virginia Register Volume 36, Issue 6, eff. December 26, 2019.

12VAC5-90-225. Additional data to be reported related to persons with active tuberculosis disease (confirmed or suspected).

A. Physicians and directors of medical care facilities [~~are required to~~ shall] submit [~~all of~~] the following [to the department] :

1. An initial report to be completed when there are reasonable grounds to suspect that a person has active TB disease, but no later than when antituberculosis drug therapy is initiated. The [~~reports must~~ report shall] include the following: the affected person's name; age; date of birth; gender; address; pertinent clinical, radiographic, microbiologic, and pathologic reports, whether pending or final; [~~such~~] other information as may be needed to locate the patient for follow-up; and name, address, and telephone number of the treating physician.

2. A secondary report to be completed simultaneously or within one to two weeks following the initial report. The report [must shall] include: the date, method, and results of ~~tuberculin skin test (TST)~~ tests for tuberculosis infection; the date and results of the initial and [~~any~~] follow-up chest radiographs; the dates and results of bacteriologic or pathologic testing, the antituberculosis drug regimen, including names of the drugs, dosages and frequencies of administration, and start date; the date and results of drug susceptibility testing; HIV status; contact screening information; and name, address, and telephone number of treating physician.

3. Subsequent reports [~~are to be made~~] when updated information is available. Subsequent reports are required when~~:~~ clinical status changes, the treatment regimen changes; treatment ceases for any reason; or there are any updates to laboratory results, treatment adherence, name, address, and telephone number of current provider, patient location or contact information, or other additional clinical information.

[~~4.~~ B.] Physicians ~~and/or~~ or directors of medical care facilities responsible for the care of a patient with active tuberculosis disease [~~are required to~~ shall] develop and maintain a written

treatment plan [~~. This plan must~~ that shall] be in place no later than the time when antituberculosis drug therapy is initiated. Patient adherence to this treatment plan must be documented. The treatment plan and adherence record are subject to review by the local health director or ~~his~~ the local health director's designee at any time during the course of treatment.

[~~5.~~ C.] The treatment plan for the following categories of patients [~~must~~ shall] be submitted to the local health director or ~~his~~ the local health director's designee for approval no later than the time when antituberculosis drug therapy is started or modified:

[~~a. For individuals~~ 1. Individuals] who are inpatients or incarcerated, [for whom] the responsible provider or facility [~~must~~ shall] submit the treatment plan for approval prior to discharge or transfer.

[~~b.~~ 2.] Individuals, whether inpatient, incarcerated, or outpatient, who also have one of the following conditions:

[~~(1)~~ a.] HIV infection [~~.~~ ;]

[~~(2)~~ b.] Known or suspected active TB disease resistant to rifampin, rifabutin, rifapentine, or other rifamycin with or without resistance to any other drug [~~.~~ ;]

[~~(3)~~ c.] A history of prior treated or untreated active TB disease, or a history of relapsed active TB disease [~~.~~ ; or]

[~~(4)~~ d.] A demonstrated history of nonadherence to any medical treatment regimen.

[~~B. Laboratories are required to~~ D. A laboratory director shall] submit the following:

1. Results of smears that are positive for acid fast bacilli [~~.~~ ;]

2. Results of cultures positive for any member of the Mycobacterium tuberculosis complex ~~(i.e., M. tuberculosis, M. bovis, M. africanum)~~ or any other mycobacteria [~~.~~ ;]

3. Results of rapid methodologies, including acid hybridization or nucleic acid amplification, which are indicative of M. tuberculosis complex or any other mycobacteria [~~.~~ ;]

4. Results of tests for antimicrobial susceptibility performed on cultures positive for ~~tubercle bacilli~~ M. tuberculosis complex [~~.~~ ; and]

5. Results of tests for tuberculosis infection. [~~6. Laboratories, whether~~ Whether] testing is done in-house or referred to an out-of-state laboratory, [a laboratory director] shall submit a representative and viable sample of the initial culture positive for any member of the M. tuberculosis complex to the ~~Virginia~~ Division of Consolidated Laboratory Services or other laboratory designated by the board to receive such specimen.

Statutory Authority

§§ 32.1-12, 32.1-35, and 32.1-42 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 20, Issue 21, eff. July 28, 2004; amended, Virginia Register Volume 23, Issue 15, eff. May 2, 2007; Volume 27, Issue 13, eff. March 28, 2011; Volume 36, Issue 6, eff. December 26, 2019.

12VAC5-90-280. Reporting of dangerous microbes and pathogens.

A. Definitions. The following words and terms when used in this part shall have the following meanings unless the context clearly indicates otherwise:

~~"Biologic agent" means any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, or other living~~

~~organism; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment.~~

~~"CDC" means the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services.~~

~~"Diagnosis" means the analysis of specimens for the purpose of identifying or confirming the presence or characteristics of a select agent or toxin, provided that such analysis is directly related to protecting the public health or safety.~~

~~"Proficiency testing" means a sponsored, time-limited analytical trial whereby one or more analytes, previously confirmed by the sponsor, are submitted to the testing laboratory for analysis and where final results are graded, scores are recorded and provided to participants, and scores for participants are evaluated.~~

~~"Responsible official" means any person in charge of directing or supervising a laboratory conducting business in the Commonwealth of Virginia. At colleges and universities, the responsible official shall be the president of the college or university or his designee. At private, state, or federal organizations, the responsible official shall be the laboratory director or a chief officer of the organization or his designee.~~

"Select agent or toxin" or "select agent and toxin" means all those biological agents or toxins as defined by federal regulations in 42 CFR Part 73, including Health and Human Services select agents and toxins and overlap select agents and toxins. <u>"Dangerous microbes and pathogens" will be known as "select agents and toxins."</u>

~~"Toxin" means the toxic material or product of plants, animals, microorganisms (including but not limited to bacteria, viruses, fungi, rickettsiae, or protozoa); or infectious substances; or a recombinant or synthesized molecule, whatever the origin and method of production; and includes any poisonous substance or biological product that may be engineered as a result of biotechnology or produced by a living organism; or any poisonous isomer or biological product, homolog, or derivative of such a substance.~~

~~"Verification" means the process required to assure the accuracy, precision, and the analytical sensitivity and specificity of any procedure used for diagnosis.~~

~~B. Administration. The dangerous microbes and pathogens will be known as "select agents and toxins." The select agent and toxin registry will be maintained by the Virginia Department of Health, Office of Epidemiology, Division of Surveillance and Investigation.~~

~~C. Reportable agents. The board declares the select agents and toxins and overlap select agents and toxins outlined in 42 CFR Part 73 to be reportable and adopts it herein by reference including subsequent amendments and editions. The select agents and toxins are to be reportable by the persons enumerated in subsection F of this section.~~

