State of Board of Health Agenda December 15, 2022 – 9:00 a.m. Perimeter Center, Boardroom 2

Call to Order and Welcome Gary Critzer, Chair

Introductions Mr. Critzer

Review of Agenda Alexandra Jansson, MPP

Approval of September 22, 2022 Minutes Mr. Critzer

Commissioner's Report Colin Greene, MD, MPH

State Health Commissioner

Regulatory Action Update Michael Capps, MPH

Acting Legislative and Regulatory Coordinator

Break

Public Comment Period

Lunch Presentation

Opioids and Substance Misuse: Liz Zaunick, Overdose Data to Action Grant

Data and Program Efforts Coordinator

Lauren Yerkes, Injury and Violence Prevention

Epidemiologist

Office of Family Health Services

Regulatory Action Items

Regulations Governing Campgrounds

Julie Henderson

12VAC5-450 Director

(Fast Track Amendments) Office of Environmental Health Services

Regulations Governing Vital Records
Seth Austin
12VAC5-550
Director

(Fast Track Amendments) Office of Vital Records

Regulations for the Licensure of Hospitals in Virginia Rebekah Allen, JD 12VAC5-410 Senior Policy Analyst

(Fast Track Amendments) Office of Licensure and Certification

Regulations for the Licensure of Nursing Facilities Ms. Allen

12VAC5-371

(Fast Track Amendments)

Non-Regulatory Action Items
Board of Heath Annual Report:
Plan for Well-Being

Khalida Willoughby, MS Director Center for Community Health Improvement

Public Policy Agenda Follow Up

Joseph Hilbert

Electronic Meeting Policy

Ms. Jansson

Other Business

Adjourn

State Board of Health September 22, 2022 - 9:00am Perimeter Center, Boardroom 2

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

Dr. Puritz attended remotely due to work obligations that required she be physically present in Norfolk. Ms. Ramos participated remotely due to a temporary medical condition (contagious disease) from her home in Alexandria. Dr. Kinser participated virtually due to a temporary medical condition (contagious disease) from her home in Richmond.

VDH Staff Present: Michael Capps, Senior Policy Analyst; Tiffany Ford, Deputy Commissioner for Administration; Colin Greene, State Health Commissioner; Joe Hilbert, Deputy Commissioner for Governmental and Regulatory Affairs; Parham Jaberi, Deputy Commissioner for Community Health Services; Alexandra Jansson, Senior Policy Analyst; Lilian Peake, State Epidemiologist and Director, Office of Epidemiology; Maria Reppas, Director, Office of Communications.

Other Staff Present: Robin Kurz, JD, Senior Assistant Attorney General

Call to Order

Mr. Critzer called the meeting to order at 9:03am.

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 June 23, 2022 Minutes

Dr. Swartz made the motion to approve the minutes from the June 23, 2022 meeting with Ms. Whipple seconding the motion. The minutes were approved unanimously by voice vote with 2 abstentions from Mrs. O'Bannon and Ms. Harrison who were absent from the previous meeting.

Commissioner's Report

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

- Agency Stars
- COVID-19 Update
- Monkeypox Update
- Opioid Abatement Authority/Substance Misuse
- Partnership for Petersburg
- Infrastructure Grant/Collaboration with DBHDS
- Emergency Preparedness Summit/Hurricane Season
- Facilities Broadband Initiative

- Electronic Health Record Initiative
- Public Policy Agenda

There was discussion regarding partnerships and help with change management; COVID in southwest and rural Virginia and outreach strategies to increase vaccinations; bivalent vaccine supply and distributions; flu trends; and if there was any impact to women's health or abortion access in Virginia as a result of the *Dobbs* decision.

Regulatory Action Update

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

Since the June 2022 meeting, the Commissioner approved four regulatory actions on behalf of the Board while the Board was not in session. First, the Commissioner approved three Notices of Intended Regulatory Action (NOIRAs) for the Virginia Hearing Impairment Identification and Monitoring System (12VAC5-80); Regulations Governing Tourist Establishment Swimming Pools and Other Public Pools (12VAC5-460); and Swimming Pool Regulations Governing the Posting of Water Quality Results (12VAC5-462). These NOIRAs followed periodic reviews and will update the respective Regulations by removing outdated information and incorporating recommendations and national best practices. The Commissioner also approved final exempt action for the Food Regulation (12VAC5-421) to comply with Chapter 393 of the 2022 Acts of Assembly, removing the requirement that an establishment that sells only prepared food have a certified food protection manager on site during all hours of operation.

Since the June 2022 meeting the Commissioner has taken no non-regulatory action on behalf of the Board while the Board was not in session.

Mr. Capps advised the Board that there are 18 periodic reviews in progress:

- •12 VAC 5-20 Regulations for the Conduct of Human Research
- 12 VAC 5-110 Regulations for the Immunization of School Children
- •12 VAC 5-125 Regulations for Bedding and Upholstered Furniture Inspection Program
- •12 VAC 5-150 Regulations for the Sanitary Control of Storing, Processing, Packing or Repacking of Oysters, Clams and Other Shellfish
- •12 VAC 5-160 Regulations for the Sanitary Control of the Picking, Packing and Marketing of Crab Meat for Human Consumption
- •12 VAC5-191 State Plan for the Children with Special Health Care Needs Program
- •12 VAC 5-200 Regulations Governing Eligibility Standards and Charges for Health Care Services to Individuals
- •12 VAC 5-216 Methodology to Measure Efficiency and Productivity of Health Care Institutions
- •12 VAC 5-217 Regulations of the Patient Level Data System
- •12 VAC 5-218 Rules and Regulations Governing Outpatient Data Reporting
- •12 VAC 5-220 Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations
- •12 VAC 5-407 Regulations for the Submission of Health Maintenance Organization Quality of Care Performance Information
- •12 VAC 5-408 Regulation for the Certificate of Quality Assurance of Managed Care Health Insurance Plan (MCHIP) Licensees
- •12 VAC 5-410 Regulations for the Licensure of Hospitals in Virginia
- •12 VAC 5-431 Sanitary Regulations for Hotels
- •12 VAC 5-508 Regulations Governing the Virginia Physician Loan Repayment Program

- 12 VAC 5-510 Guidelines for General Assembly Nursing Scholarships
- •12 VAC 5-540 Rules and Regulations for the Identification of Medically Underserved Areas in Virginia

Since the June 2022 meeting, the Executive Branch completed the review of three regulatory actions while the Board was not in session – a NOIRA for the Regulations Governing Tourist Establishment Swimming Pools and Other Public Pools (12VCA5-460), a NOIRA for the Swimming Pool Regulations Governing the Posting of Water Quality Results (12VAC5-462), and Fast Track amendments to the Sewage Handling and Disposal Regulations (12VAC5-610).

There was discussion regarding <u>Virginia Regulatory Town Hall</u> and how the public can use the site to follow the progress of regulatory actions.

Public Comment Period

There were six persons signed up for public comment at the meeting. Mary Ann Mundt spoke about her husband's death and hospital safety around COVID-19 protocols. Barbara Zeller shared a continuation of Mrs. Mundt's story and COVID-19 therapeutics. Doris Knick shared comments regarding vaccine safety and an upcoming forum hosted by the Virginia Medical Freedom Alliance around therapeutics. Tricia Stall spoke about standardized COVID-19 protocols and therapeutics and mentioned the upcoming forum as well. Susan Franz spoke about a therapeutics webinar hosted by VDH, COVID-19 treatment protocols and vaccine safety. Pamela Burnham shared concerns about COVID-19 vaccine safety. Speakers also shared comments which are included at the end of the minutes document.

Final Exempt Amendments to Regulations for the Immunization of School Children

Laurie Forlano presented the final exempt amendments to the Board. This amendment to the Regulations for the Immunization of School Children is necessary to maintain conformity with the Code of Virginia following language added in Chapter 1223 of the 2020 General Assembly Regular Session. As a result of that action, the list of minimum requirements for school required immunization in § 32.1-46 was amended to include additional vaccine requirements. This amendment to the regulations will bring them into compliance with the list specified in the Code of Virginia.

Prior to this Final Exempt Action, the Virginia Department of Health (VDH) published a Notice of Intended Regulatory Action followed by a 60-day public comment period, as required by § 32.1-46 subsection C. VDH received 26 comments. Twenty-four were in opposition to the action (11 generally for choice and against mandates, 10 concerns over HPV vaccine, 1 provided no explanation, 1 minimize chemicals in children, and 1 misunderstood action), one appeared to be for the action, and one was categorized as N/A because no comment was left and the title was "protect our children" which could go either way.

The proposed amendments seek to update the Regulations for the Immunization of School Children in order to adhere to the minimum immunization requirements specified in § 32.1-46. The proposed amendments are consistent with language added to the Code of Virginia as a result of Chapter 1223 of the 2020 Regular Session.

Dr. Klein made the motion to approve the final exempt regulations with Dr. Swartz seconding the motion. The proposed regulation was approved unanimously by voice vote.

Proposed Regulation for Sexual Assault Survivor Treatment and Transfer

Rebekah Allen presented the proposed regulation to the Board. Chapter 725 (2020 Acts of Assembly) created Article 8 of Chapter 5 of Title 32.1 of the Code of Virginia, which requires the Board to promulgate regulations to effectuate the act, specifically the standards for review and approval of sexual assault survivor (SAS) transfer plans (§ 32.1-162.15:5), pediatric sexual assault survivor (PSAS) transfer plans (§ 32.1-162.15:5 and subsection C of § 32.1-162.15:6), SAS treatment plans (subsection A of §32.1-162.15:4), and PSAS treatment plans (subsection B of § 32.1-162.15:6). As the requirement to have such plans extends to hospitals, clinics, and physician's offices, there is no already existing regulatory chapter that would best fit this mandate, so the Virginia Board of Health intends to promulgate a new regulatory chapter for these standards.

Dr. Klein made a motion to approve the proposed regulation with Dr. Swartz seconding the motion. There was discussion regarding the need for these regulations to ensure access to care for survivors and PSAS treatment and transfer requirements including Sexual Assault Forensic Examiner staffing availability, the costs to pediatric facilities, differences between treatment and transfer plans, and mandated reporting. The proposed regulation was approved unanimously by voice vote.

Proposed Regulation for Prescription Drug Price Transparency

Ms. Allen presented the proposed regulation to the Board. The rationale or justification for the regulatory change is that the General Assembly enacted Chapter 304 (2021 Acts of Assembly, Special Session I) to require VDH to adopt regulations standards for prescription drug price transparency and reporting. The regulations require that reporting entities provide vital information about prescription drug pricing, which is a driver of increased healthcare costs in the Commonwealth. The goal of the regulatory change is to increase transparency of prescription drug pricing and to identify factors that may be leading to increased healthcare costs from prescription drugs. The regulation must contain the specification of prescription drugs for the purpose of data collection and procedures for auditing information provided by health carriers, pharmacy benefits managers, wholesale distributors, and manufacturers, as well as a schedule of civil penalties for failure to report the information required, based on the severity of the violation. The specification must include information required pursuant to §§ 32.1-23.4, 38.2-3407.15:6, 54.1-3436.1, and 54.1-3442.02 of the Code of Virginia.

Ms. Whipple made a motion to approve the proposed regulation with Dr. Shuler seconding the motion. There was discussion about price transparency importance and the role of pharmacy benefits managers. Mr. Desjadon made a motion to amend the proposed regulation with Ms. Green seconding the motion. The regulation was approved as amended unanimously by voice vote.

Final Amendments to Private Well Regulations

Ms. Henderson presented the Final Amendments to the Board. There have not been significant revisions to the Regulations since their adoption in 1990. The Regulations establish the minimum location and construction requirements for private wells installed in the Commonwealth. In August 2016, the VDH began a periodic review of the Regulations and formed a Private Well Regulations Workgroup. The purpose of the workgroup was to assist VDH in the development of proposed revisions to the Regulations.

The Proposed Regulations were published in Volume 38 Issue 11 of the Virginia Register of Regulations on January 17, 2022, and advertised a public comment period ending March 18, 2022. The intent of this regulatory action is to explore amendments to the Regulations based on

current industry standards, all public comments received, and feedback received from the Private Well Regulations Workgroup. The purpose is to ensure the Regulations (i) are protective of public health and the environment, (ii) address changes in current standards and practices, (iii) clarify regulatory language, and (iv) exhibit improved consistency with other regulations related to private wells and groundwater resources. No substantive changes have been made between the Proposed and Final Stages.

Dr. Jeng made a motion to approve the final amendments with Ms. Harrison seconding the motion. There was discussion about climate change, shallow soil, salt water intrusion, drinking water wells inclusion, and adjacent property owner approvals. The final amendments were approved unanimously by voice vote.

Fast Track Amendments to Regulations for the Licensure of Home Care Organizations

Ms. Allen presented the Fast Track Amendments to the Board. Chapter 172 (2022 Acts of Assembly) amended Code of Virginia § 32.1-162.9 to change home care organization (HCOs) licenses from an annual license to a three-year license. This act also mandated that the fee for renewal of an HCO license shall be \$1,500 until such time as the Board of Health may amend or repeal regulations for the licensure of home care organizations. The regulatory change is essential to protect the health, safety, or welfare of citizens because VDH cannot provide adequate inspection and oversight for HCOs if it is losing funding equal to roughly three full-time HCO inspectors. The goal of the regulatory change is to preserve VDH's current fee revenue and to eliminate inconsistencies in receiving and processing license changes and exemption requests.

It is anticipated that this action will be noncontroversial and therefore appropriate for the fast-track process because the fee amount for the new three-year HCO licenses is the same amount on a per-year basis as what the regulations mandate for a one-year license (i.e., \$500 for the prior one-year license, now \$1,500 for a three-year license) and the vast majority of HCOs are already utilizing the forms created by VDH to communicate changes to their licenses or requests for an exemption.

Dr. Schuler made the motion to approve the fast track amendments with Dr. Jeng seconding the motion. There was discussion regarding continuing education maintenance and documentation, oversight maintenance, survey and inspection process frequency and license extension to 3 years. The Fast Track amendments were approved unanimously by voice vote.

Final Amendments to the Regulations for Disease Reporting and Control

Dr. Peake presented the final amendments to the Board. 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 ensure all health providers report necessary public health information. This regulatory action separates COVID-19 from the category "coronavirus, severe" on the reportable disease list; removes the requirement for COVID-19 to be rapidly reportable; requires COVID-19 case and laboratory report forms be submitted electronically; clarifies that the category "laboratory directors" includes any entity that holds CLIA Certificates of Waiver; adds ethnicity and hospitalization status (if applicable) to the fields required to be reported by all parties related to COVID-19; and adds "coronavirus, severe" to the list of infectious diseases that shall be reported to persons practicing funeral services.

Dr. Vaughters made a motion to approve the final amendments with Dr. Klein seconding the motion. The final amendments were approved unanimously by voice vote.

2023 Meeting Dates

Ms. Jansson presented the dates for the 2023 meetings of the Board of Health as follows:

Thursday March 23

Thursday June 15

Thursday September 15

Friday December 15

There was no objection to these dates for the 2023 meeting dates, and they were adopted by consensus.

Other Business

No other business was presented for discussion.

Adjourn

The meeting adjourned at 12:37pm



VAERS COVID Vaccine Adverse Event Reports

Reports from the Vaccine Adverse Events Reporting System. Our default data reflects all VAERS data including the "nondomestic" reports.

All VAERS COVID Reports US/Territories/Unknown

1,407,409 Reports Through September 9, 2022 o

30,935 **DEATHS**

177,050 **HOSPITALIZATIONS**

135,259 **URGENT CARE**

DOCTOR OFFICE VISITS

My name is Pamela Burnham and I am a nurse with more than 20 years of experience, primarily in Critical Care. I have been an Independent Nurse Consultant/Educator since 2015 with a primary focus on cancer patients of Specialized Programs of Research Centers.

I am a mom of three and a grandmother. I have never been anti-VAX and was compliant with all of the hospital healthcare requirements until 2015. However, after extensive review of vaccine research I find myself full of regret for having vaccinated my children. And the so-called COVID "vaccine" is not even a traditional vaccine but rather a largely untested experimental genetic injection, the first of its kind, with unknown long-term risks in terms of cancer, fertility issues in man and women, autoimmune disease, neurological disease, letc.

Early on during the COVID crisis, many of us nurses cued in on the lies and propaganda being told to the public about the one-size-fits-all uni-treatment narrative promulgated by NIH, CDC and FDA. We knew very early on that hundreds of thousands of people would die if we didn't do something and we found ways to keep up with and share information and propagants who helped thousands of Covid affected people, especially here in VA. We developed and shared promising treatment protocols using repurposed FDA-approved medications and nutritional therapies that have evolved into the highly regarded medical freedom organizations American Frontline doctors and Frontline Covid Critical Care (FLCCC). We developed a network of deep researchers, doctors, pharmacists, nurses, rescuers, attorneys, exemption filing experts who were and still all working to help as many people as possible by sharing the truth to counter the public health system's uni-narrative.

I help answer questions for people from all over the world who are experiencing horrible side effects from the shots repeated debilitating illnesses, heartbreaking family tension and rejection, work related difficulties, functional activity breakdown, isolation, etc. from the draconian lockdowns, mandates, social restrictions, in the university breakdown, violation or suspension of our fundamental human and constitutional rights and freedom, and brutal censorship and intimidation of scientific or medical viewpoint that dissents from the uninarrative.

Today I want to share with you some of that truth that we believe would help many Virginians make informed decisions and would have saved many lives had they known.

For example, during pregnancy, we've always been told to avoid taking any medications, including Tylenol. Mothers to-be are being terrified into the EUA shots and told they are safe and effective. They are far from that with upwards of 70% risk of miscarriage in those injected in the first and second trimester.

natural immunity. On the other hand, nearly 30% of young people under age 20 who are injected with 2 Pfizer shots develop myocarditis.

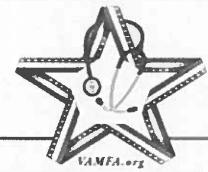
Language, Eports from the UK government's Office of National Statistics confirm that the triple vaccinated account for 91% of Covid deaths and over 24,000 unexplained deaths in 2022.

For example, the urgent need to create specific research and treatment centers for the vaccine-injured who are trapped in a horrendous situation of pain and limitation. Many suicides are taking place across the globe.

system and may be the most toxic substance ever introduced to the human body. Many trillions of spike protein particles are produced with each injection, cause suppression of natural immune function and inflammation, crosses the blood brain barrier, affects the heart, causes many neurological disorders including tremors, lethargy, stroke, Bell's Palsy, and ALS-type disorders as well as cardiovascular disease, blood clots, and menstrual irregularities and miscarriages.

This is not an Us versus You situation. We stand for Informed Consent, Freedom of Speech and from viewpoint Censorship. We need to stand together, resist the uni-narrative and fight for freedom. Board members and Dr. Greene, help restore scientific integrity and our trust with an honest, uncensored and open scientific dialogue between doctors and medical scientists about all the evidence. I'll look for you at the Forum on October 1.77

VIRGINIA MEDICAL FREEDOM ALLIANCE





VIRGINIA'S COVID MANAGEMENT:

A PUBLIC FORUM
Saturday October 1, 2022
Life Church • 8378 Atlee Rd
Mechanicsville VA 23116 • 1:00-4:00PM

Invited Speakers Include:

- Robert Malone MD
 - · Paul Marik MD

Invited Guests include:

- · Gov Glenn Youngkin
- Lt Gov Winsome Sears
- · Atty Gen Jason Miyares
- 140 Virginia Legislators
- And most importantly <u>YOU!</u>

Virginia Government Health Officials have repeatedly declined to participate

Follow the QR code or go to <u>VAMFA.org</u> for more information and to register.