~~D.~~ <u>B.</u> Items to report. Each report shall ~~be made on a form determined by the department and shall~~ contain the following: name, source<u>,</u> and characterization information on select agents and toxins and quantities held; ~~objectives of the work with the agent; location (including building and room) where each select agent or toxin is stored or used; identification information of persons with access to each agent; identification information of the person in charge of each of the agents;~~ and the <u>name and address of the laboratory and the</u> name, position<u>,</u> and identification information of one responsible official as a single point of contact for the organization. ~~The report shall also indicate whether the laboratory is registered with the CDC Select Agent Program and may contain additional information as required by 42 CFR Part 73 or the department.~~

~~E.~~ <u>C.</u> Timing of reports. ~~Reports shall be made to the department within seven calendar days of submission of an application to the CDC Select Agent Program.~~ By January 31 of every year, ~~laboratories~~ <u>the responsible official at a laboratory as designated by the [~~federal select agent program~~ Federal Select Agent Program]</u> shall provide a written update to the ~~department, which~~

~~shall include a copy of the federal registration certificate received through the CDC Select Agent Program~~ Division of Surveillance and Investigation in the Office of Epidemiology containing the information specified in subsection B of this section.

~~In the event that a select agent or toxin that has previously been reported to the department is destroyed, a copy of federal forms addressing the destruction of the select agent or toxin must be submitted to the department within seven calendar days of submission to the CDC Select Agent Program.~~

~~In the event that a select agent or toxin, or a specimen or isolate from a specimen containing a select agent or toxin, has previously been reported to the department and is subsequently transferred to a facility eligible for receiving the items, a copy of federal forms addressing the transfer of the select agent or toxin must be submitted to the department within seven calendar days of submission to the CDC Select Agent Program.~~

In the event of a suspected release, loss, or theft of any select agent or toxin, the responsible official at a laboratory as designated by the [~~federal select agent program~~ Federal Select Agent Program] shall make a report to the department immediately by the most rapid means available, preferably by telephone. The report shall be submitted to the Division of Surveillance and Investigation in the Office of Epidemiology. The rapid report shall be followed up by a written report within seven calendar days and shall include the following information:

1. The name of the biologic agent and any identifying information (e.g., strain or other characterization information);

2. An estimate of the quantity released, lost, or stolen;

3. An estimate of the time during which the release, loss, or theft occurred; [~~and~~]

4. The location (building, room) from or in which the release, loss, or theft occurred. The report may contain additional information as required by 42 CFR Part 73 or the department [~~.~~ ; and]

[5.] If a release has occurred, the report shall also include the nature, environment, and location of the release; number, names, and position of exposed individuals; and actions taken as a result of the release.

~~The department shall be notified in writing of any change to information previously submitted to the department. If a new application or an amendment to an existing application is filed with the CDC Select Agent Program, a copy of the application or amendment shall be submitted to the department within seven calendar days of submission to the CDC Select Agent Program.~~

~~F. Those required to report. The laboratory director shall be responsible for annual reporting of select agents and toxins to the Virginia Department of Health and for the reporting of any changes within the time periods as specified within these regulations. Such reports shall be made on forms to be determined by the department. Any person making such reports as authorized herein shall be immune from liability as provided by § 32.1-38 of the Code of Virginia.~~

~~G. Exemption from reporting. A person who detects a select agent or toxin for the purpose of diagnosing a disease, verification, or proficiency testing and either transfers the specimens or isolates containing the select agent or toxin to a facility eligible for receiving them or destroys them on site is not required to make a report except as required by 12VAC5-90-80 and 12VAC5-90-90. Proper destruction of the agent shall take place through autoclaving, incineration, or by a sterilization or neutralization process sufficient to cause inactivation. The transfer or destruction shall occur within seven calendar days after identification of a select agent or toxin used for diagnosis or testing and within 90 calendar days after receipt for proficiency testing.~~

~~Any additional exemptions from reporting under 42 CFR Part 73, including subsequent amendments and editions, are also exempt from reporting under this regulation; however, the~~

~~department shall be notified of the exemption by submitting a copy of federal forms addressing the exemption within seven calendar days of submission to the CDC Select Agent Program.~~

~~H.~~ D. Release of reported information. Reports submitted to the select agent and toxin registry shall be confidential and shall not be a public record pursuant to the Freedom of Information Act, regardless of submitter. Release of information on select agents or toxins shall be made only by order of the State Health Commissioner to the CDC and state and federal law-enforcement agencies in any investigation involving the release, theft, or loss of a select agent or toxin required to be reported to the department under this regulation. [~~Any~~ A] person making [~~such reports~~ a report] as authorized in this section shall be immune from liability as provided by § 32.1-38 of the Code of Virginia.

Statutory Authority

§§ 32.1-12, 32.1-35, and 32.1-42 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 20, Issue 21, eff. July 28, 2004; amended, Virginia Register Volume 23, Issue 15, eff. May 2, 2007; Volume 33, Issue 2, eff. October 20, 2016; Volume 36, Issue 6, eff. December 26, 2019.

12VAC5-90-370. Reporting of ~~healthcare-associated~~ health care-associated infections.

A. [~~Reportable infections.~~] ~~Facilities~~ [~~Health care facilities~~ A health care facility] that [~~report~~ reports] data into the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN) ~~for~~ as a requirement of the Centers for Medicare and Medicaid Services ~~Hospital Inpatient Quality Reporting Program~~ shall share the data, through the NHSN, with the department.

B. [~~Liability protection and data release. Any~~ A] person making [~~such~~ a] report as authorized ~~herein~~ in this section shall be immune from liability as provided by § 32.1-38 of the Code of Virginia. Infection rate data may be released to the public by the department upon request. Data shall be aggregated to ensure that no individual patient may be identified.

Statutory Authority

§§ 32.1-12 ~~and~~, 32.1-35, and 32.1-42 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 24, Issue 19, eff. July 1, 2008; amended, Virginia Register Volume 27, Issue 13, eff. March 28, 2011; Volume 31, Issue 26, eff. September 25, 2015; Volume 36, Issue 6, eff. December 26, 2019.

~~FORMS (12VAC5-90)~~(Repealed)</u

~~FORMS (12VAC5-90)~~

~~Confidential Morbidity Report, Epi-1 (rev. 10/2011)~~

~~Virginia Cancer Registry Reporting Form (rev. 1/1998)~~

Certification of Community Health Workers
12VAC5-402
(Proposed Regulations)

Vanessa Walker Harris, MD

Director

Office of Family 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: August 15, 2023

TO: Virginia State Board of Health

FROM: Vanessa Walker Harris, Director, Office of Family Health Services

SUBJECT: Proposed Stage – Certification of Community Health Workers (12VAC5-402)

Enclosed for your review and approval are proposed regulations to establish requirements for the certification of community health workers.