Virginia Medical Freedom Alliance P.O. Box 36120 N. Chesterfield, VA 23235-0120 804-661-6838

https://virginiamedicalfreedomalliance.org vamfa@proton.me

August 16, 2022

Dear Virginians:

The Virginia Medical Freedom Alliance (VAMFA) is a non-partisan coalition of Virginia doctors, allied healthcare professionals, organizations, and citizens who are concerned and alarmed by the public health system's encroachment on the ability of healthcare professionals to provide evidence-based ethical care to Virginians during the two-plus years of the COVID-19 pandemic. On July 19, 2022, we respectfully and urgently asked the Virginia Department of Health Commissioner Dr. Colin Greene and his medical scientists to participate with the VAMFA-selected independent expert medical scientists in a forum open to the public to present the evidence in reference to the prevention and treatment of Covid-19 and the use of vaccines. We also requested that Dr. Greene conduct an in-person VDH tour at multiple representative locations throughout the Commonwealth to listen to the people about their experiences related to the public health management of COVID. There has been no response.

Prior to our July letter, members of the VAMFA participated in a June 29, 2022, VDH-sponsored "open forum conversation on COVID-19 therapeutics" in which they would "be answering your questions and discussing the changing landscape of therapeutics in Virginia." We entered many questions into the chat stream. but were disappointed when they were ignored. The webinar facilitator stated that the VDH COVID-19 Therapeutics Group only focuses on interventions that have an FDA emergency use authorization (EUA) for COVID and that "VDH staff do not have the ability to respond to questions regarding medications that are not authorized by the FDA for the treatment of Covid-19." The VDH response to specific VAMFA concerns about the safety or efficacy of these products was that all have clinical trial data that is "very supportive regarding their safety and efficacy in treating COVID-19," they "use reliable sources of data" (defined as CDC, FDA and peer-reviewed articles) to inform Virginia professionals and they "must follow the NIH treatment guidelines." Questions and concerns about the COVID vaccines were deflected by promising to "facilitate getting them to our colleagues in the vaccine space and answered." We have heard nothing since then. After about thirty minutes all of us were suddenly dropped from the webinar without any warning. Some who were able to log back in were again dropped. This is a blatant example of the dangers facing all Virginians when open dialogue is prevented.

Many of the healthcare professionals that participated in the VDH June 29 COVID therapeutics forum have been treating patients with COVID-19 for more than two years. They know that hundreds of peer-reviewed studies clearly show that aggressive prevention and early outpatient multidrug treatment could have prevented 75 to 80 percent of hospitalizations and deaths attributed to COVID. Early in the pandemic, a group of world-renowned critical care doctors and scientists collaborated as the Frontline COVID-19 Critical Care Alliance (FLCCC) to quickly develop robust prevention and treatment protocols. These protocols repurposed and incorporate multiple common, inexpensive, remarkably safe and effective FDA-approved oral medications and over-the-counter immune-fortifying nutritional therapeutics. COVID is completely treatable; the standard of care is these multidrug FLCCC protocols

THE COVID VACCINE & CHILDREN

A SECOND OPINION



ADVERSE reported after the COVID vaccine is staggering.

VAERS¹, the US Government database that tracks vaccine reactions, shows a total of 1,205,755 adverse reactions and 26,396 deaths following the COVID-19 vaccine (as of 3/25/22)². This is more reports than from all previous vaccines combined. This number is likely underreported. An HHS funded study³ shows that the VAERS system captures only 1-10% of total vaccine reactions.

Multiple well funded studies have demonstrated the negligible risk to healthy children from COVID-19. A large german study4 showed zero deaths for children ages 5-11 and a case fatality rate of three per million in all children without comorbidities. And a Johns Hopkins study of 48,000 children showed a zero mortality rate in children under 18 without comorbidities. Another study in *Nature Medicine*⁶ showed children under 18 without comorbidities had virtually no risk of death.





CLINICAL

Pfizer's application for EUA of two doses of its vaccine failed in clinical trials as it did not produce antibodies in children 2 to <5 years old. They were forced to withdraw the application in February 2022, and will now apply to the FDA for a three-dose series once more data is available in April.

A study in Nature Communications suggests children's bodies clear the virus more easily than adults. Another study in Nature Immunology® demonstrates how children efficiently mount effective **immune responses**: "immune systems that naturally generate robust, cross-reactive and sustained immune responses to SARS-Cov-2 ..."

Children's bodies are



- digital.ahrq.gov/ahrq-funded-projects/electronic-support-public-health-vaccine-adverse-event-reporting-system
 medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=CAT&EVENTS=ON&VAX=COVID19
 digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf
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- 5. thefederalist.com/2021/07/21/johns-hopkins-study-found-zero-covid-deaths-among-healthy-kids
- nature.com/articles/s41591-021-01578-1
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- nature.com/articles/s41467-021-22236-7
 nature.com/articles/s41590-021-01089-8





COVID SHOTS & KIDS

A GUIDE FOR PARENTS + CAREGIVERS
ABOUT **INFORMED CONSENT** FOR COVID
SHOTS IN INFANTS AND CHILDREN.



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

Did you know by law you must be informed of the significant known or potential adverse effects of the treatment? Is your practitioner or healthcare worker doing their part in sharing this information?

Please read the following information carefully so that you can make an **informed decision** for the children in your life.

Did you know there are no long-term safety data for COVID-19 vaccination of young children, and the proposal is to vaccinate children under an Emergency Use Authorization (EUA)? These facts establish that vaccinating small children for COVID-19 is an experiment, not a standard medical procedure.
Did you know that children have a 99.995% recovery rate? And there's a large body of medical literature indicating that almost zero healthy children under five years old have died from COVID.
Did you know that COVID vaccines do not prevent transmission, nor do they prevent infection? There is no statistically valid evidence that they prevent severe disease or death in children. Current mRNA injections were formulated based on the original Wuhan strain and were not tested for benefits against current variants in clinical trials.
Did you know that most children are already immune? Natural immunity is superior to vaccine-induced immunity, and vaccinating the already immune is superfluous and potentially harmful. CNBC reported in April 2022, "An estimated 95% of the U.S. population ages 16 and older had developed antibodies against the virus either through vaccination or infection as of December, according to a CDC survey of blood donor samples." In February of 2022, the CDC said over 75% of children already have partial or full immunity to COVID.
Did you know that unnecessary vaccination will put children at elevated risk of vaccine harm when it appears that most are already immune and will obtain NO benefit?
Did you know that multiple studies have suggested that vaccinating after infection increases the risk of vaccine-induced side effects such as myocarditis?

Good Afternoon State Health Commissioner & Board of Health Members,

My name is Doris Knick. As a member of the Virginia Medical Freedom Alliance (VAMFA), I request that the State Health Commissioner and each of you Board members participate in the Oct. 1st Open Public Forum hosted by VAMFA. It is your opportunity to start restoring scientific integrity and healing Virginians' shattered trust in their medical establishment

You continue to deny the evidence in the Vaccine Adverse Events Reporting System (VAERS). None of us will ever be okay with the number of deaths and injuries from these Covid Shots. These are real people's lives that have been lost & impacted, not just statistics!

Here's a visual from the <u>Red Box Summaries on openvaers.com</u> since you don't seem to be aware of VAERS or its 1.4 million COVID vaccine Adverse Event Reports worldwide. (Banner of Injuries)

These Injuries are REAL and HORRIFYINGING COMMON, not RARE, yet the massive scope of the harm from the COVID injection is not represented in its VDH advertisements, FAQs or in the informed consenting process.

Did you know that more than 60% of the reports in the world are from the U.S.? In the past 2 ½ years, more than 865,000 Americans have filed adverse event reports related to the jab!

This includes 14,438 people who died after their Covid injections.

Let me repeat that: More than 14,000 Americans died.

Another 13,000 people had a LIFE-THREATENING reaction and almost 69,000 required hospitalization.

Shockingly, almost 15,000 Americans, most in the prime of their lives, are now PERMANENTLY DISABLED.

34,000 had a Severe Allergic Reaction with more than 2,000 of those almost dying of immediate anaphylactic shock.

6,000 suffered a Heart Attack and almost 9,000 more developed Myocarditis or Pericarditis.

Almost 1,800 pregnant U.S. women miscarried after being jabbed.

I could go on and on.

These Covid injections are NOT SAFE. PERIOD. End of discussion. There's no reason to even look at effectiveness if it's not safe. But to add injury to injury, this injection is also not effective in preventing transmission or infection with the COVID virus. All this is intolerable for an illness with an average 99.8% survival rate.

So where's VDH's evidence supporting your endless claims of safe and effective?

At your June 23rd quarterly meeting I shared the current VAERS data with you, but the summary sheet I provided is missing from the Public Record of that meeting. Why?

We demand that the COVID injections be immediately halted in Virginia.

We demand full and transparent investigations into the injuries and deaths caused by the COVID injections, by researchers without conflicts of interest and that the results be rapidly reported publicly.

I again urge you to participate in the Forum on October 1st, to present your evidence supporting the COVID emergency orders, regulations and other policies that you recommended and continue to promote, and their health outcomes. You still have time to take a first step toward acting on VDH's stated mission to protect the health and promote the well-being of all Virginians.

Mary Ann Mundt -

The hospital protocol killed my husband.

On January 8, 2021, my husband was weak and fell. I called for rescue to ask for assistance in getting him up. They insisted on taking him to the hospital. He did not want to go. We had done our research and knew hospitals were a dangerous place. As they took him away, I gave him his cell phone so we could communicate.

There was no need to believe that Bud had been exposed to Covid, but when he arrived at the hospital, they did their PCR test and said that he tested positive for Covid. We knew the tests were highly unreliable and expected this to happen at the hospital. We heard stories.

The ER doctor called me and told me they were giving Bud Remdesivir and going to put him on the ventilator. I immediately replied "Absolutely Not! Bud does not want either of those things for treatment".

The nurses told me that Bud had a UTI. I went over and picked him up and brought him home. I called our family doctor who put him on Levaquin. He initially was improving.

However, he was likely exposed to Covid in the hospital because he began to develop Covid symptoms. I called America's Frontline Doctors (AFLDS) and they helped get me some Ivermectin. He also received Monoclonal antibodies on Jan 18.

On January 19th(?) I called rescue again. They took him to the ER and kept him there. They wouldn't let him have his phone. The doctors wouldn't speak to me or let me in. For 3 days the doctors avoided me. I stood in the lobby every day waiting to speak to the doctors and waiting for a phone call, for someone, anyone to answer my questions and update on my husband's status.

I called Senator Bryce Reeves. I told him what was going on and the doctors lied when they told him they called me. I had my phone with me the entire time and was in the lobby of the hospital.

Reeves finally got them to call me and they set up a meeting with the nurses on the floor. I had the POA and Living Will that clearly stated "No Remdesivir" and "No Vent!"

I contact a doctor from the Front Line COVID-19 Critical Care Alliance (FLCCC). She advised me on all the aspects of the treatment protocol for hospitalized patients. Certain doctors tried to fight everything she advised. Some doctors were willing to help provide the correct supplements and additional recommendation from the FLCCC protocol, then the other doctors would come back in and change them. They gave him the wrong steroids and the wrong antibiotics. They kept saying, "It is not on our protocol" i.e., the hospital protocol. They agreed to give him crushed Vitamin C instead of IV Vitamin C as was recommended.

After battling between hospital doctors, on January 26th, he was able to get well enough to be moved from ICU to the Step Down unit. The doctors in the Step Down unit cut back on his supplements and meds. They refused Ivermectin and Hydroxychloroquine (HCQ).

On January 27th at 4:52am, the nurse called me and told me that Bud was angry. I tried to make arrangements to get him home on oxygen or to another hospital per the FLCCC doctor's recommendation. I wanted to get him to MCV where we knew Bud's heart doctor, but he progressively got worse to a point where he was having a lot of trouble breathing and was exhausted.

They made a deal with me and Bud saying that they would give Bud the meds we were requesting if I/we agreed to put him on the ventilator. We agreed and he was put on it for a couple days. They again refused to follow the FLCCC protocol. They followed the hospital protocol instead, which likely included remdesivir because they said he needed to go on dialysis because his kidneys were failing. I went into the ICU to see him and he was basically dead. He was cold, pale, terribly swollen, and his vent tube was bloody, as if he had been coughing up blood.

They called me later and told me they did CPR on him two times and he did not recover. They said he died of a cardiac arrest.

This is one example of the chaos created by rigid inflexible protocols. Doctors are not treating the patient, they are just following a protocol. My husband would be alive if the hospital would have followed the FLCCC protocol. My husband would be alive if I was allowed to visit and advocate for him. My husband would be alive if the hospital would have treated him like a human being instead of another statistic. I was repeatedly lied to and no one is being held accountable. Hospital protocols killed my husband and thousands of Covid patients because of rigid inflexibility. Members of the Virginia Department of Health are also responsible because you refused to look at the evidence in support of alternative treatment. The FLCCC protocol and other protocols save lives and you refused to listen to international experts working within the state of Virginia. Your arrogance is shameful.

Good Afternoon State Health Commissioner & Board of Health Members,

My name is Doris Knick. As a member of the Virginia Medical Freedom Alliance (VAMFA), I request that the State Health Commissioner and each of you Board members participate in the Oct. 1st Open Public Forum hosted by VAMFA. It is your opportunity to start restoring scientific integrity and healing Virginians' shattered trust in their medical establishment

You continue to deny the evidence in the Vaccine Adverse Events Reporting System (VAERS). None of us will ever be okay with the number of deaths and injuries from these Covid Shots. These are real people's lives that have been lost & impacted, not just statistics!

Here's a visual from the <u>Red Box Summaries on openvaers.com</u> since you don't seem to be aware of VAERS or its 1.4 million COVID vaccine Adverse Event Reports worldwide. (Banner of Injuries)

These Injuries are REAL and HORRIFYINGING COMMON, not RARE, yet the massive scope of the harm from the COVID injection is not represented in its VDH advertisements, FAQs or in the informed consenting process.

Did you know that more than 60% of the reports in the world are from the U.S.? In the past 2 ½ years, more than 865,000 Americans have filed adverse event reports related to the jab!

This includes 14,438 people who died after their Covid injections.

Let me repeat that: More than 14,000 Americans died.

Another 13,000 people had a LIFE-THREATENING reaction and almost 69,000 required hospitalization.

Shockingly, almost 15,000 Americans, most in the prime of their lives, are now PERMANENTLY DISABLED.

34,000 had a Severe Allergic Reaction with more than 2,000 of those almost dying of immediate anaphylactic shock.

6,000 suffered a Heart Attack and almost 9,000 more developed Myocarditis or Pericarditis.

Almost 1,800 pregnant U.S. women miscarried after being jabbed.

I could go on and on.

These Covid injections are NOT SAFE. PERIOD. End of discussion. There's no reason to even look at effectiveness if it's not safe. But to add injury to injury, this injection is also not effective in preventing transmission or infection with the COVID virus. All this is intolerable for an illness with an average 99.8% survival rate.

So where's VDH's evidence supporting your endless claims of safe and effective?

At your June 23rd quarterly meeting I shared the current VAERS data with you, but the summary sheet I provided is missing from the Public Record of that meeting. Why?

We demand that the COVID injections be immediately halted in Virginia.

We demand full and transparent investigations into the injuries and deaths caused by the COVID injections, by researchers without conflicts of interest and that the results be rapidly reported publicly.

I again urge you to participate in the Forum on October 1st, to present your evidence supporting the COVID emergency orders, regulations and other policies that you recommended and continue to promote, and their health outcomes. You still have time to take a first step toward acting on VDH's stated mission to protect the health and promote the well-being of all Virginians.

Hello VDH Members and Commissioner Greene.

I'm Tricia Stall, from Mathews County, a retired RN & Virginia Medical Freedom Alliance member advocating for all Virginians in support of Medical Freedom.

I personally lost 3 dear hospitalized friends, 2 in Sentara & one at Riverside, due to improper care, including "standardized Covid care protocols" promulgated by the CDC and NIH. It is heartbreaking to accept that these precious friends died needlessly due to rigid adherence to delayed treatment with novel, risky and expensive patented drugs. Early treatment with safe and inexpensive off-patent medications and nutritional therapies that are proven effective might have avoided hospitalization and death entirely. For example, I & my 90 yo "diabetic" mother contracted Covid in June 25 & responded quickly WITHOUT hospitalization thanks to having ivermectin available at symptom onset.

This is a critical time in Virginia to support Medical Freedom for all Virginians. That includes stopping "public health" bureaucrats, hospital systems and pharmacies from using chilling intimidation and retribution, including loss of licensure or employment, to essentially prohibit doctors from rendering individualized, ethical patient care based on their professional experience. It also chills Pharmacists from actually filling doctor's valid prescriptions. VAMFA supports the unrestricted availability of and access to all preventive and treatment options by all patients and doctors in Virginia. The declaration of a so-called public health "emergency" does not give government the authority to interfere with the private doctor-patient relationship. It does not permit government to violate the fundamental and inalienable human right of personal informed choice about bodily autonomy.

I implore each of you to please participate in or at least attend the Virginia Covid Management Public Forum on Oct 1 from 1-4:00 pm at Life Church, 8378 Atlee Rd., Mechanicsville. It is one way to help fulfill your VDH mission to be responsive to we the people of Virginia.

Thank you.

I'm Susan Franz, a retired nurse, from Williamsburg.

I participated in the June 29 VDH webinar described as an "open forum conversation on COVID-19 therapeutics." It was only after several of us were suddenly dropped from the call for asking questions about Ivermectin and Hydroxychloroquine that we were made aware of a Guidance Document for these webinars which stated only EUA COVID-19 treatments were to be discussed. They also failed to answer multiple questions we asked about safety issues regarding some of the novel drugs.

Dozens of peer-reviewed studies clearly show that aggressive prevention and early outpatient treatment could have prevented at least 75 to 80 percent of the hospitalizations and deaths attributed to COVID. If VDH would enthusiastically promote, or just *permit*, the widespread use of these proven medications there would likely be no need for a vaccine or expensive new investigational drugs, particularly ones that are neither safe nor effective. Why is VDH still aggressively promoting the risky COVID injections when there are far more effective and inexpensive medications that have been used safely for decades in millions of people?

VDH has violated doctors' legal right to prescribe an FDA-approved medication for any reason they deem appropriate in their professional judgment. Why is the Virginia healthcare system intimidating and persecuting doctors with loss of licensure or employment for having a different scientific viewpoint about the best way to treat individual patients?

It appears that a CDC-NIH uni-narrative or protocol controls what VDH is allowed to do or not do. This government tyranny of the experts is endangering the health of Virginians. Despite the CDC insisting that the vaccine is safe and effective, has VDH or this Board done your own critical and independent analysis of the voluminous adverse event information about Virginians that has been collected? Are you aware of the numbers of world class athletes dying on sports fields after being coerced to be injected to keep their jobs? Are you aware that Denmark just discontinued vaccines for anyone under the age of 60 due to their adverse effect profiles? Are you aware of the large and atypical fibrous clot-like formations found in autopsies of vaccinated individuals?

You have been invited to participate in an open public forum on October 1 to discuss the evidence about all treatments for COVID-19. World-renowned Virginians Dr. Robert Malone, the inventor of the mRNA technology, and Dr. Paul Marik will be there to discuss these issues. You should be too. Your participation would help restore our faith that you care about scientific integrity, truth and the health of Virginians more than merely complying with the CDC and NIH.