Section 32.1-15.1 of the Code of Virginia mandates that the Board of Health adopt regulations setting forth requirements for use of the title "certified community health worker" and education and training programs necessary to meet the requirements for certification as a certified community health worker. Approval of this regulatory action would result in creating a new regulatory chapter, 12-VAC5-402.

Upon approval by the Board, the proposed regulations will be submitted to the Regulatory Town Hall to begin the Executive Branch Review process. Following approval by the Governor, it will be published in the *Virginia Register of Regulations* for a 60-day public comment period.

townhall.virginia.gov

Proposed Regulation
Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC5-402
VAC Chapter title(s)	Certification of Community Health Workers
Action title	Adopt regulations setting forth the requirements for community health worker certification
Date this document prepared	July 17, 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 363 of the 2020 Acts of Assembly enacted § 32.1-15.1, which mandates the Board of Health to adopt regulations that set forth the requirements for use of the title “certified community health worker" and the training and education necessary to satisfy the requirements for certification as a certified community health worker. Section 32.1-15.1 also requires that the Board approve a certifying body that intends to certify community health workers. This action is intended to fulfill the mandate in Ch 363 (2020).

Community health workers are nonmedical professionals with the education and experience necessary to provide collaborative services to assist individuals in achieving sustained wellness by engaging, educating, supporting, and advocating on behalf of an individual's efforts to meet the goals established in a plan of care. To ensure continuity and validity in the knowledge, skills and abilities of individuals promoting themselves as certified community health workers, regulations defining the requirements for

certification are required. The primary goal of this regulation 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.

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.

“CHW” means a community health worker
“Department” or “VDH” means the Virginia Department of Health

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.”

Section 32.1-15.1 of the Code of Virginia mandates that the Board of Health adopt regulations setting forth requirements for use of the title "certified community health worker" and education and training necessary to meet the requirements for certification as a certified CHW.

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 Board is authorized by § 32.1-12 to “make, adopt, promulgate and enforce such regulations and provide for reasonable variances and exemptions therefrom as may be necessary to carry out the provisions of [Title 32.1] and other laws administered by it, the Commissioner or the Department.”

Section 32.1-15.1 of the Code of Virginia mandates that the Board of Health adopt regulations setting forth requirements for use of the title "certified community health worker" and education and training programs necessary to meet the requirements for certification as a certified CHW.

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 purpose of this regulation is to comply with the mandate of § 32.1-15.1 and to provide standardized CHW certification requirements in the Commonwealth of Virginia. Certification requirements for certified CHWs shall reflect national best practices pertaining to community-based community health worker training and certification. Individuals practicing as certified CHWs will have attained the required training, through entities approved by the Board of Health, to provide collaborative services to assist individuals in achieving sustained wellness by engaging, educating, supporting, and advocating on behalf of an individual's efforts to meet the goals established in a plan of care. A standardized CHW certification model is also beneficial to supporting and maintaining the workforce. This regulatory action will ensure that the content is clearly written.

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.

This new regulation will include the definition of a CHW as well as other relevant terminology. The regulation will outline the minimum training and education requirements for certified CHWs based on the core competences used by national organizations and community-based organizations in Virginia. In addition, the regulation will describe the minimum standards required of the entity, approved by the Board, responsible for confirming certified CHWs, approving the training and education to meet CHW certification requirements and maintaining a registry of certified CHWs available to the general public.

Issues

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

The primary advantage of the proposed regulatory action to the public is the establishment of statewide community health worker certification requirements and a public registry. Establishing minimum training and education criteria for state certification of CHWs based on national standards and best practices will provide assurance to the public that certified CHW have met those requirements. A certifying body approved by the Board of Health will verify that CHWs practicing in the Commonwealth have completed the required training to attain certification and provide collaborative services to assist individuals in achieving sustained wellness. Healthcare providers, community-based organizations and payers may be assured of standardized training requirements when vetting this critical workforce. The public registry will include all CHWs certified in Virginia and will make identification of certified CHWs easier and more accessible to the public. One disadvantage associated with this regulatory action to the public is the potential costs to applicants seeking to become a certified CHW as they will likely incur an application fee. Another potential issue regarding standardizing CHW certification requirements is that the regulation may present a perceived barrier to CHWs who are currently practicing without certification, though a CHW is

not required to be certified if they do not intend to use the title "certified CHW." This regulation will be written to ensure that these individuals are not prohibited from continuing to practice. There are no other known disadvantages to the public associated with this regulatory change.

Requirements More Restrictive than Federal

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

There are no requirements more restrictive than applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

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 other state agencies will be particularly affected.

Localities Particularly Affected

No localities will be particularly affected.

Other Entities Particularly Affected

Community health workers or others who wish to practice as a certified community health worker in Virginia will be particularly affected.

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:	The regulatory change has no economic impact on VDH.

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.	
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.	This regulatory change has no economic impact on other state agencies.
For all agencies: Benefits the regulatory change is designed to produce.	This regulatory change is intended to improve the health and well-being of individuals in Virginia through community-based collaborative services. This change is also intended to help eliminate health disparities across the Commonwealth.

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.	This regulatory change has no economic impact on localities.
Benefits the regulatory change is designed to produce.	This regulatory change is intended to improve the health and well-being of individuals in Virginia through community-based collaborative services. This change is also intended to help eliminate health disparities across the Commonwealth.

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.	Community health workers or others who wish to practice as a certified community health worker in Virginia will be particularly affected.
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.	This number is unknown as Virginia does not currently have a central repository to collect data on the number of CHWs practicing in the state. This regulatory action will establish a public registry, which will provide this information once implemented.
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;	The projected cost for each affected individual is $100 per application for CHW certification.

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.	
Benefits the regulatory change is designed to produce.	The regulatory change is designed to establish minimum standards for CHWs practicing as certified CHWs in Virginia. This regulatory change is intended to improve the health and well-being of individuals in Virginia through community-based collaborative services. This change is also intended to help eliminate health disparities across the Commonwealth.

Alternatives to Regulation

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

No alternative to this regulatory action was considered, as the Code of Virginia mandates the requirement for regulations pertaining to CHW certification.

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

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.

§32.1-15.1 mandated the Board of Health to establish requirements for use of the title "certified community health worker" and to establish training and education requirements for certified CHWs. VDH had previously partnered with key stakeholders to implement a CHW certification process based on identified core competencies. The proposed regulations will codify the existing process. VDH staff convened stakeholder workgroup meetings to receive input and feedback on the proposed regulations.