Imtiyaz Ahmad Khan (22), youth Cricket player from Pulwama district of Kashmir collapsed due to a cardiac

arrest and died while playing cricket in Anantnag district of Kashmir. He was rushed to hospital but declared DoA.

News Story News Story2

20. 02/09/2022 Spain

Cristhian Stuani (35), Uruguayan footballer who plays in Spain for Girona suffered from benign cardiac arrhythmia and is "resting for a month." News Story News Story2

21. 01/09/2022 Scotland Dead

Mike Wilson (46), Triathlete and super-fit doctor suffered a cardiac arrest and died while swimming in a loch in Scotland, while training for a triathlon. News Story

August 2022

22. 31/08/2022 Texas, USA

Zaidyn Ward (14), high school American football running back collapsed due to a cardiac arrest during a game after scoring a touchdown. Lacey Steel, a Monterey trainer resuscitated him. His heart actually stopped twice then he had a seizure and was rushed to the Fort Worth hospital. He is scheduled for open heart surgery. News Story News Story2

23. 30/08/2022 Ontario, Canada Dead Eli Palfreyman (20), Ayr Centennials Junior Ice Hockey captain collapsed and died during a pre-season tournament match. News Story News Story2 News Story3

24. 30/08/2022 Ohio, USA Dead
Kooper McCabe (17), high school student American

Footballer and wrestler died unexpectedly. News Story
News Story2

25. 28/08/2022 England Dead

Ray McGloin (64), Tri-Rivington triathlete died suddenly. He has competed in 7 Ironman events, 20 half Ironman events, as well as ultra-distance swimming, running and cycling events, and started his own triathlon club to coach others.

News Story News Story2

26. 28/08/2022 Germany Dead

Rolf Felber (67), Triathlete collapsed shortly after the start of the swim (1st leg of the event), in an Ironman triathlon in Germany. He was quickly resusciated and taken to hospital, but he died on the way. News Story News Story2

27. 27/08/2022 New Hampshire, USA Dead Unnamed (46), Hiker from Quebec, Canada, hiking on Mt. Washington in New Hampshire, USA, collapsed as he reached the summit and died despite assistance from medical personnel on the spot. News Story News Story2

28. 25/08/2022 South Africa Dead

29. 25/08/2022 South Africa Dead

Mzameleni Mthembu (43), experienced ultra-marathon runner collapsed due to a cardiac arrest and died 12km from the end of the 90km Comrades Marathon in South Africa. Phakamile Ntshiza also died and 72 other runners were holpitalized. News Story News Story2

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Bernardino Soncco Hancco (40), Kenamari Football

collapsed on the pitch due to a cardiac arrest and died in the "Copa Nuñoa" football tournament. News Story

31. 25/08/2022 California, USA Dead

Carter Stone (15), American Footballer high school student went into hospital for a routine shoulder operation, but he died unexpectedly. Doctors revealed that Carter "had a tumour on his heart likely formed by undiagnosed T-cell leukaemia and the family was not aware of it." News Story News Story2

32. 25/08/2022 Massachusetts, USA Dead Kieron Smith (51), Wrestling coach at a high school in Massachusetts for over 20 years died suddenly. <u>News</u> <u>Story</u>

33. 23/08/2022 Scotland Dead

Rab Wardell (37), cyclist who won the elite men's title at the Scottish MTB XC Championships. Just a few days later, he died in his sleep of a "cardiac arrest." News Story News Story2

34. 23/08/2022 North Carolina, USA

Grigor Dimitrov (31), Tennis player had been comfortably winning a match in the Winston-Salem Open tennis tournament but suddenly retired after he "experienced dizziness and shortness of breath." News Story News Story2

35. 23/08/2022 Spain Dead

Dani Gómez (18), Peñas Huesca Basketball Club
Baasketball player died suddenly and unexpectedly. News
Story News Story2

36. 22/08/2022 Portugal Dead Mário Cunha (31), former C.D. Cerveira Footballer retired in 2020, died of "unknown causes." News Story

22/08/2022 England Dead Ben Benn (30), Halifax RUFC Rugby Union (and other clubs) player died suddenly. News-Story News Story

38. 21/08/2022 Argentina

Manuela Bugueno (30), female amateur Runner and Chilean doctor collapsed with a cardiac arrest close to the finish line of the Buenos Aires half-marathon in Argentina. She received immediate attention and was resuscitated, then transferred to hospital. News Story News Story2

39. 20/08/2022 Switzerland Dead Unnamed (36), Cyclist collapsed and died whilst competing in the Grand Raid mountain bike race in Valais, Switzerland. Resuscitation attempts failed. <u>News Story</u> <u>News Story2</u>

20/08/2022 Norway Dead Audun Heimdal (25), World elite Orienteerer and ski orienteerer died with cancer. News Story News Story2

41. 19/08/2022 California, USA Dead Unnamed (19), Hiker was hiking in California with a large group, including his father. He went for a swim on his own in a lake and was found dead. When a helicopter arrived, the young man had already died. News Story News Story2

42. 19/08/2022 Italy Dead Filippo Dalla Venezia (18), Mogliano Rugby Rugby Union U19 player was found lifeless at home. News Story

43. 19/08/2022 Germany

Malaika Mihambo (28), was Olympic long jump champion in Tokyo 2020. In August 2022, she competed in European Championships in Germany where she won silver, but now suffers from circulatory problems and shortness of breath.

News Story News Story2

44. 19/08/2022 Virginia, USA Dead

Riddick Parker (49), former Seattle Seahawks, New
England Patriots and Baltimore Ravens American Football
player died unexpectedly while riding his bicycle. News
Story News Story2

45. 19/08/2022 England Dead

Stewart Bondi (69), very keen runner from Devon, England and a founder of a tough marathon on the South West Coast Path. His nickname was "Rambo." His body was found by the cliffs on the coast after an apparent fall. News Story News Story2

46. 19/08/2022 Brazil Dead

Pietra Medeiros (20), Taboao Magnus SP Futsal player died in hospital due to complications from autoimmune hepatitis. News Story News Story2

47. 19/08/2022 Georgia, USA

Yordan Alvarez (25), Houston Astros Baseballer was playing in Georgia against the Atlanta Braves when he was short of breath. He was taken to hospital for treatment.

News Story News Story2

48. 19/08/2021 Indiana, USA Dead

Devyn Williams (18), Volleyball playing student at Indiana University died unexpectedly. The cause of death "was found to be related to an asthma attack." Devyn was vaccinated with the Pfizer vaccine in April 2021. News

Stony Nowe Stony? Nowe Stony?

49. 18/08/2022 Florida, USA Dead

Luke Knox (22), Florida International University American Football player died suddenly. News Story News Story2
News Story3

50. 17/08/2022 Germany Dead

Unnamed (Age), Footballer collapsed and died after taking part in a friendly football match. <u>News Story News Story2</u>

51. 17/08/2022 Missouri, USA

Davis Dwight (17), Baseballer and high school student collapsed during baseball practice from cardiac arrest.

Coaches revived him with CPR. News Story News Story2

52. 17/08/2022 Peru Dead

Michele Gironella (25), Italian Footballer was on holiday in Peru where he collapsed due to a cardiac arrest while playing in a local football match. He never recovered.

News Story News Story2

53. 16/08/2022 Belgium Dead

Kevin Revillod (26), Standario FC Onoz Footballer collapsed from a cardiac arrest and died during training despite resuscitation attempts. News Story News Story2

54. 16/08/2022 Austria

Katrin Beierl (29), very successful bobsleigh pilot who won the overall two-man bobsleigh World Cup rankings in 2020/21 season, the first Austrian ever, suffered a stroke while on holiday and spent time in hospital in Vienna, Austria. News Story News Story2

55. 16/08/2022 Germany

Tim Nowak (27), decathlete abandoned the 2022 European Championships in Germany due to serious circulatory

problems. He was unable to compete in the fifth discipline over 400 meters. "Unfortunately, my competition ends in

the hospital. After the high jump I collapsed for unknown reasons. I would have given anything to finish this competition." News Story

56. 15/08/2022 Romania Dead

Alessia Maria Raiciu (18), Agronomia Bucharest Basketball and national team player died suddenly on her 18th birthday. News Story

57. 15/08/2022 Michigan, USA Dead Tyler Edwards (27), high school basketball coach died unexpectedly of a suspected cardiac arrest. News Story

- 58. 14/08/2022 Northern Ireland Dead
 Molly White (Age), St James' Swifts Footballer died
 suddenly. News Story News Story2
- 59. 14/08/2022 Italy Dead
 Giovanni Malvestio (48), Cyclist suffered a cardiac arrest while cycling, was seen staggering to the ground.
 Bystanders provided first aid, but he died before an ambulance arrived. News Story
- 60. 13/08/2022 England Pablo Martinez (21), Chippenham Town FC Footballer collapsed on the pitch in a match against Chelmsford. His condition was later said to have stabilised. Match abandoned. News Story News Story2
- 61. 11/08/2022 French Guiana Dead
 Djouby Laura (20), USC de Roura Footballer had a cardiac arrest after a training session and could not be revived.
 News Story
- 62. 11/08/2022 Northern Ireland Dead

Dominic Oscar (19), St Michael's ABC Boxer died suddenly. News Story News Story2

63. 10/08/2022 Illinois, USA Dead

Avery Gilbert (18), Trinity International University American
Football freshman at Trinity International University had
only been on campus for 3 days, when was found
collapsed and died later in hospital. News Story News
Story2

64. 10/08/2022 Brazil Dead Maurice Miranda (40), former São Paulo Football player suffered a cardiac arrest at home. He was taken to hospital but died. News Story News Story2

- 65. 10/08/2022 Maharashtra, India Dead
 Sameer Jivangikar (Age), Runner and real estate agent but also a keen runner collapsed and died due to a sudden cardiac arrest while driving home after a training session.

 News Story News Story2
- 66. 10/08/2022 Argentina Dead
 Aleli (9), Pioneras FIF Football goalkeeper for a children's football team in Argentina. She died suddenly. News Story
- 67. 10/08/2022 North Carolina, USA
 Sam Hartman (22), Wake Forest University Athletics
 American Footballwe will miss an 'extended period of time'
 due to a "mystery condition." News Story News Story2
- 68. 10/08/2022 Germany Dead
 Unnamed (28), Water Skier died while water skiing. "Police believe the cause of death was medical." News Story
- 69. 09/08/2022 South Africa Rick Hendriks (12), Rugby Union player suffered a cardiac arrest on 9th August 2022, on a rugby field in Pretoria,

South Africa. He was airlifted to hospital. Four days later, it was reported that he regained consciousness. <u>News Story</u>

70. 09/08/2022 Telangana, India Dead

Thushar Aamra Bedwa (32), Cricket player and software employee in Hitec City, Telangana, India was playing cricket with friends in the evening when he complained of chest pain and collapsed. He was taken to hospital but he died. Doctors suspect a cardiac arrest. News Story

71. 09/08/2022 Virginia, USA Dead Caitlyn Gable (20), Bluefield University Rams Softball player died in her sleep. News Story

72. 09/08/2022 Belgium Dead

Claude Gomez (53), former R. E. Virton Footballer in the 1980's and 1990's suffered a cardiac arrest on a bike ride with friends, and died. News Story News Story2

73. 09/08/2022 Belgium

Tim Wellens (31), Lotto Soudal professional cyclist has ended racing activities due to heart problems. "I felt disturbing palpitations. Not only in the race, but also in training and at rest. My cardiologist found this far from reassuring." News Story

74. 08/08/2022 Belgium Dead

Jurgen Groothaerd (44), KVV Zelzate Football youth coach suffered a cerebral thrombosis and died while cycling to work. News Story

75. 07/08/2022 Malaysia Dead

Marc Marie (52), Hiker was on holiday in Malaysia and hiking with friends in the mountains, when he suddenly collapsed. A rescue team sent to the scene immediately performed CPR but he died. News Story

76. 07/08/2022 California, USA Dead Braden Fahey (12), middle school American Footballer lost consciousness after football practice at Clayton Valley Charter High School in California. Recorded as a "severe medical emergency." He was rushed to hospital on Friday evening and died on Sunday. <u>News Story News Story2</u> <u>News Story3 News Story4</u>

- 77. 07/08/2022 California, USA Dead

 Brian Reynolds (50), Swimmer, golfer, and former American football youth team coach trained for months to be ready for a 1½ mile swimming event off the California coast. He was said to be in "great shape" for the swim, but during the event he "suffered an unknown medical incident" and died.

 News Story
- 07/08/2022 France Dead
 Laura Domecq (21), French AS Monaco women's footballer
 died suddenly. News Story News Story2 News Story3
- 79. 06/08/2022 Chile Dead

 Cristian Cáceres (38), Union Cordillera Football
 goalkeeper. Suffered a cardiac arrest in the second half of
 a match and died on the way to hospital. News Story
 News Story2
- 80. 06/08/2022 Connecticut, USA Dead
 Djemayley Vernet (16), American Football player died
 unexpectedly after a series of seizures. News Story
- 81. 05/08/2022 Germany Dead
 Marco Memenga (38), FC Brookmerland Football player
 scored a goal and then died during the cup match with BW
 Filsum in Germany. News Story
- 82. 05/08/2022 Ireland Dead

collapsed in a match against Kilruane McDonaghs. He received instant medical attention on the pitch, then transferred by ambulance to hospital where he later died.

News Story News Story2

Dillon Quirke (24), Clonoulty Rossmore Hurling player

83. 05/08/2022 Kentucky, USA Dead Aaron Crawford (18), Knott County Central HS American Football player and wrestler. He had a cardiac arrest and died. <u>News Story News Story2 News Story3</u>

- 85. 04/08/2022 New Zealand Dead
 Unnamed school girl (12), Runner "collapsed while running in an Auckland (New Zealand) park. She died in hospital the same evening. News Story
- 86. 03/08/2022 Botswana Dead
 Unnamed girl (15), Mexican Girls Football player collapsed
 during training and died at the hospital. News Story
- 87. 02/08/2022 Florida, USA Dead Lars Tate (56), former Georgia Bulldogs American Football, and later for Tampa Bay Buccaneers and Chicago Bears. He had very recently been diagnosed with cancer and died suddenly before he was due to begin chemotherapy. News Story News Story2
- 88. 02/08/2022 Ireland Dead

 Frank O'Dwyer (Age), Cyclist and accident & emergency

 (A&E) consultant at a hospital in Kilkenny, Ireland. During

the Tour de Kilkenny. He had an "incident" during the event and died a few days later. News Story News Story2

89. 02/08/2022 Arizona, USA Dead Cesar Vazquez (17), Peoria Centennial High School American Footballer died over night. News Story News Story2

- 90. 02/08/2022 Georgia, USA Dead Tony Jones (Age), Lubbock Christian University Basketball player died unexpectedly. <u>News Story News Story2 News Story3</u>
- 91. 01/08/2022 Germany Dead
 Mario Pirner (48), Esslingen Handball player died unexpectedly. News Story
- 92. 01/08/2022 Mississippi, USA Dead Phillip Laster (17), American Footballer and high school student collapsed while working out with the football team, and died at the local hospital. News Story

July 2022

93. 31/07/2022 Croatia Dead
Mato Matić (20), HNK Mladost Football goalkeeper for.
Played a match on Saturday and died on Sunday. No further details available. News-Story2

94. 31/07/2022 Italy Dead
Giuseppe Fortunato (44), Cyclist and master watchmaker who had a passion for cycling. Died suddenly in his sleep.

News Story News Story2

95. 31/07/2022 France Dead
Anthony Janiec (37), Lion Truck Racing champion

- collapsed due to a cardiac arrest and died. News Story
 News Story2
- 96. 31/07/2022 Wyoming, USA Dead Jay Collins (41), former Idaho Stampede Basketballer who played for several clubs before moving into coaching. Died suddenly overnight. <u>News Story News Story2</u>
- 97. 31/07/2022 New York, New York Dead Param Dhaliwal (23), former West Kelowna Warriors Ice Hockey player was found Dead in a hotel in New York. News Story News Story2
- 98. 31/07/2022 Wales Dead
 Gareth Lewis (42), Rugby Union coach. He coached
 Caerphilly Rugby Club and at schools. He also served in
 various roles at the Welsh Rugby Union. He died "following
 a short illness." News Story
- 99. 31/07/2022 Germany Dead
 Sabine Oberdieck (55), Dressage star was a lawyer who rode and trained dressage horses in Germany very successfully. She died unexpectedly. News Story News Story2
- 100. 30/07/2022 Nova Scotia, Canada Satchel Tate (12), Hammonds Plains Baseballer was playing in an U-13 baseball tournament for his team Hammonds Plains, in Canada. During the match he suffered a stroke. News Story News Story2
- 101. 29/07/2022 Victoria, Australia Dead
 Rohan Cosgriff (17), Waubra Football Netball Club
 Footballer. The student with a keen interest in playing
 football and looking after race horses died suddenly. News
 Story News Story2

102. 28/07/2022 Ontario, Canada Dead Candace Nayman (27), Triathleta and medical doctor collapsed during the swim section of a triathlon and died a few days later. She is the fifth doctor in the Greater Toronto Area (GTA) to die unexpectedly in July 2022. News Story News Story2

103. 28/07/2022 Germany Dead Rok Kosir (46), successful judoka in his native Slovenia and in Germany where he took up coaching. He died suddenly and unexpectedly. News Story News Story2

- 104. 27/07/2022 Iowa, USA Dead Lily Ernst (20), UNI Panthers Swimmer and student died suddenly. No further details available. <u>News Story News</u> <u>Story2 News Story3</u>
- 105. 27/07/2022 Croatia Dead Maro Perak (39), Mixed Martial Arts exponent, the "world heavyweight and light heavyweight champion." He died suddenly. <u>News Story</u> <u>News Story2</u> <u>News Story3</u>
- 106. 24/07/2022 Wisconsin, USA Dead Derek Gray (20), UW-Whitewater Basketballer and psychology student. collapsed due to a cardiac arrest during a training session and died suddenly. Suspected blood clot. No further information available. <u>News Story</u> <u>News Story2 News Story3</u>
- 107. 23/07/2022 Italy Dead

 Andrea Musiu (20), Footballer was playing a football game with friends in his home town of Cagliari, Italy. He collapsed at the end of the game, received immediate attention from spectators and then ambulance staff, but died. News

 Story News Story2

- 108. 22/07/2022 Pennsylvania, USA Dead

 Jerry Ward (46), well-known bodybuilder who also judged

 contests and ran his own training company.Died

 unexpectedly in bed after complaining of "rib pain." News

 Story News Story2
- 109. 21/07/2022 Australia Dead Justin Crawford (45), Hawthorn Australian Rules Footballer died suddenly. Further details awaited. <u>News Story</u>
- 110. 21/07/2022 South Carolina, USA Dead
 Phil Petty (43), former University of South Carolina
 American Footballer from 1998-2001. Died after a short
 illness. News Story News Story2
- 111. 18/07/2022 France
 Jonathan Castroviejo (35), Ineos Grenadiers Cyclist, one of five to quit the Tour de France due to breathing problems.
 Victor Lafay said "Castroviejo can't breathe either." News
 Story
- 112. 18/07/2022 France Pierre Rolland (35), B&B Hotels p/b KTM Cyclist, one of five to quit the Tour de France due to breathing problems. Victor Lafay said Rolland had "no strength, and then impossible to breathe." News Story
- 113. 18/07/2022 France
 Oliver Naesen (31), AG2R Citroën Cyclist, one of five out of the Tour de France due to breathing problems. Victor Lafay reported Naesen had "no strength, and then impossible to breathe." News Story
- 114. 18/07/2022 British Columbia, CanadaDoug Eyolfson (59), Runner and emergency physician inManitoba, Canada. Suddenly collapsed with a cardiac

arrest while marathon training in the park while visiting Vancouver. On 20th July 2022 he confirmed on Twitter that

115. 17/07/2022 Wales

Ryan Jones (41), Rugby Union captain of the Wales team.