There are no other applicable regulations to consolidate that impact establishing requirements for use of the title "certified community health worker" or establishing training and education requirements for certification as a certified CHW. Small businesses may not be exempted as a category because health services must be managed equitably by their providers, regardless of business size, to assure optimal

outcomes. There are no viable alternatives to the proposed regulatory action to achieve the necessary regulatory changes.

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

Periodic Review and Small Business Impact Review Report of Findings

If you are using this form to report the result of a periodic review/small business impact review that is being conducted as part of this regulatory action, and was announced during the NOIRA stage, indicate whether the regulatory change meets the criteria set out in EO 19 and the ORM procedures, e.g., is necessary for the protection of public health, safety, and welfare; minimizes the economic impact on small businesses consistent with the stated objectives of applicable law; and is clearly written and easily understandable. In addition, as required by § 2.2-4007.1 E and F of the Code of Virginia, discuss the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, discuss why the agency's decision, consistent with applicable law, will minimize the economic impact of regulations on small businesses.

This form is not being used to report the result of a periodic review or a small business impact review.

Public Comment

Summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency'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 following publication of the NOIRA stage.

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.

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, (ii) any alternative approaches, (iii) the potential impacts of the regulation, and (iv) the agency's regulatory flexibility analysis stated in that section of this background document.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: https://townhall.virginia.gov. Comments may also be submitted by mail, email or fax to Heather Board, 109 Governor St, 9th Floor, Richmond, VA 23219,

communityhealthworker@vdh.virginia.gov and 804-864-7748. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

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

Detail of Changes

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

If a new VAC Chapter(s) is being promulgated and is not replacing an existing Chapter(s), use Table 2.

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

New chapter-section number	New requirements to be added to VAC	Other regulations and laws that apply	Change, intent, rationale, and likely impact of new requirements
10	Defines terms used throughout the regulations	Not applicable.	**Change:** The section defines terms used in the regulation. **Intent:** The intent is to ensure clarification for and allow the agency to control the meaning of terms used. **Rationale:** Definitions sections are required as part of regulations. **Likely Impact:** VDH staff and the public will clearly understand the terms used.
20	Describes use of the title certified community health worker	Not applicable.	**Change:** This section prohibits use of the title “certified CHW” without meeting the requirements in the chapter. It also exempts CHWs who do not desire to use that title from the requirements of the chapter. **Intent:** The intent is to clarify who is allowed to use the title. **Rationale:** The requirement in subsection A come directly from § 32.1-15.1 (B). **Likely Impact:** The likely impact of the requirements is clarity and distinction between certified CHWs and other CHWs to members of the public when reading the regulatory chapter. The impact of the certification exemption is intended to assure individuals who are currently practicing as

			CHWs in the state that they may continue to do so.
30	Describes the qualifications for a certified community health worker and continuing education	Not applicable.	**Change:** This section requires someone desiring to be certified to be an adult, complete at least 60 hours of approved training, and perform at least 2,000 hours of community health services within three years before the application, 50 of which being supervised. The applicant is also required to verify that information to the approved certifying body. The section also allows someone who was certified in another state to become certified in Virginia by providing their certification to the certifying body, as long as they meet the stated training hours requirements. The section also requires recertification every two years and 30 hours of approved continuing education during the two-year period. **Intent:** The requirements are intended to make the distinction between initial CHW certification requirements and recertification requirements. They are also intended to ensure that a "certified CHW" has met acceptable training and education standards consistent with a "certified" professional. The recertification requirements are intended to ensure that a certified CHW remains up-to-date on relevant training and education over time. **Rationale:** The rationale is that § 32.1-15.1 required the Board to promulgate the education and training requirements. **Likely Impact:** The impact of these requirements will likely result in clarity to members of the public regarding minimum applicant qualifications. Also, members of the public will know that certified CHWs have met widely accepted training and education standards and possess the associated knowledge, skills, and abilities.
40	Describes the standards for certifying bodies	Not applicable.	**Change:** This section describes the minimum standards for the entity approved by the Board of Health that will certify CHWs, approve continuing education for the recertification of CHWs. The certifying body must establish a public registry of certified CHWs, submit annual reports to the Board on approved certified CHWS and

			training entities, ensure applicants' compliance with the training and education requirements, and establish a code of ethics for certified CHWs. **Intent:** The intent is to describe the minimum expectations of a certifying body to be approved by the Board and to maintain and provide data on certified CHWs and training entities. **Rationale:** The registry and reporting requirements will allow for public transparency and the ability for the public to confirm the certification status of a certified CHW. It will also allow for VDH and the public to analyze trends regarding the certification of CHWs across the Commonwealth. **Likely Impact:** The likely impact is that bodies who demonstrate the ability to meet the requirements in the section will be approved certifying bodies and will begin issuing certifications.
50	Describes the curriculum requirements	Not applicable.	**Change:** This section requires training entities to provide 60 hours of training, broken down according to the section, in the following topic areas: community health concepts and approaches; service coordination and system navigation; health promotion and prevention; advocacy, outreach, and engagement; communication; cultural humility and responsiveness; and ethical responsibilities and professionalism. **Intent:** The intent is to ensure that training entities provide a consistent framework for certified CHW education programs that are sufficient to provide the expected knowledge, skills, and abilities of a "certified" professional. **Rationale:** The rationale is that § 32.1-15.1 requires the Board to set requirements for education and training programs. **Likely Impact:** The likely impact is that certified CHWs will have solid, consistent educational backgrounds sufficient to perform the typical duties of a CHW. Also, training entities providing compliant training programs will be approved by certifying bodies to provide the programs to CHWs seeking certification in Virginia.

Office of Regulatory Management

Economic Review Form

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC 5-402
VAC Chapter title(s)	Certification of Community Health Workers
Action title	Adopt regulations setting forth the requirements for community health worker certification
Date this document prepared	7/17/2023
Regulatory Stage (including Issuance of Guidance Documents)	Proposed

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 projected direct monetized cost for each individual is approximately $100 per application for community health worker certification. **Indirect Costs:** There are no monetized indirect costs associated with the proposed regulations. **Direct Benefits:** There are no direct monetized benefits associated with the proposed regulations. **Indirect Benefits:** There are no indirect monetized benefits associated with the proposed regulations.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $100	(b) $0
(3) Net Monetized Benefit	$0	
(4) Other Costs & Benefits (Non-Monetized)	There are no non-monetized costs for the proposed regulations. The non-monetized benefits of the proposed regulations are that qualified individuals will provide collaborative services to assist individuals in achieving sustained wellness by engaging, educating, supporting, and advocating on behalf of an individual's efforts to meet the goals established in a plan of care. Healthcare providers, community-based organizations and payers may be assured of standardized training requirements when vetting this critical workforce. The public registry will include all community health workers certified in Virginia and will make identification of certified community health workers easier and more accessible to the public.	
(5) Information Sources		

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

(1) Direct & Indirect Costs & Benefits (Monetized)	This will be the initial promulgation of the chapter and is intended to meet the mandate in § 32.1-15.1, thus the status quo of no regulatory structure is not a viable option to assess. Thus, there are no monetized direct or indirect costs or benefits associated.	
(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 or benefits under the Status Quo.	
(5) Information Sources	N/A	

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

(1) Direct & Indirect Costs & Benefits (Monetized)	The regulation in this action is mandated by § 32.1-15. The requirements in the regulation represent the consensus of extensive stakeholder engagement as the least burdensome approach to accomplish the legislative mandate and ensure that certified CHWs meet a consistent set of requirements. Additional requirements, such as increased training or education hour requirements to be eligible to be certified or additional requirements on certifying bodies or training entities to be approved were considered, but are not included in these proposed regulations. The monetized costs would be higher under such alternatives, seen as potential delayed wage increases that a CHW may receive after certification, higher costs to attend training programs if the entity had to deliver a lengthier course or one meeting additional requirements imposed by the Board.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) undetermined	(b) 0
(3) Net Monetized Benefit		
(4) Other Costs & Benefits (Non-Monetized)	While increased training or education hour requirements may increase the knowledge and experience of a certified CHW applicant, but the non-monetized cost of the increased regulatory burden would not outweigh any incremental benefit associated, as the current standards are sufficient to ensure properly trained certified CHWs.	
(5) Information Sources		

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 direct or indirect monetized costs or benefits to local partners associated with this change.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $0
(3) Other Costs & Benefits (Non-Monetized)	There are no non-monetized costs associated with this regulatory action. This regulatory change is intended to improve the health and well-being of individuals in Virginia through community-based collaborative services. This change is also intended to help eliminate health disparities across the Commonwealth. Localities, such as local health departments, social services agencies, mental and behavioral health services, or other locality-administered entities who hire certified CHWs would benefit from the certification of their knowledge, skills, and abilities.	
(4) Assistance	No assistance needed.	
(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 direct or indirect monetized costs or benefits to families associated with this change.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits

	(a) $0	(b) $0
(3) Other Costs & Benefits (Non-Monetized)	There are no non-monetized costs to families associated with the proposed change. The non-monetized benefits of the proposed regulations include that qualified individuals will provide collaborative services to assist families in achieving sustained wellness by engaging, educating, supporting, and advocating on behalf of an individual's efforts to meet the goals established in a plan of care.	
(4) Information Sources		

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 or benefits to small businesses associated with this regulatory action.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $0
(3) Other Costs & Benefits (Non-Monetized)	There are no non-monetized costs to small businesses associated with this regulatory action. Healthcare providers and community-based organizations of any size may be assured of standardized training requirements when vetting this critical workforce. The public registry will include all community health workers certified in Virginia and will make identification of certified community health workers easier and more accessible to employers.	
(4) Alternatives		
(5) Information Sources		

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
12.5.402.10	**Statutory:**	0	0		0
	Discretionary:	0	0		0
12.5.402.20	**Statutory:**	0	2 (R/S)		+2
	Discretionary:	0	0		0
12.5.402.30	**Statutory:**	0	0		0
	Discretionary:	0	6 (R/D)		+6
12.5.402.40	**Statutory:**	0	1 (G/S) 3 (R/S)		+4
	Discretionary:	0	4 (R/D)		+4
12.5.402.50	**Statutory:**	0	1 (R/S)		+1
	Discretionary:	0	7 (R/D)		+7

Project 6685 - Proposed

Department of Health

Adopt regulations setting forth the requirements for community health worker certification

Chapter 402

Certification of Community Health Workers [Under Development]

12VAC5-402-10. Definitions.

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

"Approved training entity" means an organization whose training program or curriculum are approved by a certifying body to meet the curriculum requirements for community health worker certification pursuant to this chapter.

"Board" means the State Board of Health.

"Certified community health worker" means a community health worker who is deemed by a certifying body to be professionally qualified, by education and experience, to provide collaborative community health support services to assist individuals in achieving sustained wellness.

"Certifying body" means an organization approved by the Board to certify community health workers.

"Community health support services" means activities that engage, educate, support, and advocate on behalf of an individual's efforts to meet the goals established in a plan of care. Activities include care coordination, coaching or social support, health education, direct services, community assessments and engagement, advocacy, outreach, and contact tracing.

"Community health worker" means a person who provides community health support services to individuals for the purpose of achieving the goals set forth in a plan of care.

"Individual" means a person who is receiving community health worker services. This term includes the terms "consumer," "patient," “member,” “participant,” "resident," "recipient," and "client."

"Plan of care" means a set of goals, strategies, and actions an individual creates in collaboration with a health care team to guide the individual toward the maximum achievable independence and autonomy in the community.

Statutory Authority

§§ 32.1-12 and 32.1-15.1 of the Code of Virginia.

12VAC5-402-20. Certified community health worker.

A. No person may use or assume the title of "certified community health worker" unless the person (i) meets the qualifications, education, and experience requirements established in this chapter and (ii) holds a certification as a certified community health worker from a certifying body approved by the Board.

B. This chapter shall not be construed to require a community health worker to be certified in order to practice as a community health worker in Virginia.

Statutory Authority

§§ 32.1-12 and 32.1-15.1 of the Code of Virginia.

12VAC5-402-30. Qualifications for certification; continuing education.

A. An applicant to be a certified community health worker shall submit documentation to a certifying body verifying that the applicant:

1. Is 18 years of age or older;

2. Has completed at least 60 hours of community health worker training provided by one or more approved training entities; and

3. Has performed at least 2,000 hours of experience providing community health support services completed within the three years before the application date, 50 of which shall be verified as supervised.

B. A certified community health worker who was certified in a state other than Virginia may apply to be a certified community health worker in Virginia by submitting documentation to a certifying body verifying (i) the applicant's certification and (ii) that the applicant has performed at least 2,000 hours of community health support services, 50 of which shall be verified as supervised.

C. A certified community health worker shall obtain re-certification by submitting documentation to a certifying body verifying at least 30 hours of continuing education every two years from the date of certification that (i) are approved by the certifying body, and (ii) cover the topics listed in 12VAC5-402-50.