Diagnosed with early-onset dementia aged 41. News Story

116. 17/07/2022 France

Alexis Renard (23), Cofidis team Cyclist. Suffered sudden onset of a heart rhythm disorder at the Tour de France. One of five to pull out of the tour. Set to have surgery. "During exercise, I have a heart rate that increases like everyone else," Renard said. "But when I stop cycling, the intensity is always the same." News Story

117. 16/07/2022 Ontario, Canada Dead

Paul Hannam (50's), Runner, medical doctor, Olympic sailor and marathon runner. Was Chief of Emergency Medicine and Program Medical Director at North York General Hospital (NYGH). Collapsed and died unexpectedly while out for a run. News Story News Story2

118. 15/07/2022 France

Victor Lafay (26), Cofidis Cyclist taking part in the Tour De France. One of five to pull out of the tour. "I'm having a very hard time breathing. I feel like I don't have enough oxygen, pain everywhere..." News Story News Story2

119. TUIVIIZUZZ NUSSIA DEAU

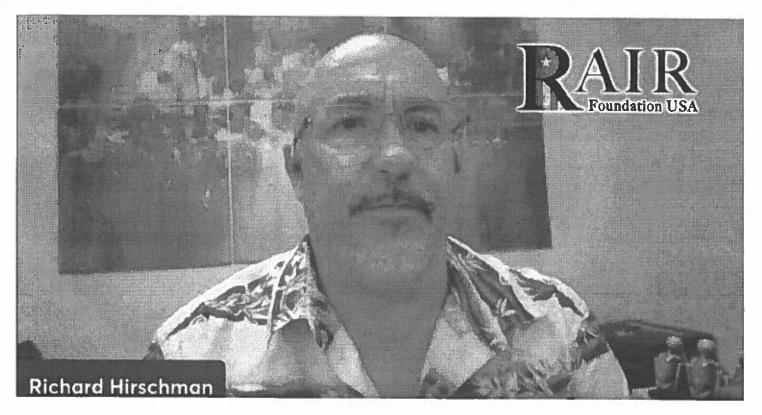
Aleksandr Kozlov (29), Footballer described as one of the

top football talents of a generation. He played for the Russian youth national team and played his first Champions League game at the age of 17. Suffered a blood clot during a training session and died. News Story

- 120. 15/07/2022 Georgia, USA Dead Paul Duncan (35), Denver Broncos American Footballer collapsed due to a cardiac arrest after going for a run in his neighbourhood. He died. <u>News Story News Story2</u>
- 121. 15/07/2022 New Jersey, USA Dead Anthony Joseph Zeoli (16), Skateboarder & Snowboarder and high school student. Died unexpectedly. <u>News Story</u>
- 122. 15/07/2022 New South Wales, Australia Dead
 Carl Robinson (41), Surfer and realestate agent He
 suddenly collapsed in the sea during a morning surf.
 Surfers and paramedics performed CPR but were unable to
 save him. News Story
- 123. 14/07/2022 Western Australia, Australia Dead Unnamed (50's), Wind Surfer had been wind surfing off the coast of Shoal water, Western Australia. Found Dead in the sea. <u>News Story News Story2</u>
- 124. 13/07/2022 Mississippi, USA Dead
 Rashard Anderson (45), former Carolina Panthers
 American Footballer was first-round pick in 2000, played in
 27 games with nine starts over two seasons with the team.
 Died suddenly. News Story News Story2
- 125. 13/07/2022 Argentina Dead Néstor Flores (37), amateur Footballer and police inspector in the town of Rivadavia. After the match, he went home,

Embalmer Sounds Alarm: Massive Increase in Strange Blood Clots and Cancer, 'It's not Normal, It's Drastic' (Exclusive Interview)

Miranda Sellick September 16, 2022 29 comments 5 min read



"I've talked to so many other embalmers, and we are all seeing the same thing, but governments don't want to look at it." - Richard Hirschman

In an exclusive interview with RAIR Foundation USA, an Alabama-based embalmer and licensed funeral director revealed a massive increase in strange blood clots found in the bodies that he is now embalming.

Richard Hirschman, who has been an embalmer since 2001, has noticed "a change of condition of bodies since the roll-out of mRNA vaccines." These changes include the huge increase in people with blood clots. the strange nature of these blood clots, and patients who have died of cancer without any of the tell-tale signs, such as hair loss and emaciation. "Unfortunately, there is a new normal," he says.

Hirschman has embalmed thousands of bodies during the course of his career. Last year, he handled over 600 himself. So he knows the signs to look for, and he knows what blood looks like. "In all my years of embalming, we would run across clots from time to time," he says, "but since May last year, something about the blood has changed. It's not normal. It's drastic."

When Hirschman first started seeing anomalies, he thought it strange, "but when you see the same thing over and over, you start to realize that something's not right."

Hirschman and many of his colleagues in the industry noticed an increase in clotting during the pandemic, "but it wasn't until the roll-out of the vaccine that these really unusual fibrous structures started appearing." He describes a normal blood clot as having a texture like grape jelly or jam. If you were to pick it up, it would likely disintegrate in your fingers. Before 2021, blood clots would appear in between five and 10 percent of bodies. These days, says Hirschman, those numbers are more like 85 percent. "The majority of bodies I embalm are clotted," he says. "Out of 358 bodies this year, only around 60 were not clotted, and a half of those were heavily clotted. Prior to last year, it wasn't like that. Nothing like what we see now."

What is more, these clots are unlike anything he's ever seen before. He describes them as "a white fibrous structure, like calamari, a rubber band or spaghetti. Even the small ones are unusual looking, like worms. They resemble a small parasite." Typically, blood clots come out of veins during the embalming process, very, very rarely out of an artery. However, Hirschman recently took one out of an artery 33 inches long. "Normally, I wouldn't be able to pull a clot of that length without it falling apart," he explains. "It's the white, fibrous length that's unusual. I cannot possibly imagine that being inside a healthy person."

Hirschman suspects the vaccine is causing these clots. "The reason why I feel the vaccine is related is that I have found these strange structures inside of people who supposedly never had covid but had been vaccinated."

Looking back, Hirschman sees a date correlation. "It was January 2021 when they really started pushing the vaccines," he recalls. "I have never been so busy in all my life. I was running into clots like crazy; even in February and March, the clotting was huge. Initially, it was in elderly people, and those were the first they tried to protect."

Typically, Hirschman's patients have been in their late 60s, 70s, and 80s. But he's seeing increasingly younger bodies, "some in their 20s, too," he says, but just not as many as elsewhere because Alabama has a low vaccination rate amongst young people, according to the embalmer. "I know they are dying, though; I'm hearing about it everywhere," he says. "But it seems like in Alabama, people are waking up."

Not so for 17-year-old Ohio football player Kaden Clymer, who recently had six feet of strange clots removed from his legs. Mainstream media continues to deny any link between these clots and the covid-19 vaccine, even though Clymer was diagnosed with inferior vena cava atresia, a disease that typically only affects men in their 30s.

Hirschman has also noticed a change in the bodies he is receiving who have died from cancer. Typically, these people have tumors, hair loss and are emaciated due to their struggle with the disease and harsh treatments. "Lately, had I not been fold these people had cancer, I'd not have known. People are getting cancers and are dead before they know it," he says. "They don't live long enough to go through the stages." His observations jive precisely with reports from a senior Swedish physician and researcher, Dr. Ute Kruger, who recently expressed alarm at the extraordinary rates of aggressive cancers she is now seeing.

Hirschman would like to understand what's going on. He's sent three dozen clots out for analysis, some of them to Mike Adams, who runs an ISO-17025 accredited lab in Texas. Adams has compared these clots to the blood of unvaccinated individuals and has concluded that these are not blood clots because they lack iron, potassium, magnesium, and zinc.

"We have tested one of the clots from embalmer Richard Hirschman via ICP-MS. Also tested side by side, live human blood from an unvaccinated person," Adams told <u>The Epoch Times</u>.

But nobody knows quite what these things are, nor how they are caused. "I've talked to so many other embalmers, and we are all seeing the same thing," says Hirschman. "But governments don't want to look at it."

EXCLUSIVE: Fibrous clots harvested from dead bodies of vaccinated individuals found to contain higher concentrations of electrically conductive elements - Mike Adams tells Dean Ryan

Thursday, August 25, 2022 by: Belle Carter
Tags: Aluminum, badhealth, badmedicine, badscience, Big Pharma, biological weapon, Blood
clots, COVID, Dangerous Medicine, Dean Ryan, fibrous clots, lab tests, metals, Mike
Adams, pandemic, pharmaceutical fraud, real investigations, Richard Hirschman, Steve
Kirsch, tin, Vaccine deaths, vaccines

This article may contain statements that reflect the opinion of the author

Bypass censorship by sharing this link:



(Natural News) The Health Ranger Mike Adams recently released the ICP-MS elemental analysis of the fibrous clots pulled out of the cadavers by whistleblower embalmer Richard Hirschman. The lab results confirmed the gooey blobs contained elements that are electrically conductive.

"The clots are almost entirely lacking the normal biomarkers of human life. Instead, it has higher concentrations of things associated with circuitry," Adams said during a recent exclusive interview at "World at War" with Dean Ryan.

These self-assembling clots were pulled out of the bodies of dead people who have died suddenly in the weeks or months after receiving one or more Wuhan coronavirus (COVID-19) vaccinations. As per Adams' report, these clots are harvesting electrically conductive elements out of the blood such as tin, aluminum and sodium.

"Tin has been harvested at 588 percent higher concentrations than what's found in human blood. Aluminum is being found about 35 to 40 percent or higher and sodium is about 50 percent or higher in these clots," he said.

Tin is used as a solder alloy in electrical circuits and circuit repair, whereas aluminum is the alternative to copper for electrical conductive wires in commercial residential wiring.

The Health Ranger added that blood samples from a healthy living person would include iron, potassium, magnesium, zinc, chlorine, phosphorus and so on. However, the post-vaccine clot sample only contains 4.4 percent of iron that would be seen in human blood, which confirmed that the mass is not a blood clot. Also, there is a near-total lack of potassium in the sample and it contains less than 0.6 percent of the potassium and magnesium compared to human blood.

"What we did is an elemental analysis using an inspected, audited and ISO-accredited laboratory for the elements. However, we did not conduct a radio frequency analysis, that could detect receiving or sending signals. That would have to be done by some other lab that specializes in these kinds of

technologies," Adams said in response to Ryan's inquiry about whether the electrically conductive elements could send or receive electromagnetic fields.

"But the question is leading in the right direction, that's just not something that we can provide," he added.

Ryan went on to say that people in Sweden dropped like flies when its 5G, the fifth generation of wireless technology, went up. "They were not getting any help in hospitals and so forth. We see strange behavior and people just mowing down. We're just trying to connect the dots because this is some science fiction that is starting to become a science fact here," Ryan said.

According to telephone companies, this technological advancement can provide higher speed, lower latency and one of the most robust technologies the world has ever seen. However, this development has been criticized to have environmental and health hazards, such as the elevated risk of brain cancer and acoustic neuroma.

As the clots have electrically conductive elements, Adams pointed to what happened to Dr. Charles Lieber, who was convicted by the Department of Justice for sharing secrets with communist China.

"His patents are all about nanocircuitry and bio interfaces at the cellular and subcellular level. So if you read his patents, it's all self-assembling nanocircuits inside human structures. So, follow the yellow brick road and see where that leads," said Adams, also a best-selling author, environmental scientist and multi-awarded journalist and publisher.

COVID-19 vaccines kill thousands of people daily

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"A rigorous analysis based on excess death data included anywhere from five to 12 million fatalities have likely occurred worldwide. And with these self-assembling clots continuing to gain size and mass inside the bodies of those who have received the mRNA experimental medicine injections, it is certain that many people who have not yet died from the vaccines will experience death in the coming months and years," Adams said.

He likened the ones who have received the mRNA injections to walking time bombs. However, he said there's a majority chance that if people stop taking them, they may be spared.

"If you took the vaccine, there's a big chance that if you stop taking them, you may not die. There's a slight chance that you are going to die if you got the wrong lot. The bottom line is to stop taking these shots. If you took it, pray to God that you didn't get one of the lots that have these clots," he said.

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Colin M. Greene, MD, MPH State Health Commissioner Department of Health
P O BOX 2448
RICHMOND, VA 23218

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

MEMORANDUM

DATE: November 7, 2022

TO: Virginia State Board of Health

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

SUBJECT: (Fast Track Action - Amend Rules and Regulations Governing Campgrounds (12VAC5-450) Amend Regulations: Temporary Campground Water Quality/Handwashing

Stations)

Enclosed for your review is a Fast Track Action to amend the Rules and Regulations Governing Campgrounds (12VAC5-450) to clarify standards for water storage and distribution at temporary campgrounds. Temporary campgrounds are those associated with temporary events, such as fairs, festivals, or music concerts. These events often do not have permanent infrastructure, and thus basic sanitation needs are met through the use of portable toilets, and often, portable hand washing sinks. The current regulations provide that any tanks, hoses, or appurtenances that are used to distribute water shall be of "food-grade construction"; current industry design of the majority of portable hand washing sinks do not meet this requirement. The proposed regulatory amendment will exempt portable handwashing sinks from being of food grade construction, require water used in handwashing sinks to maintain certain water quality standards, and have signage informing the public that water hand washing stations is not for human consumption.

The Virginia Department of Health recommends that the Board act pursuant to its authority provided in § 35.1-11 of the Code of Virginia, and approve the Fast Track actions. Should the Board of Health approve the Fast Track action, it will be submitted for Executive Branch review. Following Executive Branch review and approval, the proposed regulations will be published in the Virginia Register of Regulations and on the Virginia Regulatory Town Hall website and a 30 day public comment period will begin. Fifteen days after the close of the public comment period the Regulations will become effective.



Form: TH-04 August 2022



townhall.virginia.gov

Fast-Track Regulation Agency Background Document

Agency name	State Board of Health	
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC5-450-187	
VAC Chapter title(s)	Rules and Regulations for Campgrounds	
Action title	Fast-track Amendments: Temporary Campground Water Quality/hand washing Sinks	
Date this document prepared	Oct 25, 2022	

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 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 Virginia Department of Health (VDH) seeks to amend the Rules and Regulations Governing Campgrounds (12VAC5-450; hereinafter referred to as 'Regulations') to clarify standards for water storage and distribution at temporary campgrounds. Temporary campgrounds are those associated with temporary events, such as fairs, festivals, or music concerts. These events often do not have permanent infrastructure, and thus basic sanitation needs are met through the use of portable toilets, and often, portable hand washing sinks.

The Regulations provide that any tanks, hoses, or appurtenances that are used to distribute water shall be of food-grade construction. This requirement extends to any tanks or appurtenances providing water, including those associated with portable hand washing sinks. Current industry design of the majority of portable hand washing sinks do not meet this requirement through standard materials and design. As a result, the current regulation may discourage the use of portable hand washing sinks, and thus hand

washing, at temporary campgrounds. As hand washing is a primary component to reducing communicable disease, it is not the goal of the regulation to prohibit or discourage hand washing. VDH proposes to amend the Regulations to allow for the use of equipment that is more in line with industry standard, less burdensome to regulated entities, while protecting the public through signage stating that water in portable handwashing sinks is not for human consumption.

Acronyms and Definitions

Form: TH-04

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

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

"VRRM" means the Virginia Register of Regulations Form, Style and Procedure Manual for Publication of Virginia Regulations (April 2014).

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 amendment was prompted by industry stakeholders notifying local health department staff that the food grade equipment requirement for portable hand washing sinks was unattainable, as many portable hand washing sinks did not certify equipment to meet such requirements.

This proposed rulemaking is expected to be noncontroversial because it relaxes the requirements related to water in portable handwashing sinks and is expected to be welcomed by the regulated industry, therefore 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 35.1-11 of the Code of Virginia states:

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

Form: TH-04

In addition, subsection A of § 35.1-17 of the Code of Virginia states:

"The regulations of the Board governing campgrounds shall include minimum standards for (i) an approved drinking water supply; (ii) an approved sewage disposal system; (iii) an approved solid waste disposal system; (iv) the proper maintenance of buildings, grounds, and equipment; (v) vector and pest control; (vi) toilet, swimming, and bathing facilities, including shower facilities; (vii) effective measures for the control of animals and pets; (viii) appropriate procedures and safeguards for hazardous situations, including specifically the maintenance and sale of propane gas or other explosives and combustibles; and (ix) a procedure for obtaining a license. B. The Board may in its sole discretion prescribe regulations for classes of campgrounds and different requirements for each class."

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 regulatory change is to clarify standards for material used in the conveyance and storage of hand washing water at temporary campgrounds. Currently, the Regulations require any tanks, hoses, or appurtenances used to store or distribute water to be of "food-grade" construction. However, most portable hand washing sinks used by industry do not meet this standard. In traditional plumbed settings, hand washing water is considered potable water, and thus is required to meet the standard of water provided for drinking. In the settings of temporary campgrounds, temporary hand washing sinks, when used, provide extra sanitation for campers using portable toilets, but are not used as drinking water fountains.

The proposed amendment exempts portable hand washing sinks from meeting the full requirements applied to other water provided for drinking or showering in temporary campgrounds. To ensure this change has no adverse impact on public health, any portable hand washing sink that does not meet foodgrade standards will be required to post a sign notifying campers not to drink the water.

Without this fast-track amendment, the current language potentially creates a hardship on temporary campground operators and portable hand washing sink distributors and service providers, could discourage hand washing and the use of hand washing sinks, or unintentionally promote certain brands or 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 proposed amendment exempts portable hand washing sinks at temporary campgrounds from meeting the existing construction requirement for water distribution or storage tanks, while displaying a sign stating "Hand washing water is not for drinking."

Form: TH-04

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 this regulatory change is additional flexibility provided to campground operators and companies that supply portable sanitation facilities. The amendments align requirements to current industry standards, while still protecting public health through other existing provisions and the requirement for signage. This is not only a benefit to the public, but the agency will benefit from clearer and practical standards for portable hand washing sinks.

There are no known or anticipated disadvantages to the public or the Commonwealth associated with the proposed changes or pertinent matters of interest to the regulated community, government officials or the public.

Requirements More Restrictive than Federal

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

There are no requirements in this regulatory action that exceed 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

There are no other state agencies particularly affected by this regulatory change.

Localities Particularly Affected

There are no localities particularly affected by this regulatory change.

Other Entities Particularly Affected

Temporary campground operators, portable hand washing sink distributors, and service providers will be affected by this change.

Form: TH-04

Economic Impact

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

Impact on State Agencies

For your agency: projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	There are no projected costs, savings, fees or revenues anticipated to the agency due to this change; temporary campgrounds are already regulated and inspected by VDH.
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 anticipated to other state agencies due to this change.
For all agencies: Benefits the regulatory change is designed to produce.	There are no direct impacts on state agencies, with the potential exception of any state agency that hosts a temporary campground. These agencies may experience benefits as campground operators.

Impact on Localities

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

Projected costs, savings, fees or revenues resulting from the regulatory change.	There are no projected costs, savings, fees or revenues anticipated to localities due to this change.
Benefits the regulatory change is designed to produce.	There are no direct impacts on localities, but localities hosting temporary campgrounds may
p.o.u.so.	experience benefits as campground operators.