Statutory Authority

§§ 32.1-12 and 32.1-15.1 of the Code of Virginia.

12VAC5-402-40. Minimum standards for certifying bodies.

A. The Board shall approve a certifying body that provides certified community health worker certification by implementing standards and testing for certification pursuant to this chapter.

B. A certifying body shall:

1. Maintain a publicly-available registry of certified community health workers that displays the certification status of certified community health workers;

2. Submit to the Board, by the end of a fiscal year, an annual report that identifies the number of new and cumulative certified community health workers and the number of new and cumulative training entities;

3. Ensure applicants possess the qualifications in subsections A and B of 12VAC5-402-30 before approving an application to be a certified community health worker;

4. Require the certified community health workers it has certified to adhere to a code of ethics established by the certifying body;

5. Ensure the certified community health workers complete the required continuing education pursuant to 12VAC5-402-30 C; and

6. Approve a training entity to provide training and education programs or courses if they meet the minimum standards established by this chapter and the certifying body.

Statutory Authority

§§ 32.1-12 and 32.1-15.1 of the Code of Virginia.

12VAC5-402-50. Training and education; curriculum requirements.

To be approved by a certifying body, a training entity shall ensure that the curriculum for a training and education program includes a minimum of 60 hours in the following topics:

1. Community Health Concepts and Approaches (10 Hours);

2. Service Coordination and System Navigation (10 Hours);

3. Health Promotion and Prevention (8 Hours);

4. Advocacy, Outreach and Engagement (8 Hours);

5. Communication (10 Hours);

6. Cultural Humility and Responsiveness (8 Hours); and

7. Ethical Responsibilities and Professionalism (6 Hours.)

Statutory Authority

§§ 32.1-12 and 32.1-15.1 of the Code of Virginia.

2024 TRAVEL MEETING RECOMMENDATIONS

2024 Proposed Meeting Dates

Wednesday, April 10

Thursday, June 13 (suggested travel meeting)

Thursday, September 19

Thursday, December 5

Holidays of interest:

Easter – March 31, 2024
Memorial Day – May 27, 2024
Juneteenth – June 19, 2024
Labor Day – September 2, 2024
Thanksgiving – November 28, 2024

NOTE: The Board has the option to have an all virtual meeting if they choose in 2024

REPORT OF THE POLICY COMMITTEE

OTHER BUSINESS

ADJOURN

Virginia State Board of Health Membership Roster – July 2023

Name/Address	Affiliation/Contact	Term Expires
Gary P. Critzer, NRP, CCEMTP **Chair** 250 S Wayne Avenue, Suite 301 Waynesboro, Virginia 22980	**EMS** (540) 942-6698 Email: critzergp@ci.waynesboro.va.us	**30-June-2025**
Michael Desjadon **Executive Committee** 560 Hodges Draft Lane West Augusta, Virginia 24485	**Corporate Purchaser of Health Care** Email: mike@mdvirginia.com	**30-June-2026**
Melissa L Green 5100 Jackson River Road Hot Springs, Virginia 24445	**Nursing Home Industry** (404) 520-4841 Email: Melissa.Green@NevaSeniorCare.com	**30-June-2025**
Elizabeth Ruffin Harrison 1100 Coggins Point Road N. Prince George, Virginia 23860	**Consumer** (804) 337-2578 Email: lisaruffinharrison@gmail.com	**30-June-2025**
Anna Jeng, ScD **Executive Committee** 1147 Surrey Crescent Norfolk, Virginia 23508	**Public Environmental Health** (504) 430-3571 Email: hjeng@odu.edu	**30-June-2025**
Lee R. Jones, DMD Carilion Clinic Dental Care 4348 Electric Road Roanoke, Virginia 24018	**Virginia Dental Association** (540) 776-0222 Email: lrjones@carilionclinic.org	**30-June-2026**
Patricia Anne Kinser, PhD, WHNP-BC, RN **Vice Chair** 1100 East Leigh Street Richmond, Virginia 23298	**Virginia Nurses Association** Email: kinserpa.boh@gmail.com	**30-June-2025**
Melissa Nelson, MD 600 Levering Lane Richmond, Virginia 23226	**Medical Society of Virginia** (804) 397-0695 Email: mnelson98@mac.com	**30-June-2027**
The Honorable Patricia O'Bannon P.O. Box 90775 Henrico, Virginia 23273	**Local Government** (804) 501-4208 Email: tuckahoe@henrico.us	**30-June-2026**
Holly S. Puritz, MD, FACOG The Group for Women 880 Kempsville Road, Suite 2200 Norfolk, Virginia 23502	**Medical Society of Virginia** (757) 466-6350 Email: h.puritz@tgfw.com	**30-June-2024**
Maribel E. Ramos 7509 Digby Green Alexandria, Virginia 22315	**Consumer** Email: ramosmvaboh@gmail.com	**30-June-2025**
Douglas Daniels, DVM Virginia Equine, PLLC 1994 Shallow Well Rd Manakin Sabot, Virginia 23103	**Virginia Veterinary Medical Association** (804) 784-5419 Email: Virginiaequinepllc@gmail.com	**30-June-2027**
Stacey Swartz, PharmD 2204 Mt. Vernon Avenue Alexandria, Virginia 22301	**Virginia Pharmacists Association** (703) 836-1700 Email: stacey.swartz@gmail.com	**30-June-2024**
Ann B. R. Vaughters, MD 3829 Gaskins Road Richmond, Virginia 23233	**Managed Care Health Insurance Plans** Email: abrvmdmba@gmail.com	**30-June-2026**
Mary Margaret Whipple 4200 Innslake Drive, Suite 203 Glen Allen, Virginia 23060	**Hospital Industry** (804) 366-1050 Email: mmwhipple@erols.com	**30-June-2024**

STATE BOARD OF HEALTH
BYLAWS

ARTICLE I. APPLICABILITY

Section 1. General.

The Board of Health has the authority to adopt bylaws pursuant to Va. Code § 32.1-7. The provisions of these Bylaws are applicable to all proceedings of the State Board of Health ("Board") to the extent that the same are not otherwise governed by the requirements set forth in the Code of Virginia or by Executive Order. Whenever the provisions and authorizations of these Bylaws are in conflict with the provisions and authorizations mandated by the Code of Virginia or by Executive Order, the latter shall control.

Section 2. Authority and Limitations.

The Board is constituted under Va. Code §§ 32.1-5, *et seq.* and 2.2-2100 as a "Policy Board." As a "Policy" board pursuant to Va. Code § 2.2-2100, the Board is specifically charged with the duties and responsibilities set forth in the basic law governing the actions of the Board, as generally established in Title 32.1, as well as in such other Titles of the Code of Virginia. As set forth in and consistent with the basic law, the Board may promulgate public policies or regulations, set rates, distribute federal funds, and adjudicate regulatory or statutory violations.