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	Temporary campground operators, portable hand washing sink distributors and service providers.
regulatory change. If no other entities will be	

affected, include a specific statement to that effect.	
Agency's best estimate of the number of such entities that will be affected. 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 were approximately 45 temporary campground applications processed in CY 2021, and 35 in 2022 to date. VDH does not require submission of information regarding the ownership status or number of employees. There are 408 campgrounds currently permitted in the Commonwealth for 2022. Based on employing 500 or fewer employees, an estimated 95 to 100% of these campgrounds are small businesses.
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, for affected individuals, businesses or other entities resulting from the regulatory change for localities.
Benefits the regulatory change is designed to produce.	Amending the regulations will provide more flexibility to campgrounds and companies that provide portable sanitation equipment, with no negative impact to public health.

Form: TH-04

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 information has been reported in Table 1b of the ORM Economic Impact form.

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 in Table 1b of the ORM Economic Impact form.

Public Participation

Form: TH-04

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

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

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

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

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall website at: https://townhall.virginia.gov. Comments may also be submitted by mail, email or fax to Briana Bill 109 Governor Street Richmond, VA 23235 (804) 584-6340 Fax number (804) 864-7475 briana.bill@ydh.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 <u>existing VAC Chapter(s)</u> 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 <u>and replaced</u>, 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- 450-187		This section provides standards for temporary campgrounds. Currently, the tanks, hoses, or appurtenances that are used to distribute water are required to be of food-grade construction, be disinfected between uses, and be protected from contamination and backflow	Change: Portable hand washing sinks are exempted from the requirement that tanks, hoses, or appurtenances used to distribute water be of food-grade construction, disinfected between uses, and protected from contamination and backflow. A requirement is added that the sinks maintain a one-parts-per million free chlorine residual, and display a sign stating "Hand washing water is not for drinking." Additionally, text amended to update regulatory citations, to comply with VRRM style requirements, and grammatical edits. Intent: To exempt portable handwashing sinks from unnecessary regulatory requirements.
			Rationale: Current regulation limits the use of tanks and accessories used to transport and convey water, including portable hand washing sinks at temporary campgrounds, to those made out of food grade material. This is not the industry standard for portable hand washing sinks and may negatively impact small business, with no associated public health rationale, as portable hand washing sinks are not used as drinking water fountains. The proposed language is in line with industry practice and easily understood.
			Impact: It will add flexibility for campground operators when procuring portable hand washing sinks, remove a limitation to businesses that rent portable sanitation equipment, and align regulations with industry standards. It is expected that more temporary campgrounds may elect to provide portable hand washing sinks due to the reduced regulatory requirements.

Form: TH-04

Department of Health

Amend Regulations: Temporary Campground Water Quality/Handwashing Stations 12VAC5-450-187. Temporary campgrounds.

Temporary campgrounds, <u>A temporary campground</u>, as permitted <u>under pursuant to</u> 12VAC5-450-40 F, shall be exempt from the following requirements of this chapter:

- 1. Density The density, size, and designation requirements of 12VAC5-450-70 B through D. However, temporary campgrounds A permit holder shall establish a maximum number of campsites and campers. Temporary campground permit holders shall: ensure that the size, location, and orientation of campsites do not prohibit the safe and timely evacuation of campsites in the event of an emergency; and ensure that vehicular traffic routes and parking are located where they do not endanger pose a safety risk to campers.
- 2. Permanent The permanent water supply requirements of 12VAC5-450-80.
 - a. If the permit holder provides potable water is provided in the form of a waterworks or private well, the permit the-permit holder shall make available bottled water that complies with 21 CFR Part 129 shall be available, and shall advertise the unavailability of piped water must-be-advertised to campers prior to the time-of-the-temporary camping event.
 - b. Water may be transported in from a source that meets If the permit holder provides water that is transported to a temporary campground, the source of the water shall meet the requirements of 12VAC5-450-80 A. Water shall be The permit holder shall ensure that water is transported in tanks of food-grade construction and maintain maintains a one-parts-per-million chlorine residual. With the exception of portable hand washing sinks, the permit holder shall ensure that Any tanks, hoses, or appurtenances that are used to distribute water shall be are of food-grade construction, be disinfected between uses, and be protected from contamination and backflow.
 - c. If the permit holder provides portable hand washing sinks, the permit holder shall ensure that the sink water maintains a one-parts-per million chlorine residual, and shall display a sign stating "Hand washing water is not for drinking."
- 3. The dump station and slop sink requirements of 12VAC5-450-90 D, E, and G.
 - a. Greywater disposal barrels or approved equivalents shall be provided and serviced during the event unless all of the following conditions apply: (i) piped water is not available, (ii) portable showers and handwashing sinks are provided, and (iii) cooking and campfires are prohibited. Only water from cooking, washing, or bathing shall be disposed of in greywater barrels.
 - b. a. If self-contained camping units are present at the campground, the permit holder shall ensure that a sewage handler who possesses a valid sewage handling permit as required by 12VAC5-610 and any license required by the Board for Waterworks and Wastewater Works Operators and Onsite Sewage System Professionals Licensing Regulations (18VAC160-40 et seq.) and Title 54.1 of the Code of Virginia shall be is available to pump holding tanks as appropriate during the event. Sewage handlers must possess a valid sewage handling permit as required by 12VAC5-610 and any licensure required by the Board for Waterworks and

- Wastewater Works Operators and Onsite Sewage Professionals in accordance with that board's regulations (18VAC160-30 and 18VAC160-40) and Title 54.1 of the Code of Virginia.
 - <u>b. The permit holder shall service and provide greywater slop sinks or disposal barrels at least daily during an event held at a temporary campgrounds when:</u>
 - (1) Piped water is not available;
 - (2) Portable showers and hand washing sinks are provided; and
 - (3) Cooking and campfires are prohibited.
 - The permit holder shall ensure that water from cooking, washing, or bathing is disposed of in greywater barrels.
 - 4. Permanent The permanent sanitary facility requirements in 12VAC5-450-100 A, B, and I. However, The permit holder shall provide portable toilet facilities shall be provided at the ratio of at least one toilet for every 75 campers, and shall ensure that at least one toilet shall comply complies with the Americans with Disabilities Act (42 USC § 12101 et seq.). No campsite shall may be farther than 500 feet from any a portable toilet. Portable sinks and showers are not required, although The permit holder shall provide hand sanitizer must be provided in all portable toilets where if portable sinks are not provided. All portable units shall be serviced The permit holder shall ensure that the portable sanitary facilities are serviced at least daily during the event unless the applicant or permit holder can demonstrate that they are provided in numbers significant there are enough portable sanitary facilities to warrant a reduced-maintenance service schedule. If the temporary campground has permanent bathroom facilities, the facilities may count towards the required number of portable toilets. Campers The permit holder may exclude campers who will be camping in self-contained camping units shall not be counted toward from the total number of campers in for the purposes of calculating the required number of portable toilets.
 - **Statutory Authority**
- 74 § 35.1-11 and 35.1-17 of the Code of Virginia.
- 75 Historical Notes

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Derived from Virginia Register Volume 35, Issue 5, eff. November 28, 2018.

Office of Regulatory Management

Economic Review Form

Agency name	Virginia Department of Health		
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC 5-450		
VAC Chapter title(s)	Rules and Regulations Governing Campgrounds		
Action title	Fast-track Amendments: Temporary Campground Water Quality/Hand Washing Sinks		
Date this document	October 25, 2022		
prepared			

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

(1) Direct Costs & Benefits	• This action would exempt portable hand washing sinks from the requirement that any tanks, hoses, or appurtenances that are used to distribute water shall be of food grade construction Temporary Campgrounds (12VAC5-450-187).		
	Direct Costs: The only potential direct cost associated with the proposed change would be the purchasing of the signage to be required if a temporary campground uses portable hand washing sinks without food-grade water equipment. On average the sign is \$16.00.		
	Direct Benefits: As hand washing is a primary component to reducing communicable disease, it is not the intention of the Virginia Department of Health to prohibit or discourage handwashing. The benefit is the allowance to use equipment that is more in line with industry standard and less burdensome to the regulant population, while protecting the public through encouraging handwashing, ensuring portable hand washing sinks meet adequate disinfection requirements, and requiring signage informing the public that water used for hand washing is not for human consumption. The use of portable hand washing sinks is not required at temporary campgrounds, however, if used, the campground operator must comply with regulatory requirements that currently restrict the water equipment to certain standards and potentially increase the cost burden to provide a public health amenity that many campground operators and patrons want or expect at a temporary campground. In the settings of temporary		

campgrounds, temporary hand washing sinks, when used, provide extra sanitation for campers using portable toilets, but are not used as drinking water fountains.

Cost Calculation

Average cost of portable food-grade sink: \$1,519
 Number of temporary campgrounds as of September, 2022: 35
 (\$1,519 * 35=\$53,165)

(\$1,519 * 35=\$53,165) *This is an astimate at a mate of

*This is an estimate at a rate of one food-grade sink per temporary campground

Average cost of portable non food-grade sink: \$1,031.25
 Number of temporary campgrounds as of September, 2022: 35
 (\$1,031.25 * 35=\$36,093.75)

*This is an estimate at a rate of one non food-grade sink per temporary campground

The difference in costs of portable food-grade and non-food grade sinks: \$17,071.25 yearly or \$487.75 per unit.

(2) Quantitative				
Factors	Estimated Dollar Amount	Present Value		
Direct Costs		(c) \$4,920		
	per sign, ~35 temp.			
	campgrounds per year)			
Direct Benefits	(b) \$170,713 (10 years,	(d) \$149,990		
	\$487.76 per unit, 35 temp.			
	campgrounds)			
(3) Benefits-		(4) Net	\$145,070	
Costs Ratio	30.48	Benefit		

(5) Indirect Costs & Benefits

Indirect Costs: The agency is unable to determine possible indirect costs associated with the proposed regulatory change as the change would reduce restrictions on providing portable hand washing sinks and therefore improve and increase the ability for use at temporary campgrounds.

Indirect Benefits: Indirect benefits include removing the burden of complying with outdated requirements that do not align with current industry practices and added clarity to operational requirements that improve campground performance and protection of the health and safety of campers and the public. In addition, campground operators and companies that supply portable sanitation facilities may save an average of

	\$488 per portable sink by not replacing existing sinks that do not meet existing regulatory requirements.					
(6) Information Sources	Monetary value of portable hand washing sinks gathered from online research (Poly John, MOBI, Monsam, Cambro, and Regency) and industry representative outreach (Crown Verity, Satellite,) to determine food grade construction and estimated cost per unit. The chart below provides additional information on the various types of handwashing stations and their costs. "USDA" means United States Department of Agriculture "FDA" means Food and Drug Administration "NSF" means National Science Foundation					
	Manufacturer USDA FDA Food Food Grade?					
	PolyJohn	No	No	No	\$700	<u>Link</u>
	Crown Verity No Yes Yes-NSF/ANSI \$1600 Link					<u>Link</u>
	MOBI	No	No	No	\$525	<u>Link</u>
	Monsam No Yes Yes \$2191 Link					
	Satellite	No	Yes- Resin Only	Yes- Resin Only	\$766	<u>Link</u>
	Cambro	No	No	No	\$1200	<u>Link</u>
	Regency	No	No	No	\$1700	Link
(7) Optional	None					

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

This table addresses current requirements and the implications of not making any changes. In other words, describe the costs and benefits of maintaining the current regulatory requirements as is.

(1) Direct Costs & Benefits

 Current regulations for temporary campgrounds require that any tanks, hoses, or appurtenances that are used to distribute water shall be of food grade construction.

Direct Costs: Current industry design of the majority of portable hand washing sinks do not meet current regulatory construction requirements through standard materials and design, and may in effect discourage the use of such sinks, and thus prohibit or discourage handwashing at temporary campgrounds. The agency is unable to determine the direct monetary cost of reduced hand washing at temporary campgrounds but attests that the reduction of hand washing may jeopardize the safety, health and welfare of the public. Requiring portable hand washing sinks to be food grade would limit campground operators to select vendors, and may in effect, limit and target the market to specific providers. The ability to determine if a portable hand washing sink is of food grade construction can be difficult as various components of the sink design may be of different materials and certification, further burdening the industry on meeting compliance with the regulation.

Cost Calculation

Average cost of portable food-grade sink: \$1,519
 Number of temporary campgrounds as of September, 2022: 35
 (\$1,519 * 35=\$53,165)

*This is an estimate at a rate of one food-grade sink per temporary campground.

Direct Benefits: The agency did not identify a direct benefit of maintaining the current regulation related to portable hand washing sinks at temporary campgrounds.

(2) Quantitative		
Factors	Estimated Dollar Amount	Present Value
Direct Costs	(a) \$531,650 (10 yrs, \$53,165 per year)	(c) \$467,113

Direct Benefits	(b) \$0	(d) \$0		
(3) Benefits- Costs Ratio	0	(4) Net Benefit	-\$467,113	
(5) Indirect Costs & Benefits	on temporary campground oper sinks. Maintaining the status qu companies that supply portable existing sinks that do not meet	costs may include unnecessary operational burden d operations related to portable hand washing atus quo could result in campground operators or ortable sanitation facilities having to replace meet existing regulatory requirements. direct benefits were identified if the regulations		
(6) Information Sources	Same as Table 1.a(6)			
(7) Optional	None			

Table 1c: Costs and Benefits under an Alternative Approach

This table addresses an alternative approach to accomplishing the objectives with different requirements. These alternative approaches may include the use of reasonably available alternatives in lieu of regulation, or information disclosure requirements or performance standards instead of regulatory mandates.

(1) Direct Costs & Benefits	the water in a portable consumption. One alteremove the requirement water in a portable has consumption. Temporation of the above proposed consumption of may lead to the the public may display infection and display health and health	the posting of a sign to inform the public to handwashing station is not for human to the proposed regulations to the proposed regulations to the proposed regulations to the public the the mode washing station is not for human to direct quantitative costs were identified if used alternative is adopted. However, the water not intended for human consumption transmission of disease, and without signage, think water from the sinks. Waterborne transmission of disease could result in significant burden on the case spending. The average cost of a sign is \$16.00
	o breet benefit. The average cost of a sign is \$10.00	
(2) Quantitative Factors	Estimated Dollar Amount	Present Value

Direct Costs	(a) \$0.00	(c) \$0.00	
Direct Benefits	(b) \$5,600 = (10 years, \$16 per sign, ~35 temp. campgrounds per year)	(d) \$4,920	
(3) Benefits- Costs Ratio	\$0	(4) Net Benefit	\$4,920
(5) Indirect Costs & Benefits	Indirect Costs: The agency is unable to determine any indirect cost associated with adopting the proposed alternative. Indirect Benefits: The agency is unable to determine any indirect benefit associated with adopting the proposed alternative.		
(6) Information Sources	¹ Collier, Sarah A et al. "Estimate of Burden and Direct Healthcare Cost of Infectious Waterborne Disease in the United States." <i>Emerging infectious diseases</i> vol. 27,1 (2021): 140-149. doi:10.3201/eid2701.190676		
(7) Optional	N/A		

Table 2: Impact on Local Partners

(1) Direct Costs & Benefits	Direct Costs: Local partners or authorities such as the Virginia Restaurant, Lodging and Travel Association or Virginia Campground Association may be affected by this action in regards to notification and support to their constituents. Local and tribal governments, school divisions or other authorities are likely not affected by this action, unless they implement a local ordinance or other code specific to temporary campground facilities and portable hand washing provisions.
	Direct Benefits: No indirect benefits were identified for local partners.
(2) Quantitative Factors Direct Costs	Estimated Dollar Amount (a) N/A
Direct Benefits	(b) N/A
(3) Indirect Costs & Benefits	Indirect Costs: The agency is unable to determine any indirect cost to local partners associated with this proposed amendment.

	Indirect Benefits: Potential indirect benefits to local partners associated with this proposed amendment may include improved public health protections during temporary events that involve permitted temporary campgrounds. The ability to easily provide portable hand washing sinks could improve event operations and public perception and approval through the providing of hand washing opportunities that increases public comfort and trust of an event, location, and community partners.
(4) Information Sources	N/A
(5) Assistance	N/A
(6) Optional	N/A

Table 3: Impact on Families

Table 5. Impact	
(1) Direct Costs	Direct Costs: The agency did not identify any direct costs to families
& Benefits	related to the proposed amendment.
& Delicitis	Totaled to the proposed amendment.
	Direct Benefits: The agency did not identify any direct benefits to families
	related to the proposed amendment.
	related to the proposed amendment.
(2) Quantitative	
Factors	Estimated Dollar Amount
Direct Costs	(a) N/A
Direct Benefits	(b) N/A
(3) Indirect	Indirect Costs: The agency is unable to determine the indirect cost to
Costs &	families regarding the proposed amendment.
Benefits	Imminos 1980manik ma brobesean amazarania
Benefits	
	Indirect Benefits: The potential indirect benefits to families could include
	increased opportunities to wash hands during temporary camping events
	and thus improve the health and safety of the family.
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(4) Information	N/A
Sources	

(5) Optional	N/A

Table 4: Impact on Small Businesses

	on Small Businesses
(1) Direct Costs	Direct Costs: The agency did not identify any direct costs to small
& Benefits	businesses related to this change.
	Direct Benefits: The direct benefits of amending the regulations to small businesses may include less regulatory burden, and therefore less potential cost to provide a public health amenity at temporary campgrounds that is often expected by the public. The agency is recommending the regulation be amended to minimize the economic impact on small businesses while maintaining appropriate regulatory standards to ensure the safety, health, and welfare of the public.
(2) Quantitative	
Factors	Estimated Dollar Amount
Direct Costs	(a) N/A
Direct Benefits	(b) N/A
(3) Indirect	Indirect Costs: The agency did not identify any indirect costs to small
Costs & Benefits	businesses associated with the change.
	Indirect Benefits: Indirect benefits may include the removal of
	unnecessary operational burden on temporary campground operations that could be reduced or removed through the proposed amendments. Amending the regulations may also reduce expenditures necessary to meet the current regulatory requirements.
(4) Alternatives	Alternatives to an amendment would include no action and to retain the regulation as is. As stated, this lack of change may maintain a status quo that is burdensome for the campground industry and small business. Review and consideration of amendments to the regulations is the only way for Virginia to stay current with industry standards and to ensure that the agency's statutory requirements are executed in the least burdensome and most efficient and cost-effective manner possible while protecting the health, safety and welfare of the citizens of Virginia.
(5) Information Sources	N/A

(6) Optional	N/A

Changes to Number of Regulatory Requirements

For each individual VAC Chapter amended, repealed, or promulgated by this regulatory action, list (a) the initial requirement count, (b) the count of requirements that this regulatory package is adding, (c) the count of requirements that this regulatory package is reducing, (d) the net change in the number of requirements. This count should be based upon the text as written when this stage was presented for executive branch review. Five rows have been provided, add or delete rows as needed.

Table 5: Total Number of Requirements

	Number of Requirements			
Chapter number	Initial Count Additions Subtractions Net Change			
450	0	1	1	0



Colin M. Greene, MD, MPH State Health Commissioner Department of Health P O BOX 2448 RICHMOND, VA 23218

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

MEMORANDUM

DATE: November 7, 2022

TO: Virginia State Board of Health

FROM: Seth Austin, Director, Office of Vital Records

SUBJECT: Amending regulations following statutory changes – 12VAC5-550

Enclosed for your review are Fast Track amendments to the Board of Health Regulations Governing Vital Records (12VAC5-550-5 et seq.)

The purpose of the proposed amendments is to update definitions in the Virginia Administrative Code to provide clarity to Virginia regulations; repeal sections that are not regulatory in nature; updates forms used by sections impacted by the action; and conforms the requirements of the following sections to the Code of Virginia:

- 12VAC5-550-440, 12VAC5-550-450, 12VAC5-550-460: Amending death certificates and requirements to conform with §32.1-269.1
- 12VAC5-550-125: Stillbirth certificate fee removal to conform with §32.1-.258.1
- 12VAC5-550-520: Updating fees for vital records requests, amendments or delayed registrations to conform with §32.1-273
- 12VAC5-550-320: Change of sex on birth certificate requirements to conform with §32.1-261
- 12VAC5-550-130: Removing the item "race" on marriage and divorce certificates to conform with §§32.1-267, 32.1-268 and 32.1-268.1

The Board of Health is requested to approve the Fast Track Action; if approved it shall be published in the Virginia Register of Regulations. This will initiate a 30-day public comment period. The regulations become effective 15-days after the public comment period ends unless there is objection pursuant to Va. Code § 2.2-4012.1; in which case the Fast Track regulation will serve as Notice of Intended Regulatory Action and the standard rulemaking process shall be followed to promulgate the regulation.



Form: TH-04 August 2022



townhall.virginia.gov

Fast-Track Regulation Agency Background Document

Agency name State Board of Health	
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-550
VAC Chapter title(s)	Board of Health Regulation Governing Vital Records
Action title	Amend Regulations Following Statutory Changes
Date this document prepared	11-14-2022

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 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 purpose of the proposed amendments is to amend the Regulations to reflect several recent changes in the Code of Virginia, including changes to §32.258.1, §32.1-269.1, §32.1-261, and §32.1-267. Several sections will be repealed, as these sections were not regulatory in nature. The amendment to 12VAC5-550-520 changes the certification fee from \$10 to \$12 because this fee was changed in the Code and implemented several years ago.

Chapter 171 of the 2022 Acts of Assembly removed the authority to charge a fee to obtain a stillbirth certificates. The business operations of the Office of Vital Records have already been changed to conform to the new law, but the regulations have not yet been changed. Chapters 209, 210, and 211 of the 2020 Acts of Assembly removed race from the data to be collected regarding marriages, divorces, and annulments. Chapters 465 and 466 of the 2020 Acts of Assembly amended the process to change one's sex on a birth certificate. Chapters 116 and 117 of the 2022 Acts of Assembly changed the process and timelines associated with amending a death certificate.

The amendments improve the regulatory language used in the Virginia Administrative Code so that both the public and government organizations have better direction concerning the responsibilities and requirements needed to perform their duties. This should reduce time spent dealing with challenges to processes that are presented by members of the public and will make the operations of the Office of Vital Records more efficient.

Form: TH-04

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.

There are no acronyms used in this Agency Background Document that are not also defined in the "Definitions" section of the regulation.

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.

Chapter 171 (2022) removed the authority to charge a fee to obtain a stillbirth certificates. 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.

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.

Form: TH-04

The regulation is promulgated by the State Board of Health under the authority of §§ 32.1-12 and 32.1-250 of the Code of Virginia.

Section 32.1-12 grants the Board of Health the legal authority to make, adopt, promulgate, and enforce regulations necessary to carry out the provisions of Title 32.1 of the Code and other laws of the Commonwealth administered by it. Section 32.1-250 of the Code of Virginia requires the Board of Health to install, maintain and operate the only system of vital records throughout the Commonwealth.

Specific changes being made are authorized by Chapters 209, 210, 211, 465, and 466 (2020) and 116, 117, and 171 (2022). The fee amount in Section 520 is being updated to reflect the amount in Item 290 A, Chapter 2 of the 2022 Acts of Assembly, Special Session I.

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 fast track action is essential to ensure the regulations that govern the business processes of the Office of Vital Records are aligned with the Code of Virginia. The Office of Vital records has also increased the clarity, accuracy, and completeness of the regulations governing vital records.

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.

- 12VAC5-550-5. Definitions are updated to make the Regulations easier to understand.
- 12VAC5-550-20, 12VAC5-550-30, 12VAC5-550-50, and 12VAC5-550-60 have been repealed. These provisions do not meet the statutory definition of a "regulation" in § 2.2-4001 and are unnecessary.
- 12VAC5-550-125. Certificate of birth resulting in a stillbirth. The changes remove the fee for this type of vital record.
- 12VAC5-550-130. Marriage return and certificate items. The changes identify the specific form that will be used for this action, which facilitates the removal of race as a certificate item.
- 12VAC5-550-140. Report of divorce or annulment. The changes identify the specific form that will be used for this action, which facilitates the removal of race as a certificate item.
- 12VAC5-550-320. Change of Sex. The changes identify the specific form that will be used for this action, clarify the language, and conform the regulation to the Code of Virginia.
- 12VAC5-550-440. Applications for correction. The changes update the timeframe for amending a death certificate and clarify how the amendment can be accomplished consistent with the Code.

• 12VAC5-550-450. Evidence required for corrections or amendments. The changes add to and clarify the requirements for changes made to a death record.

Form: TH-04

- 12VAC5-550-460. Methods of correcting or altering certificates. The changes define "amendment" to bring consistency and clarity to the regulations.
- 12VAC5-550-520. Fees. This fee is being updated to reflect Item 290 A, Chapter 2 of the 2022 Acts of Assembly, Special Session I.
- 12VAC5-550-9998 FORMS. Forms that are only used internally by OVR staff are being removed, the effective dates of all necessary forms are being updated, along with links to the documents.

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, the agency, and the Commonwealth include the enhanced integrity of the regulations governing Vital Records and in turn the system of vital records within the Commonwealth. There are no known disadvantages to the public, regulated entities, business entities, or the Commonwealth.

Requirements More Restrictive than Federal

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

There are no requirements of this proposal which are 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 agency will be affected by these fast track amendments. Localities Particularly Affected: There are no localities that will be affected by these fast track amendments.

Form: TH-04

Other Entities Particularly Affected: Members of the public filing or amending vital records are
affected by the process changes – however, because the regulatory changes are to comply with
previous changes in the Code, no other entity will be affected solely by the regulatory changes.

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 projected cost to the Virginia Department of Health to implement and enforce this regulatory proposal is negligible. It will not interrupt or affect business operations within the Office of Vital Records.
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 is no projected cost to other state agencies to implement and enforce this regulatory proposal.
For all agencies: Benefits the regulatory change is designed to produce.	None

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	Implementing and enforcing this regulatory
resulting from the regulatory change.	proposal will not produce a cost to any localities.
Benefits the regulatory change is designed to	None
produce.	

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	The analysis has been reported in tables 1a, 3, and 4 on the ORM Economic Impact form.
regulatory change. If no other entities will be	
affected, include a specific statement to that	
effect.	

Agency's best estimate of the number of such entities that will be affected. 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 analysis has been reported in tables 1a, 3, and 4 on the ORM Economic Impact form.
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.	The analysis has been reported in tables 1a, 3, and 4 on the ORM Economic Impact form.
Benefits the regulatory change is designed to produce.	The analysis has been reported in tables 1a, 3, and 4 on the ORM Economic Impact form.

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.

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.

There are no viable alternatives to the proposal considered. Regulatory action is necessary to make corrections to the existing regulations, provide clarification to regulatory language, and add additional regulatory sections required by changes to the Code of Virginia.

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.

No alternative regulatory methods are available to the agency. These changes are being made to comply with the Code of Virginia and make non-substantive changes for the purpose of clarity and readability; they do not address compliance and reduce reporting requirements, and the regulations do not impact small businesses.

Form: TH-04

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 describe the nature of, and reason for, your objection to using this process.

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

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: https://townhall.virginia.gov. Comments may also be submitted by mail, email or fax to

Yolanda Aponte, Office of Vital Records,

P. O. Box 1000 Richmond, VA 23218, Phone: (804) 482-7939, Fax: (804) 662-6256.

Email: yolanda.aponte@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 <u>existing VAC Chapter(s)</u> 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 <u>and replaced</u>, 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	New chapter- section	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
number	number, if applicable		
15VAC5- 550-5		"In addition to the words and terms defined in § 32.1-249 of the Code of Virginia, the following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise: "Primary evidence" means valid first-hand documentation established before the registrant's 18th birthday, such as school admission records, physician's records, immunization records, passport, federal census abstracts, baptismal records and insurance applications. "Registrant" means the person whose personal information is registered and filed in the systems of vital records. "Secondary evidence" means valid documentation established after the registrant's eighteenth birthday such as marriage records, child's birth certificate, school records, social security records, driver's records, work permit and employment records. Such evidence must be at least five years old."	change: The definitions for "primary evidence," "registrant," and "secondary evidence" are being updated. A definition for "registrar" is being added. INTENT: The intent is to increase the clarity of those definitions being amended. The intent of adding a definition for "registrar" is to be able to identify tasks that can be performed by the State Registrar or any other in the Commonwealth. RATIONALE: The rationale is that clearer regulations are better for the public and for agency staff administering them. The definition for "secondary evidence" also contained a substantive requirement, which should not be included in a "Definitions" section. LIKELY IMPACT: The likely impact is that the regulations will be more readable.
12VAC5- 550-20		This section identified the purpose of the regulations.	CHANGE: The section is being repealed INTENT: The intent is to repeal non- regulatory provisions, which are unnecessary. RATIONALE: The rationale is that the provisions are not regulatory in nature pursuant to the definition of a regulation in § 2.2-4001. The Registrar of Regulations, pursuant to 1VAC7-10-40 (C) has the authority to omit purpose statements from publication. LIKELY IMPACT: The regulations will be shorter and not contain unnecessary language.
12VAC5- 550-30		This section identifies the "administration" of the chapter.	CHANGE: The section is being repealed INTENT: The intent is to repeal non- regulatory provisions, which are unnecessary.

		RATIONALE: The rationale is that the provisions are not regulatory in nature pursuant to the definition of a regulation in § 2.2-4001. By nature of being promulgated by the Board of Health under its basic laws, the administration of the chapter is already set forth in the Code of Virginia. The Registrar of Regulations, pursuant to 1VAC7-10-40 (C) has the authority to non-regulatory provisions from publication.
		LIKELY IMPACT: The regulations will be shorter and not contain unnecessary language.
12VAC5- 550-50	This section indicates that the Administrative Process Act (APA) applies to the regulation.	CHANGE: The section is being repealed INTENT: The intent is to repeal non- regulatory provisions, which are unnecessary. RATIONALE: The rationale is that the provisions are not regulatory in nature
		pursuant to the definition of a regulation in § 2.2-4001. The APA applies without including a statement to that effect in the regulation. The Registrar of Regulations, pursuant to 1VAC7-10-40 (C) has the authority to non-regulatory and unnecessary provisions from publication. LIKELY IMPACT: The regulations will be shorter and not contain unnecessary
12VAC5-	"The board reserves the right to	language. CHANGE: The section is being repealed
550-60	authorize any procedure for the enforcement of this chapter that is not inconsistent with the provisions set forth herein and the provisions of Chapter 7 of Title 32.1 of the Code of	INTENT: The intent is non-regulatory provisions, which are unnecessary.
	Virginia."	RATIONALE: The rationale is that the provisions are not regulatory in nature pursuant to the definition of a regulation in § 2.2-4001. The section does not define or specify any specific power or procedure to be followed by a regulated entity or by the agency, and the Board's powers are already set forth in the Code of Virginia. The Registrar of Regulations, pursuant to 1VAC7-10-40 (C) has the authority to non-regulatory and unnecessary provisions from publication.
		LIKELY IMPACT: The regulations will be shorter and not contain unnecessary language.
12VAC5- 550-125	This section describes the process by which a parent may receive a	CHANGE: The change is to remove the requirement to pay a fee to receive a

	Certificate of Birth Resulting in Stillbirth.	Certificate pursuant to the section. Multiple changes in style and form are also made.
		INTENT: The intent is to provide stillbirth certificates free of charge. The requirements for the certificate have been re-organized for clarity and to make the section consistent with the Registrar of Regulations' Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code ("Style Requirements").
		RATIONALE: Chapter 171 (2022) removed the authority to charge a fee associated with obtaining a stillbirth certificate. Also, regulatory language should conform to the Style Requirements to ensure concise, clear, and consistent regulatory language.
		LIKELY IMPACT: The impact of the change is negligible, as there are very few stillbirth certificates produced each year, and the loss of revenue is minimal. In Virginia, there were approximately 2,800 stillbirths between 2018 and 2020 and these led to only 229 applications for certificates. For those wishing to obtain a certificate, though, they can do so free of charge. The language will also be more readable.
12VAC5- 550-130	This section included the form to be used to register a marriage and the items to be included on the form.	CHANGE: The section will be updated to reference the process by which an officer issuing marriage license is to report those marriages to the State Registrar of Vital Records, including the form. It will also reference the form required to be used by members of the public to obtain a certified copy of a marriage certificate. The word "items" is also being stricken from the section title, as the section no longer lists the items in the form but makes reference to the form itself, instead.
		INTENT: The intent is make the regulations clearer and more reflective of the processes governed by the State Registrar and to reference the required forms to be used. In effect, because the forms no longer require race to be reported, it removes the current requirement which is unenforceable.
		RATIONALE: The rationale is that Chapters 209, 210, and 211 (2020), prompted by the order in a federal court case, 507 F. Supp. 3d 664 (E.D. Va. 2019), removed the reporting of race from marriage applications, licenses, and records.

		LIKELY IMPACT: The regulations will
12VAC5- 550-140	This section included the form to be used to register a divorce or annulment and the items to be included on the form.	comply with the Code of Virginia. CHANGE: The section will be updated to reference the process by which a clerk of the court granting decrees of divorce and annulment to the State Registrar of Vital Records, including the form. It will also reference the form required to be used by members of the public to obtain a certified copy of a divorce or annulment certificate. The word "items" is also being stricken from the section title, as the section no longer lists the items in the form but makes reference to the form itself, instead. INTENT: The intent is make the regulations clearer and more reflective of the processes governed by the State Registrar and to reference the required forms to be used. In effect, because the forms no longer require race to be reported, it removes the current requirement which is unenforceable. RATIONALE: The rationale is that Chapters 209, 210, and 211 (2020), prompted by the order in a federal court case, 507 F. Supp. 3d 664 (E.D. Va. 2019), removed the reporting of race from divorce and annulment records.
12VAC5- 550-320	This section describes the process by which a person may obtain a new birth certificate to reflect a change in sex.	LIKELY IMPACT: The regulations will comply with the Code of Virginia. CHANGE: The section still describes the process but updates the style and form of the language and makes reference to the specific form to be used, which itself contains the requisite information. The change adds in the process by which a person changing the sex on their birth certificate can also change their name. INTENT: The intent is clarify the process and form to change one's sex as it appears on a birth certificate and confirm that process to the Code of Virginia. Also, regulatory language should conform to the Style Requirements to ensure concise, clear, and consistent regulatory language. RATIONALE: The rationale is that Chapters 465 and 466 (2020) amended the change of sex process in the Code of Virginia. LIKELY IMPACT: The regulations will comply with the Code of Virginia.
12VAC5- 550-440	This section describes the process and requirements to correct or amend a vital record.	CHANGE: The subsections related to amending a birth certificate or marriage, divorce, or annulment record will be updated

		to make style and form changes. The death certificate amendment procedure will also be updated to allow for changes to be made administratively (i.e. without a court order) within 45 days instead of 30 and beyond 45 days in certain circumstances.
		INTENT: The intent of the style and form changes is to conform the section to the Style Requirements. The intent of the substantive change is to clarify the process by which a person may amend a death certificate, which includes an additional 15 days to request an administrative amendment.
		RATIONALE: The rationale is that the death certificate amendment process in the Code of Virginia was changed by Chapters 465 and 466 (2022). Also, regulatory language should conform to the <i>Style Requirements</i> to ensure concise, clear, and consistent regulatory language.
		LIKELY IMPACT: The regulations will comply with the Code of Virginia and members of the public who wish to amend a death certificate will utilize the new process and timelines. Additionally, the regulation will be clearer and more readable.
12VAC5- 550-450	This section describes the evidence that a person is required to submit to request an amendment to a vital record.	CHANGE: The requirements related to amending birth and death certificates are separated. There are also minimal style changes made to the first paragraph of subsection A.
		INTENT: The intent is to clarify the difference between the evidence required to change a birth certificate vs. a death certificate. Also, regulatory language should conform to the <i>Style Requirements</i> to ensure concise, clear, and consistent regulatory language.
		RATIONALE: The rationale is that the process by which a death certificate can be amended, and subsequently the evidence needed were changed by Chapters 465 and 466 (2022). The current requirements do not distinguish between the two types of certificates, though the process for each is now different.
		LIKELY IMPACT: The regulations will comply with the Code of Virginia and members of the public who wish to amend a death certificate will utilize the new process

		The ending to
		and timelines. Additionally, the regulation will be clearer and more readable.
12VAC5- 550-460	This section describes the manner by which the registrar makes requested and authorized amendments to vital records.	CHANGE: The changes are mostly non- substantive and in only style and form. Subsection A will be amended to remove the provision that a birth certificate on which a name is amended within seven years will not be considered to be amended and reduced to one year. INTENT: The intent is of the style changes is to conform the regulations to the Style Requirements. The change regarding the time in which a name may be changed without considering a birth certificate to be amended is intended to comply with § 32.1- 269 (B) of the Code.
		RATIONALE: Regulatory language should conform to the <i>Style Requirements</i> to ensure concise, clear, and consistent regulatory language. Also, § 32.1-269 (B) requires the Board to "prescribe by regulation the conditions under which omissions or errors on certificates[]may be corrected within one year after the date of the event without the certificate being marked amended." The process will be updated to reflect that one year point instead of seven years.
		LIKELY IMPACT: The The changes are for the most part to clarify the language, but also include a clarification of the timeline associated with the term "amendment" to now refer to changes made after one year from the date of the vital event. This change is needed to support the other changes to Regulations pertaining to vital records amendments which are necessary due to Chapters 116 and 117 of the 2022 Acts of Assembly.
12VAC5- 550-520	A. The fee to be charged by the State Registrar or by the city or county registrar shall be \$10 for each full certification or short form certification of a vital record, or for a search of the files or records when no copy is made. B. When documents are amended or delayed birth registration is requested, the requester shall be charged an administrative fee of \$10.	CHANGE: The change is to update the fee for a certified copy from \$10 to \$12 unless otherwise directed in the Code. There are also style and form changes made to the section. INTENT: The intent is to conform the regulations to the Appropriation Act, which sets the fee at \$12 and to make reference to the special circumstances in which no fee is to be charged. The intent is also to conform the language to the Style Requirements.
		RATIONALE: Item 309 A, Chapter 4 of the 2004 Acts of Assembly, Special Session I initially updated the "standard vital records fee" to \$12. Item 290 A, Chapter 2 of the 2022 Acts of Assembly, Special Session I,

		includes that language. Also, regulatory language should conform to the <i>Style</i>
		Requirements to ensure concise, clear, and
		consistent regulatory language.
		LIKELY IMPACT: The regulations will
FORMO	The	conform to the Appropriation Act language.
FORMS (12VAC5-	The section listed 17 forms used by the State Registrar of Vital Records.	CHANGE: Forms only used by the Office of Vital Records, which include vital record
550)	the State Registral of Vital Records.	templates, will be removed. The applications
000)		for a Birth Record, Marriage-Divorce
		Record, Death record, Stillbirth Certificate,
		form to change sex designation, and request
		to amend a birth certificate are all added.
		Additionally, the report of adoption,
		acknowledgement of paternity, and affidavit
		for correction of a record are all updated to reflect the most updated effective version of
		the Form.
		alo i olili.
		INTENT: The intent is to only list those
		forms that are used by the public and to
		ensure access to the most up to date
		versions of the forms.
		RATIONALE: The rationale is that forms
		listed in the section should include access to
		printable or downloadable versions of the
		form and vital record / certificate templates
		should not be publicly accessible. The forms
		that members of the public do need or are
		required to use should be listed and
		accessible.
		LIKELY IMPACT: The public will have
		access via the regulations in the VAC online
		to all relevant forms. Also, the section will be
		more concise with the removal of
		unnecessary references to other forms.