Section 3. Members

The Board shall consist of residents of the Commonwealth appointed by the Governor for terms of four years each in accordance with Va. Code § 32.1-5. A vacancy other than by expiration of term shall be filled by the Governor for the unexpired term. No person shall be eligible to serve more than two full consecutive four year terms.

Section 4. Representation.

When the Board is requested to appear before the General Assembly, or any legislative or study committees, the Board shall be represented by the State Health Commissioner ("Commissioner") or his designee or by duly designated member(s) who are nominated by the Chair and when practicable, confirmed by the Board.

Individual members of the Board may provide comments to the media, social media, local, state, or federal officials, or members of the public. Any comments made shall be identified as the member's personal views and not the position of the Board unless the member has been authorized by the Board to express its official position.

Section 5. Orientation.

All new members appointed to the Board shall receive an orientation from the Virginia Department of Health (Department) that includes information about the roles and responsibilities of the Board; the committee structure and Bylaws of the Board; the roles and responsibilities of the Department; an overview of the Virginia regulatory process; and the Virginia Freedom of Information Act.

ARTICLE II. MEETINGS

Section 1. Regular Meetings.

Regular meetings of the Board shall be held at least on a quarterly basis at such time and place as the Board may determine, provided, however, that at least one meeting shall be held in the City of Richmond. No business requiring a vote or final decision of the Board may be conducted in the absence of a quorum, as defined under Va. Code § 32.1-8.

Section 2. Annual Meetings.

The regular meeting held in the second quarter of the calendar year shall be designated as an annual meeting. Elections shall be held at the Annual Meeting.

Section 3. Committee Meetings.

The Executive Committee, the establishment and constitution of which are hereinafter set forth, and such other Committees as the Board or Chair may designate, pursuant to Article IV, Section 3 of these Bylaws, may convene at such times as may be established by each committee; provided, however, that all such meetings are open to the public and comply with the notice requirements set forth in Va. Code § 2.2-3707 of the Virginia Freedom of Information Act, Va. Code § 2.2-3700 *et seq.*

Section 4. Special Meetings.

The Chair or any three members of the Board may call a special meeting for a specific purpose or purposes. No business shall be transacted at such special meeting except that expressly set out in the notice of the special meeting.

Section 5. Notice of Meeting.

Public notice of meetings shall be provided in accordance with the requirements of the Freedom of Information Act, Va. Code § 2.2-3700 *et seq.*

Section 6. Quorum.

A quorum of the Board for transaction of any lawful business shall be that established by Va. Code § 32.1-8.

Section 7. Conduct of Meetings.

The Chair shall preside over all meetings of the Board, except that, in the absence or disability of the Chair, the Vice Chair shall preside. The Commissioner, the executive officer of the Board pursuant to Va. Code § 32.1-18, shall serve as Secretary or, with the approval of the Board, shall name his designee to serve as Secretary, as specified by Va. Code § 32.1-9. The Secretary or Secretary-designees shall provide staff support, record all minutes of the meetings, and record in a minute book all resolutions adopted and all transactions occurring at the meeting. The then current edition of Robert's Rules of Order shall govern the conduct of all meetings of the Board when not in conflict with statutory requirements set forth in the Code of Virginia or Executive Orders. Pursuant to Va. Code § 2.2-3710, the Board shall not vote by written or secret ballot. All voting shall be accomplished by voice vote, show of hands, or roll-call vote.

Section 8. Closed Session.

Prior to meeting in a closed session, the Board must vote affirmatively to do so and must announce the purpose of the session. This purpose shall consist of one or more of the purposes for which a closed session is permitted in accordance with the Virginia Freedom of Information Act, Va. Code § 2.2-3700, *et seq*. Minutes may be taken during a closed session but are not required. Such minutes shall not be subject to mandatory public disclosure.

Section 9. Official Records.

All official records of the Board shall be kept on file at the Department and shall be open to inspection as required by law. All files shall be kept in accordance with the applicable Records Retention and Disposition Schedule maintained by the Library of Virginia in accordance with the Virginia Public Records Act, Va. Code § 42.1-76, *et seq*.

ARTICLE III. OFFICERS

Section 1. Number and Title.

The officers of this Board shall be as follows:

1. Chair
2. Vice Chair
3. Secretary, who shall be the Commissioner or, with the approval of the Board, his designee, as prescribed by Va. Code § 32.1-9

Section 2. Duties.

The duties of the officers shall be those usually incident to the respective office and such other special duties as may, from time to time, be specified by the Board. Officers shall be elected annually and shall assume their duties at the close of the meeting at which they are elected.

Section 3. Vacancies.

Vacancies in the position of Chair or Vice Chair shall be filled for the remainder of the term by voice vote, show of hands, or roll-call vote of the Board at its next full meeting following the departure or resignation of the former incumbent.

ARTICLE IV. COMMITTEES

Section 1. Executive Committee.

The Executive Committee of the Board shall be composed of the Chair, the Vice Chair, and two non-officer members of the Board, who shall be elected by the Board. . At each year's Annual Meeting, the Board shall elect the two non-officer members of the Executive Committee from the Board's membership for the coming year. Those elected shall assume their duties at the close of

the meeting at which they are elected. The Chair of the Board shall also serve as Chair of the Executive Committee.

Section 2. Duties.

The Executive Committee shall undertake all such responsibilities as are required or requested by the Board, and, to the extent the Board may officially delegate certain duties to the Executive Committee, all such delegated duties when the full Board is not in session. All actions taken on delegated duties shall be described in full report to the Board at the next successive full Board meeting for review, approval or disapproval, or ratification by the Board, as appropriate

Section 3. Other Committees.

The Board or Chair, as its or his discretion, may appoint such other committees of its members as it may deem advisable and may designate the responsibilities of any such committees.

Section 4. Vacancies.

Vacancies arising on the Executive Committee or any other committee established by the Board or Chair may be filled for the unexpired term by the Board at its next full meeting.

ARTICLE V. ELECTIONS

Section 1. Nominations.

Nominations for Chair, Vice Chair, and two Executive Committee members may be made by a nominating committee appointed by the Chair or the Board for that purpose. Additional nominations may be received by voice from the floor.

Section 2. Voting.

Elections of officers and Executive Committee members must be conducted in open session of at least a quorum of the Board by voice vote, show of hands, or roll-call vote, as required by Va. Code § 2.2-3710. Election to office or Executive Committee membership shall be determined by a simple majority of those present and voting.