Project 7299 - Fast-Track

Department of Health

Amend Regulations following Periodic Review - Amendments to comply with the Code of Virginia.

12VAC5-550-5. Definitions.

In addition to the words and terms defined in § 32.1-249 of the Code of Virginia, the following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Board" means the State Board of Health.

"Commissioner" means the State Health Commissioner.

"Department" means Virginia Department of Health.

"Immediate family" means a registrant mother, father (name must be shown on the certification), sibling, current spouse and adult children.

"Informant" means person providing information to complete the filing of a vital record in order to document a vital event.

"Midwife" means a registered nurse who has met the additional requirements of education and examination for licensure as a nurse practitioner in the Commonwealth.

"Primary evidence" means valid first-hand documentation established before the registrant's 18th birthday, such as including school admission records, physician's records, immunization records, passport, federal census abstracts, baptismal records and insurance applications.

"Registrant" means the person whose personal information is <u>primarily</u> registered <u>on a vital record</u> and filed in the systems of vital records.

"Registrar" means the State Registrar of Vital Records or a county, city, or special registrar to whom the State Registrar of Vital Records has delegated functions or duties.

"Secondary evidence" means valid documentation established after the registrant's eighteenth birthday such as <u>including</u> marriage records, child's <u>a</u> birth certificate, school records, social security records, driver's records, work permit and employment records. Such evidence must be at least five years old.

Statutory Authority

31 §§ 32.1-12 and 32.1-250 of the Code of Virginia.

32 Historical Notes

33 Derived from Virginia Register Volume 19, Issue 26, eff. October 8, 2003.

12VAC5-550-20. Purpose of chapter. (Repealed.)

The board has promulgated this chapter to facilitate the vital record registration activities and health statistical services in a manner to ensure the uniform and efficient administration of the system. Required certificates, reports, and forms shall be prescribed, where feasible, to include data collected nationally for the benefit of all citizens. The protection of individual data from casual perusal is essential to the validity of the program as well as a desirable shield of sensitive personal information while providing health statistics for the protection of society as a whole.

42 Statutory Authority

43 § 32.1-273 of the Code of Virginia.

44 Historical Notes

45 Derived from VR355-29-100 § 1.2, eff. April 1, 1995.

46 12VAC5-550-30. Administration of chapter. (Repealed.)

This chapter is administered by the board, the commissioner, and the State Registrar of Vital Records and Health Statistics.

The State Registrar shall carry out the provisions of Chapter 7 (§ 32.1-249 et seq.) of Title 32.1 of the Code of Virginia and the regulations of the board.

51 Statutory Authority

52 §§ 32.1-12 and 32.1-250 of the Code of Virginia.

53 **Historical Notes**

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Derived from VR355-29-100 § 1.3, eff. April 1, 1995; amended, Virginia Register Volume 19, Issue 26, eff. October 8, 2003.

12VAC5-550-50. Application of Administrative Process Act. (Repealed.)

Except where specifically provided otherwise by statute, the provisions of the Virginia
Administrative Process Act, which is codified as Chapter 1.1:1 of Title 9 of the Code of
Virginia, shall govern the adoption, amendment, modification, and revision, of this chapter,
and the conduct of all proceedings hereunder.

61 Statutory Authority

62 § 32.1-273 of the Code of Virginia.

63 **Historical Notes**

64 Derived from VR355-29-100 § 1.6, eff. April 1, 1995.

12VAC5-550-60. Powers and procedures of chapter not exclusive. (Repealed.)

The board reserves 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 Chapter 7 of Title 32.1 of the Code of Virginia.

69 Statutory Authority

70 § 32.1-273 of the Code of Virginia.

71 Historical Notes

72 Derived from VR355-29-100 § 1.7, eff. April 1, 1995.

12VAC5-550-125. Certificate of birth resulting in a stillbirth.

In accordance with A. Pursuant to § 32.1-258.1 of the Code of Virginia, a certificate of birth resulting in a stillbirth shall be issued upon request from the parent the State Registrar shall, upon the request of either individual listed as the parent on a report of fetal death in Virginia, issue a Certificate of Birth Resulting in Stillbirth for a fetal death occurring after a gestational period of 20 weeks or more gestation and payment of the appropriate fee for a vital record. This

- B. The certificate shall contain the following information; name (optional),:
 - 1. The registrant's name, if one is provided,
 - 2. The mother's maiden name,
- 3. The father's name (if indicated), if indicated,
- 84 <u>4. The</u> date of event the fetal death, and
- 5. The hospital of occurrence or location the fetal death occurred.

- When <u>C. If</u> no report of spontaneous fetal death is available to establish the event, documentation from the following sources is acceptable: the parent may provide documentation from the following sources to establish that the fetal death occurred:
 - <u>1. The licensed</u> physician or licensed nurse midwife who provided care to the mother, documentation from the
 - <u>2. The</u> medical record maintained at the hospital of occurrence, copy of the report of spontaneous fetal death or documentation from where the fetal death occurred, or
 - 3. The funeral service director (if such services were provided). if funeral services were provided.

Statutory Authority

97 §§ 32.1-12 and 32.1-250, and 32.1-258.1 of the Code of Virginia.

98 Historical Notes

99 Derived from Virginia Register Volume 19, Issue 26, eff. October 8, 2003.

12VAC5-550-130. Marriage return and certificate items.

The record of marriage to be used shall be the Marriage Return and Certificate, Commonwealth of Virginia, and shall contain the following items: city or county of the court of issuance; court clerk's number; for the groom: full name, age, date and place of birth, social security number or control number issued by the Department of Motor Vehicles, race, marital status if previously married, number of marriage, education, usual residence, the names of parents; for the bride: full name, maiden name, age, date and place of birth, social security number or control number issued by the Department of Motor Vehicles, race, marital status if previously married, number of marriage, education, usual residence, and names of parents; signature of clerk of court and date of license; date and place of marriage; whether civil or religious ceremony; certification and signature of officiant indicating title, address, and year and court of qualification; date received by clerk of court from officiant; and state file number.

- A. An officer issuing marriage licenses shall, on or before the tenth day of each calendar month, forward to the State Registrar a record of each marriage filed with him during the preceding calendar month pursuant to § 32.1-267.
- B. To request a certified copy of a certificate of marriage, an applicant shall submit to the registrar a completed form VS6MD.

118 Statutory Authority

119 §§ 32.1-12 and 32.1-250 of the Code of Virginia.

120 Historical Notes

Derived from VR355-29-100 § 3.4, eff. April 1, 1995; amended, Virginia Register Volume 19, Issue 26, eff. October 8, 2003.

12VAC5-550-140. Report of divorce or annulment items.

The report of divorce or annulment to be used shall be the Report of Divorce or Annulment, Commonwealth of Virginia, and shall contain the following items: city or county of court of issuance; for the husband: full name, date and place of birth, social security number or control number issued by the Department of Motor Vehicles, education, number of marriage, usual residence; for the wife: full maiden name, date and place of birth, social security number or control number issued by the Department of Motor Vehicles, education, number of the marriage, usual residence; date and place of marriage; identity of plaintiff and to whom divorce granted; number and custody of children under 18 in this family; date of separation; date of divorce; legal grounds or cause of divorce; signature of attorney or

- petitioner; certification and signature of clerk of court indicating type of decree; court file number; date final order entered; and state file number.
- A. A clerk of court shall, on or before the tenth day of each calendar month, forward to the State Registrar the report of each final decree of divorce and annulment granted during the preceding calendar month pursuant to § 32.1-268.
- B. To request a certified copy of a certificate of divorce or annulment, an applicant shall submit to the registrar a completed form VS6MD.

Statutory Authority

141 §§ 32.1-12 and 32.1-250 of the Code of Virginia.

142 Historical Notes

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Derived from VR355-29-100 § 3.5, eff. April 1, 1995; amended, Virginia Register Volume 19, Issue 26, eff. October 8, 2003.

12VAC5-550-320. Change of sex.

Except as provided in subdivision 3 of 12VAC5-550-450, upon presentation of acceptable evidence (preoperative diagnosis, postoperative diagnosis and description of procedure) and a notarized affidavit from the physician performing the surgery, a new certificate of birth may be prepared by the State Registrar for a person born in this Commonwealth whose sex has been changed by surgical gender reassignment procedure. A certified copy of the court order changing the name of the registrant as well as designating the sex of the registrant must be in the possession of the State Registrar together with a request that a new certificate be prepared.

- A. Upon request of a registrant or the registrant's legal representative, the State Registrar shall issue a new certificate of birth to a show a change of sex of the registrant. The person requesting issuance of a new certificate of birth pursuant to this section shall use the Changing Sex Designation, VS42 Form.
- B. The State Registrar shall also issue, upon request of a registrant or the registrant's legal representative requesting a change of sex pursuant to this section, a new certificate of birth to show a new name if the registrant or the registrant's legal representative submits a certified copy of a court order changing the registrant's name.

162 **Statutory Authority**

163 §§ 32.1-12 and 32.1-250 of the Code of Virginia.

Historical Notes

Derived from VR355-29-100 § 9.5, eff. April 1, 1995; amended, Virginia Register Volume 19, Issue 26, eff. October 8, 2003.

167 Part XI

168 Correction and Amendment

169 12VAC5-550-440. Applications for correction.

A. After 30 days from the date of filing, no change or alteration in any birth or death certificate on file with the State Registrar or on file in any city or county of this Commonwealth shall be made except upon application to the State Registrar.

1. To change or alter a birth certificate, such application shall be made by the reporting source, one of the parents, guardian, or legal representative of the child, or, if the person whose certificate is involved is 18 years of age or over, by the person himself.

2. To change or alter a death certificate, such application shall be made by the surviving spouse or the next of kin of the deceased, attending funeral service licensee, or other reporting source, such as hospital medical records.

- 3. Changes or alterations of the medical certification of cause of death may be requested only by the attending physician or by the medical examiner.
- B. Within 30 days from the date of filing, A. The State Registrar may enter missing data or corrected information may be entered on a birth or death certificate by the State Registrar or by the city or county registrar when the original record is in his possession. If the missing or corrected data is obtained at the initiative of the State Registrar within 30 calendar days from the date of filing, the State Registrar shall not consider the record to be amended.
- B. The following persons may request an amendment to a birth certificate by filing an application with the State Registrar in the form of a written letter or the Birth Certificate Amendment Request, VS43 Form:
 - 1. If the registrant is under 18 years of age, the informant who filed the birth certificate, the registrant's parent, guardian, or legal representative, or
 - 2. If the registrant is 18 years of age or over or has been emancipated pursuant to Article 15 (§ 16.1-331 et seq.) of Chapter 11 of Title 16.1 of the Code of Virginia, the registrant or the registrant's legal representative.
 - 1. Applications for changes or alterations may be made by persons outlined in subdivision A 1 or A 2 of this section.
 - 2. Missing or corrected data may be obtained at the initiative of the city or county registrar by personal call, telephone, or query form from the reporting source responsible for filing the birth or death certificate. Data so obtained by the registrar shall not be deemed an amendment.
- C. The State Registrar shall, upon receipt of an application pursuant to subsection B of this section, advise the person whether the amendment can be made administratively, subject to the evidence requirements of this chapter or if the amendment requires a court order.
- C. Marriage and D. The registrar may amend a record of marriage, divorce, or annulment records on file with the State Registrar may be amended only by upon notification from the clerk of court in which the original record is filed. Such The notification to the State Registrar shall indicate what which items have been amended on the original record and shall indicate that the State Registrar's registrar's copy should shall be amended accordingly. Evidence The court in which the original record is filed shall determine the evidence required for amending a record of marriage and indicate its filed.
- E. A person may request the State Registrar to amend a death certificate by submitting an affidavit and supporting documentary evidence testifying to the corrected information to be amended. The State Registrar shall amend the death certificate to reflect the new information upon receipt of the affidavit and supporting documentary evidence.
- F. Pursuant to § 32.1-269.1, if more than 45 calendar days have elapsed since the filing of a death certificate, the surviving spouse or immediate family of the registrant, attending funeral service licensee, or other reporting source may file a petition, along with a sworn affidavit under oath that supports the request, with the circuit court of the county or city in which the registrant resided at the time of his death or the Circuit Court of the City of Richmond requesting an order to amend a death certificate other than correction of the following information by the State Registrar:

- 225 <u>1. The spelling of the name of the registrant, registrant's parent or spouse, or the informant;</u>
- 227 <u>2. The sex, age, race, date of birth, place of birth, citizenship, social security</u> 228 <u>number, education, occupation or kind of business, military status, or date of death</u> 229 <u>of the registrant;</u>
 - 3. The place of residence of the registrant, if located within Virginia; or
- 231 <u>4. The name of the institution, county, city, town, street, or place where the death</u> occurred.
 - G. The State Registrar shall amend the death certificate upon receipt from the clerk of the circuit court of the county or city in which the registrant resided at the time of his death or the Circuit Court of the City of Richmond a certified copy of the court's order to amend the death certificate in accordance with the order.
- H. Only the provider who completed the registrant's medical certification pursuant to § 32.1-263 may request a change or amendment to the medical certification of cause of death.
- 240 **Statutory Authority**
- 241 §§ 32.1-12 and 32.1-250 , and 32.1-269.1 of the Code of Virginia.
- 242 Historical Notes

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- Derived from VR355-29-100 § 11.1, eff. April 1, 1995; amended, Virginia Register Volume 19, Issue 26, eff. October 8, 2003.
 - 12VAC5-550-450. Evidence required for corrections or amendments.
 - Every A. A person shall include a correction affidavit and documentary evidence pursuant to this section with an application for a correction or amendment of to amend a birth or death certificate shall be accompanied by appropriate documentary evidence as follows:
 - 1. Except as provided in subdivisions 2 and 3 of this section, name changes, other than minor corrections in spelling involving the given names or surname of a registrant, or the given names or surnames of the parents or of a spouse as listed on a certificate, shall require that a certified or attested copy of a court order changing the name be obtained.
 - a. In cases where the mother's married surname is listed instead of her maiden name, a correction can be made administratively with a correction affidavit and copy of her birth record.
 - b. In cases where the given name shown on a birth certificate was not used or known to the registrant and this fact can be proven by the registrant, the birth certificate can be amended administratively with primary evidence showing the name at birth and a correction affidavit.
 - 2. Within one year of birth, the given names listed on a birth certificate may be changed by the affidavit of:
 - a. Both parents;
 - b. The mother in the case of a child born out of wedlock:
 - c. The father in the case of the death or incapacity of the mother;
 - d. The mother in the case of the death or incapacity of the father; or
 - e. The guardian or agency having legal custody of the registrant.
 - 3. In cases of hermaphroditism or pseudo-hermaphroditism, given names of a registrant may be changed on a birth certificate by affidavit of the parents or

- guardian as listed in subdivision 2 of this section, or by affidavit of the registrant if 18 years of age or older. Additionally, a statement from a physician must be submitted which certified the birth record of the registrant contains an incorrect designation of sex because of congenital hermaphroditism, pseudohermaphroditism, or ambiguous genitalia which has since been medically clarified.
- 4. Except as otherwise provided in the Code of Virginia or this chapter, after one year from the date of birth, any change of name shall be made only by court order, and any second change of name within one year shall be made only by court order.
- 5. Within seven years after birth, given names may be added to a birth certificate where such information has been left blank by use of an affidavit only prepared by the parent, guardian, or legal representative of the child.
- 6. If the date of birth on a birth certificate is to be changed more than one year, a certified copy of a court order changing the date of birth shall be submitted. Evidence to be supplied to the court in support of such change should include a federal census transcript from the Bureau of the Census.
- 7. If the date of birth on a birth certificate is to be changed to one year or less from the date of birth, a federal census transcript from the Bureau of the Census shall be required as documentary evidence.
- 8. If a federal census transcript cannot be obtained, an affidavit shall be obtained which sets forth: the identity of the incorrect record, the incorrect data as it is listed, the correct data as it should be listed, and the documentary evidence supporting the facts. In addition to the affidavit, a document or certified or true copy of such document must be obtained which was written before the registrants' eighth birth date and will establish the identity of the certificate to be altered or corrected and will support the true and correct facts. Any item of a vital record which has been previously corrected may only be changed again by court order.
- 9. All documents, except the affidavit, shall be returned to the applicant after review.
- B. To amend a death certificate pursuant to 12VAC5-550-440, an applicant shall submit to the State Registrar a certified copy of a court order obtained pursuant to § 32.1-269.1 or a correction affidavit and primary or secondary documentary evidence testifying to the amended information.
- Statutory Authority
- 304 §§ 32.1-12 and 32.1-250 of the Code of Virginia.
- **Historical Notes**

- Derived from VR355-29-100 § 11.2, eff. April 1, 1995; amended, Virginia Register Volume 19, Issue 26, eff. October 8, 2003.
 - 12VAC5-550-460. Methods of correcting or altering certificates.
 - A. A <u>The registrar shall record a</u> new name authorized by court order <u>shall be recorded</u> by drawing a single line through the name appearing on the <u>certificate record</u> and inserting <u>the new name</u> above it or to the side of it <u>the new name</u>. In addition, <u>there shall be inserted on the certificate the registrar shall insert on the record</u> a statement that the name was changed by court order and the date and place of <u>such the court</u> order. <u>The The registrar shall also insert the</u> word "Amended" <u>shall be written</u> in the top margin of the <u>certificate record</u>. <u>Certificates on which given names are added within seven years after birth or on which given names have been changed The registrar shall not consider a record as amended if the registrant's name is amended within one year of the vital event that was</u>

- recorded, or if the name is amended at any time pursuant to subdivision 3 of 12VAC5-550-450 shall not be considered as amended.
- 320 B. In all other cases, corrections or alterations shall be made The registrar shall record 321 amendments to other items by drawing a single line through the incorrect item, if listed, and by inserting the correct or missing data immediately above it or to the side of it, or by 322 completing the blank item, as the case may be. In addition, there shall be inserted on the 323 certificate the registrar shall insert a statement identifying the affidavit and documentary 324 325 evidence used as proof of the correct facts amended information and the date the correction amendment was made. If the registrar receives the request to amend a record 326 three months have elapsed from after the date of filing, the registrar shall insert the word 327 "Amended" shall be written in the top margin of the certificate unless otherwise stated in 328 329 this chapter.
- 330 Statutory Authority
- § 32.1-273 of the Code of Virginia.
- 332 Historical Notes
- 333 Derived from VR355-29-100 § 11.3, eff. April 1, 1995.
- 334 **12VAC5-550-520**. Fees.
- A. The fee to be charged by the State Registrar or by the city or county registrar shall be \$10, except if otherwise directed in the Code of Virginia, charge a fee of \$12 for each full certification or short form certification of a vital record, or for a search of the files or records when no copy is made.
- B. When documents are amended or delayed birth registration is requested, the requester shall be charged an administrative fee of \$10. The registrar shall charge a fee of \$10 to amend a vital record or register a delayed birth registration.
- 342 **Statutory Authority**
- 343 §§ 32.1-12 and 32.1-250 of the Code of Virginia.
- 344 Historical Notes
- Derived from VR355-29-100 § 13.2, eff. April 1, 1995; amended, Virginia Register Volume
- 346 19, Issue 26, eff. October 8, 2003.
- 347 FORMS (12VAC5-550)
- 348 Certificate of Live Birth, VS1 (eff. 1/93).
- 349 Certificate of Death, VS2 (eff. 1/89).
- 350 Certificate of Death (Medical Examiner's Certificate), VS2A (eff. 1/89).
- 351 Marriage Register, VS3 (eff. 1/90).
- 352 Report of Divorce or Annulment, VS4 (eff. 1/90).
- 353 Report of Spontaneous Fetal Death, VS5 (eff. 1/93).
- 354 Report of Induced Termination of Pregnancy, VS5A (eff. 1/90).
- 355 Application for Certification of a Vital Record, VS6 (eff. 7/02).
- 356 Out-of-State Transit Permit, VS10 (eff. 7/85).