ARTICLE VI. AMENDMENTS TO THE BYLAWS

The Board shall review and amend the Bylaws as necessary. At a minimum, the Board shall review its Bylaws every four years. The Bylaws of the Board may be amended at any regular meeting of the Board at which at least a quorum is present by an affirmative vote of two-thirds of the Board membership present and voting, provided that the amendment has been submitted in writing at the previous regular meeting.

These Bylaws are effective on March 7, 2019, and until subsequently amended.

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Gary Critzer, Chair
State Board of Health

Reviewed June 2023

Revised March 2019

Revised March 2012

Virginia State Board of Health
Public Participation Policy

The Board of Health (Board) encourages public participation in the performance of its duties and responsibilities. To assure that public comment submitted to the Board is properly processed and to assure that all Board actions are made in compliance with the Administrative Process Act, the Board hereby adopts this Public Participation Policy.

A. Public Comments at Board of Health Meetings

These procedures establish the times for the public to provide appropriate comment to the Board for its consideration. In light of these established procedures, the Board accepts public comment on regulatory actions, as well as general comments, at Board meetings.

The Board schedules a public comment period at the beginning of each regular meeting to provide an opportunity for citizens to address the Board. Anyone wishing to speak to the Board during this time should, at the beginning of the Board meeting, indicate his or her desire on the sign-in sheet. Presentations during the Public Forum shall not exceed two minutes per person. The public comment period shall be no more than twenty minutes.

The Board reserves the right to alter the time limitations set forth above without notice and to ensure that comments presented at the meeting conform to this policy.

B. Public Comment submitted to the Board of Health outside of Board of Health Meetings

1. Any member of the public may submit comments concerning pending non-emergency, non-exempt regulatory actions to the Virginia Regulatory Town Hall at www. townhall.virginia.gov .

2. In accordance with the provisions of the Board's Public Participation Guidelines governing public comment (12VAC5-11-50), any member of the public may submit written comments concerning pending non-emergency, non-exempt regulatory actions directly to the Board of Health, care of the Department of Health:
   - in writing to 109 Governor Street, Richmond Virginia 23219,
   - by fax at 804-864-7022, or
   - via email at healthcommissioner@vdh.virginia.gov.

   The Board of Health shall accept public comments in writing after the publication of a regulatory action in the Virginia Register of Regulations as follows:

   i. For a minimum of 30 calendar days following the publication of the notice of intended regulatory action.

ii. For a minimum of 60 calendar days following the publication of a proposed regulation.

iii. For a minimum of 30 calendar days following the publication of a reproposed regulation.

iv. For a minimum of 30 calendar days following the publication of a final adopted regulation.

v. For a minimum of 30 calendar days following the publication of a fast-track regulation.

vi. For a minimum of 21 calendar days following the publication of a notice of periodic review.

vii. Not later than 21 calendar days following the publication of a petition for rulemaking.

The Board of Health may determine if any of the comment periods listed in this subsection shall be extended.

3. Whenever a Board member receives written or verbal comment pertaining to the Department of Health's programs or personnel, such as comments or complaints about the implementation of specific health programs, or actions of agency staff, he or she should decline to make a substantive response and should refer the comment to the [Commissioner/ or other agency designee] for appropriate review and handling. A Board member may, in the alternative, inform the author of the public comment that it should be directed to the appropriate agency staff. Comments received through the Town Hall or the above-specified methods will be summarized for the Board and considered by the Board when making a decision on regulatory action.

Adopted October 23, 2003
Revised December 14, 2012

Overview of Robert's Rules of Order

Following presentation by staff of each regulatory action item, the Chair will ask for a motion to adopt the regulatory action item. Upon receiving a second, the Chair will ask if there is any discussion concerning the motion. At that point, the regulatory action item will then be in the proper posture to be discussed and considered by the Board. It will also be in the proper posture at that point for any Board member to offer amendments to regulatory language.

Each Board member who wishes to participate in the discussion of any of the regulatory action items needs to first be recognized by the Chair prior to speaking. If you wish to be recognized, simply raise your hand. The Chair has the discretion to ask a member the purpose for which they wish to be recognized and if, in the Chair's opinion, such purpose is not germane to the current discussion, could cause confusion, or interfere with the efficient and orderly operation of the Board, the Chair may choose to delay recognition of the member until after the current discussion or item before the Board is completed.

If any Board member wishes to offer an amendment to any regulatory action items, the amendment needs to be offered in the form of a motion. In making that motion, the member needs to state to the Board the language change or changes that they are proposing to the regulatory text. If that motion receives a second from another Board member, the Board will discuss and subsequently vote on the motion.

If, upon hearing the proposed PRIMARY amendment, another Board member desires to further amend that amendment, that member must make a SECONDARY AMENDMENT in the form of a motion, which also must receive a second.

Upon receiving a second, the Board will discuss, and then vote on the SECONDARY AMENDMENT prior to voting on the PRIMARY amendment. If the amendment(s) is(are) adopted, they will be added to the main motion and the Board will move on to the next amendment and repeat the process. Please note that a secondary amendment that is worded such that it completely negates the primary amendment's meaning can get confusing, but if it is adopted, it will be attached to the main motion directly.

According to Robert's Rules, there can only be one secondary amendment offered. There can be no "amendment to the amendment to the amendment".

Board members may provide VDH with written copies of proposed amendments prior to the Board meeting, which will be included in the back of the Board notebooks. Board members may also bring written copies of proposed amendments with them to the meeting which will be photocopied by VDH staff and distributed to the Board prior to consideration. If any Board member wishes to make amendments but has not yet reduced them to writing, VDH will be able to type the proposed amendment into the computer and the proposed amendment language will be displayed on the screen for the Board's consideration prior to voting on the motion. The Chair will ask VDH staff to read the draft amendment aloud. Once the member is satisfied that the amendment has been correctly stated, the Chair will ask the member to offer the amendment in the form of a motion.

The Board must vote on any individual amendments and on the regulatory action as a whole. Votes can be taken via a voice vote with a simultaneous show of hands or a roll call vote. All votes are recorded as part of the official Board meeting minutes.

Robert's Rules provides that any member can make a motion to "call the previous question", or "call for the question". If that motion is seconded, it is not debatable; hence the Board will proceed with the vote on the motion to call the question. If it is agreed to by two-thirds majority of the members, discussion of the pending motion (for example, an amendment that is under consideration) will end and the Board will immediately vote on the motion. If the motion to call the previous question does not receive a two-thirds majority of the votes cast, the discussion will continue.

Finally, please note that under Robert's Rules, a motion must receive a majority vote among the members present and voting in order to be approved. If a motion receives a tie vote, the motion is rejected and does not pass.