357	Permit for Disinterment, Transit, and Reinterment, VS11 (eff. 7/85).
358	Delayed Certificate of Birth, VS12 (eff. 4/85).
359	Birth Record Application VS6B (eff. 07/2020)
360	Marriage-Divorce Record Application VS6MD (eff. 02/2020)
361	Death Record Application VS6D (eff. 07/2022).
362	Stillbirth Application VS6FD (eff. 07/2022).
363	Report of Adoption, VS21 (eff. 7/85).
364	Report of Adoption, VS21 (eff. 07/2012).
365	Acknowledgement of Paternity, VS22 (eff. 9/93).
366	Acknowledgement of Paternity, VS22 (eff. 07/2004).
367	Affidavit for Correction of a Record, VS32 (eff. 1/87).
368	Affidavit for Correction of a Record, VS32 (eff. 09/2005).
369	Hospital Monthly Vital Statistics Report, VS33 (eff. 7/89).
370	Funeral Director's Monthly Vital Statistics Report, VS33-A (eff. 3/90)
371	Court Order Establishing Record of Birth, VS40 (eff. 10/88).
372	Form for Changing Sex Designation, VS42 (eff. 07/2020).
373	Birth Certificate Amendment Request Form, VS43 (eff. 07/2021).

Office of Regulatory Management

Economic Review Form

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5 – 550
VAC Chapter title(s)	Certificate of birth resulting in a stillbirth, Marriage return and certificate items, Change of sex, Applications for correction, Evidence required for corrections or amendments.
Action title	Amend Regulations Following Statutory Changes
Date this document prepared	11/1/22

Cost Benefit Analysis

Table 1a must be completed for all actions. Tables 1b and 1c must be completed for actions (or portions thereof) where the agency is exercising discretion, including those where some of the changes are mandated by state or federal law or regulation. Tables 1b and 1c are not needed if <u>all</u> changes are mandated, and the agency is not exercising any discretion. In that case, enter a statement to that effect.

- (1) Direct Costs & Benefits: Identify all specific, direct economic impacts (costs and/or benefits), anticipated to result from the regulatory change. (A direct impact is one that affects entities regulated by the agency and which directly results from the regulatory change itself, without any intervening steps or effects. For example, the direct impact of a regulatory fee change is the change in costs for these regulated entities.) 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. One bullet has been provided, add additional bullets as needed.
- (2) Quantitative Factors:
 - (a) Enter estimated dollar value of total (overall) direct costs described above.
 - (b) Enter estimated dollar value of total (overall) direct benefits described above.
 - (c) Enter the present value of the direct costs based on the worksheet.
 - (d) Enter the present value of the direct benefits based on the worksheet.
- (3) Benefits-Costs Ratio: Calculate d divided by c OR enter it from the worksheet.
- (4) Net Benefit: Calculate d minus c OR enter it from the worksheet.
- (5) Indirect Costs & Benefits: Identify all specific, indirect economic impacts (costs and/or benefits), anticipated to result from the regulatory change. (An indirect impact is one that results from responses to the regulatory change, but which are not directly required by the regulation. Indirect impacts of a regulatory fee change on regulated entities could include a change in the prices they charge, changes in their operating procedures or employment levels, or decisions to enter or exit the regulated profession or market. Indirect impacts also include responses by other entities that have close economic ties to the regulated

- entities, such as suppliers or partners.) If there are no indirect costs or benefits, include a specific statement to that effect.
- (6) Information Sources: Describe the sources of information used to determine the benefits and costs, including the source of the Quantitative Factors. If dollar amounts are not available, indicate why they are not.
- (7) Optional: Use this space to add any further information regarding the data provided in this table, including calculations, qualitative assessments, etc.

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

(1) Direct Costs
& Benefits

• The regulatory action will amend <u>Definitions</u> (12VAC5-550-5). Minimal updates clarify language used in the Regulations to support a clearer understanding of the requirements and information included in 12VAC5-550.

Direct Costs: There are no direct costs associated with this change.

Direct Benefits: Individuals will benefit insomuch as the regulatory language will be more clear and easier to understand.

• The regulatory action will repeal 12VAC5 – 550-20, 12VAC5 – 550-30, 12VAC5 – 550-50, 12VAC5 – 550-60 which are not regulatory in nature

Direct Costs: There are no direct costs associated with this change.

Direct Benefits: The benefit of this change is to reduce the length of the regulation by removing unnecessary language.

• The regulatory action will amend the <u>Certificate of birth</u> resulting in a stillbirth regulation (12VAC5-550-125) removing the requirement of a fee to be established for this certificate type. This action is required to conform to Chapter 171 of the 2022 Acts of Assembly.

Direct Costs: There are no direct costs to entities regulated by the agency as a result of this change.

Direct Benefits: Individuals requesting a certificate of birth resulting in a stillbirth will no longer be charged a \$12 fee. From 2018 through 2020, the Office of Vital Records issued 229 of these certificates, equaling an average savings of \$916 per year if fees were not charged during that time period.

• The regulatory action will amend the <u>Marriage return and</u> <u>certificate items</u> (12VAC5-550-130) and <u>Report of divorce or</u>

<u>annulment items</u> (12VAC5-550-140) removing the item "race" on marriage and divorce certificates. This action is required to comply with Chapters 209, 210 and 211 of the 2020 Acts of Assembly.

Direct Costs: There are no direct costs associated with this change.

Direct Benefits: The direct benefits of this change are that the regulations will comply with the Code of Virginia.

• The regulatory action will amend the <u>Change of sex</u> (12VAC5-550-320) to update the requirements for changing the sex on a birth certificate to conform to Chapter 466 of the 2020 Acts of Assembly.

Direct Costs: There are no direct costs associated with this change.

Direct Benefits: Individuals seeking to change the sex on their birth certificate can now accomplish this through a simplified administrative process which does not require court costs. Legal fees can range widely so VDH does not have a way to calculate this potential benefit.

The regulatory action will amend the <u>Applications for correction</u> (12VAC5-550-440), <u>Evidence required for corrections or amendments</u> (12VAC5-550-450), and <u>Methods of correcting or altering certificates</u> (12VAC5-550-460) to allow information on a death certificate to be amended with supporting evidence for 45 days after the filing of the death certificate, and to clarify amendment forms and processes to create internal consistency within the Regulations. This action is required to conform to Chapter 117 of the 2022 Acts of Assembly. The change to Section 460 is to conform to § 32.1-269 (B) of the Code of Virginia.

Direct Costs: There are no direct costs associated with this change.

Direct Benefits: Individuals seeking to amend a death certificate no longer need to pay court fees in order to obtain a court order to request an amendment to the decedent's name, informant's name, name of spouse, marital status, name of parents and place of residency when outside of the Commonwealth, if an amendment is made within 45 days of filing the death certificate. Legal fees can range widely so VDH does not have a way to calculate this potential benefit.

• The regulatory action will amend the <u>Fees</u> (12VAC5-550-520) to document the fee charged for a vital record as established by Chapter 534 of the 2013 Acts of Assembly and the 2004 Budget Bill – HB5001 (Chapter 4).

Direct Costs: Because the fee being reflected in the new regulation is being updated to simply reflect the fee that has been in effect since 2004, there is no additional new cost associated with this effort to align the Regulation to the Code.

Direct Benefits: Individuals will benefit insomuch as the Regulatory language will be more clear and easier to understand when it is consistent with the Code.

• The regulatory action will amend the <u>Forms</u> (12VAC5-550-9998) to document and link to forms being explicitly referenced in these amendments, while removing those forms not referenced in the Regulations, and updating the effective dates.

Direct Costs: There are no direct costs associated with this change.

Direct Benefits: Forms will be easier to find.

• In addition to substantive changes mentioned above, a number of style and form changes are also being made to conform the language to the Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code. If these changes were promulgated in their own action, they would be exempt from the requirements of Article 2 of the Administrative Process Act, pursuant to § 2.2-4006 (A)(3).

Direct Costs: There are no direct costs associated with this change.

Direct Benefits: The language will conform to the *Form and Style Requirements* and be clearer and more readable.

(2) Quantitative				
Factors	Estimated Dollar Amount	Present Value		
Direct Costs	(a) \$0	(c) \$0		
Di D C	(1) (0) (10)	(1) 00 040		
Direct Benefits	(b) \$9,160 (over 10 years)	(d) \$8,048		
(3) Benefits-		(4) Net		
Costs Ratio	8,048/0	Benefit	\$8,048	

(5) Indirect	Indirect Costs: There are no indirect costs associated with this regulatory
Costs &	action.
Benefits	
	Indirect Benefits: There are no indirect benefits associated with this
	regulatory action.
(6) Information	Report of the number of certificates of birth resulting in stillbirth issued
Sources	from the Virginia Vital Events and Screening Tracking System (VVESTS)
	for years 2018 - 2020
(7) Optional	

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

This table addresses current requirements and the implications of not making any changes. In other words, describe the costs and benefits of maintaining the current regulatory requirements as is.

(1) Direct Costs & Benefits	1	
(2) Quantitative		
Factors	Estimated Dollar Amount	Present Value
Direct Costs	(a)	(c)

Direct Benefits	(b)	(d)
(3) Benefits-		(4) Net
Costs Ratio		Benefit
(5) Indirect Costs & Benefits	There are no indirect costs or be options listed above.	enefits associated with the "status quo"
(6) Information Sources		
(7) Optional		

Table 1c: Costs and Benefits under an Alternative Approach

This table addresses an alternative approach to accomplishing the objectives with different requirements. These alternative approaches may include the use of reasonably available alternatives in lieu of regulation, or information disclosure requirements or performance standards instead of regulatory mandates.

(1) Direct Costs & Benefits	The changes made in this action are required to conform to Chapters 116, 117 and 171 of the 2022 Acts of Assembly; Chapters 209, 210, 211, 465, and 466 of the 2020 Acts of Assembly; Item 290 (A), Chapter 2, 2022 Acts of Assembly, Special Session I; and § 32.1-269 (B). These changes are non-discretionary and not subject to consideration of alternative approaches. The repeal of sections 20, 30, 50, and 60, along with the style and form changes, make no substantive changes to regulatory requirements associated with the chapter, are non-regulatory, and do not affect the rights or powers of any person or agency. As such, there are no viable alternative approaches to be considered.		
(2) Quantitative Factors	Estimated Dollar Amount	Present Value	
Direct Costs	(a)	(c)	
Direct Benefits	(b)	(d)	
(3) Benefits-		(4) Net	
Costs Ratio		Benefit	

(5) Indirect Costs & Benefits	
(6) Information Sources	
(7) Optional	

Impact on Local Partners

- (1) Describe the direct costs and benefits (as defined on page 1) for local partners in terms of real monetary costs and FTEs. Local partners include local or tribal governments, school divisions, or other local or regional authorities, boards, or commissions. If local partners are not affected, include a specific statement to that effect and a brief explanation of the rationale.
- (2) Quantitative Factors:
 - (a) Enter estimated dollar value of total (overall) direct costs described above.
 - (b) Enter estimated dollar value of total (overall) direct benefits described above.
- (3) Indirect Costs & Benefits: Describe any indirect benefits and costs (as defined on page 1) for local partners that are associated with all significant changes. If there are no indirect costs or benefits, include a specific statement to that effect.
- (4) Information Sources: describe the sources of information used to determine the benefits and costs, including the source of the Quantitative Factors. If dollar amounts are not available, indicate why they are not.
- (5) Assistance: Identify the amount and source of assistance provided for compliance in both funding and training or other technical implementation assistance.
- (6) Optional: Use this space to add any further information regarding the data provided in this table, including calculations, qualitative assessments, etc.

Note: If any of the above information was included in Table 1, use the same information here.

Table 2: Impact on Local Partners

(1) Direct Costs & Benefits	• Direct Costs: There are no direct costs to local partners associated with this regulatory action.
	Direct Benefits: There are no direct benefits to local partners associated with this regulatory action.
(2) Quantitative	
Factors	Estimated Dollar Amount

Direct Costs	(a) \$0
Direct Benefits	(b) \$0
(3) Indirect Costs & Benefits	 Indirect Costs: There are no indirect costs to local partners associated with this regulatory action. Indirect Benefits: There are no indirect benefits to local partners associated with this regulatory action.
(4) Information Sources	N/A
(5) Assistance	N/A
(6) Optional	N/A

Economic Impacts on Families

- (1) Describe the direct costs and benefits (as defined on page 1) to a typical family of three (average family size in Virginia according to the U. S. Census) arising from any proposed regulatory changes that would affect the costs of food, energy, housing, transportation, healthcare, and education. If families are not affected, include a specific statement to that effect and a brief explanation of the rationale.
- (2) Quantitative Factors:
 - (a) Enter estimated dollar value of direct costs.
 - (b) Enter estimated dollar value of direct benefits.
- (3) Indirect Costs & Benefits: Describe any indirect costs and benefits (as defined on page 1) to a typical family of three that are most likely to result from the proposed changes.
- (4) Information Sources: describe the sources of information used to determine the benefits and costs, including the source of the Quantitative Factors. If dollar amounts are not available, indicate why not.
- (5) Optional: Use this space to add any further information regarding the data provided in this table, including calculations, qualitative assessments, etc.

Note: If any of the above information was included in Table 1, use the same information here.

Table 3: Impact on Families

(1) Direct Costs & Benefits	 Direct Costs: There are no direct costs to families associated with this regulatory action. Direct Benefits: As stated in Table 1a, families who experience a stillbirth within the Commonwealth and require a certificate of birth resulting in stillbirth will not be required to pay the \$12 fee for the certificate. 	
(2) Quantitative		
Factors	Estimated Dollar Amount	
Direct Costs	(a) \$0	
Direct Benefits	(b) \$916/year throughout the entire Commonwealth.	
(3) Indirect Costs & Benefits	Indirect Costs: There are no indirect costs to families associated with this regulatory action. Indirect Costs: There are no indirect costs to families associated with this regulatory action.	
	• Indirect Benefits: There are no indirect benefits to families associated with this regulatory action.	
(4) Information Sources	N/A	
(5) Optional	N/A	

Impacts on Small Businesses

- (1) Describe the direct costs and benefits (as defined on page 1) for small businesses. For purposes of this analysis, "small business" means the same as that term is defined in § 2.2-4007.1. If small businesses are not affected, include a specific statement to that effect and a brief explanation of the rationale.
- (2) Quantitative Factors:
 - (a) Enter estimated dollar value of direct costs.
 - (b) Enter estimated dollar value of direct benefits.
- (3) Indirect Costs & Benefits: Describe the indirect benefits and costs (as defined on page 1) for small businesses that are most likely to result from the proposed changes.
- (4) Alternatives: Add a qualitative discussion of any equally effective alternatives that would make the regulatory burden on small business more equitable compared to other affected business sectors, and how those alternatives were identified.

- (5) Information Sources: describe the sources of information used to determine the benefits and costs, including the source of the Quantitative Factors. If dollar amounts are not available, indicate why not.
- (6) Optional: Use this space to add any further information regarding the data provided in this table, including calculations, qualitative assessments, etc.

Note: If any of the above information was included in Table 1, use the same information here.

Table 4: Impact on Small Businesses

(1) Direct Costs & Benefits	 Direct Costs: There are no direct costs to small businesses associated with this regulatory action. Direct Benefits: There are no direct benefits to small businesses associated with this regulatory action.
(2) Quantitative	
Factors	Estimated Dollar Amount
Direct Costs	(a)\$0
Direct Benefits	(b)\$0
(3) Indirect	Indirect Costs: There are no indirect costs to small businesses
Costs &	associated with this regulatory action.
Benefits	
	• Indirect Benefits: There are no indirect benefits to small businesses associated with this regulatory action.
(4) Alternatives	The agency is not exercising any discretion with regard to the substantive provisions of this chapter and there are no direct or indirect costs to small businesses associated with this regulatory action. Alternatives are not available.
(5) Information Sources	N/A
(6) Optional	N/A

Changes to Number of Regulatory Requirements

For each individual VAC Chapter amended, repealed, or promulgated by this regulatory action, list (a) the initial requirement count, (b) the count of requirements that this regulatory package is adding, (c) the count of requirements that this regulatory package is reducing, (d) the net change in the number of requirements. This count should be based upon the text as written when this

stage was presented for executive branch review. Five rows have been provided, add or delete rows as needed.

Table 5: Total Number of Requirements

	Number of Requirements			
Chapter number	Initial Count	Additions	Subtractions	Net Change
20	1	0	1	-1
30	1	0	1	-1
50	1	0	1	-1
60	0	0	0	0
125	2	0	0	0
130	2	0	1	-1
140	2	0	0	0
320	0	3	0	3
440	7	0	0	0
450	8	2	1	1
460	7	7	7	0
520	2	1	1	0
9998	0	0	0	0



COMMONWEALTH of VIRGINIA

Colin M. Greene, MD, MPH State Health Commissioner Department of Health
P O BOX 2448
RICHMOND, VA 23218

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

MEMORANDUM

DATE: November 7, 2022

TO: State Board of Health

FROM: Rebekah E. Allen, JD

Senior Policy Analyst, Office of Licensure and Certification

SUBJECT: Fast Track Action – Regulations for the Licensure of Hospitals in Virginia – Amend

Regulation After Periodic Review

Enclosed for your review are proposed amendments to Regulations for the Licensure of Hospitals in Virginia (12VAC5-410-10 *et seq.*).

This fast-track action is being utilized to conform 12VAC5-410-10 et seq. to the Code of Virginia and to update out-of-date regulatory provisions. Changes include amendments to address mandates found in:

- Chapters 80 and 81 of the 2022 Acts of Assembly (minimum standards for any hospital that voluntarily installs a newborn safety device for the reception of children);
- Chapter 218 of the 2022 Acts of Assembly (requiring hospitals that makes minors' health records available to minors through a secure website to also make the health records available to the minor's parent or guardian through the same website);
- Chapters 678 and 679 of the 2022 Acts of Assembly (minimum standards for payment plans and providing information about charity care and financial assistance policies);
- Chapter 72 of the 2021 Acts of Assembly, Special Session I (prohibition on discriminating against health insurance enrollee on the basis of the enrollee being a litigant or potential litigant due to a motor vehicle accident);
- Chapter 220 of the 2021 Acts of Assembly, Special Session I (minimum requirements for designated support persons);
- Chapters 1080 and 1081 of the 2020 Acts of Assembly (prohibition on balance billing);
- Chapter 1088 of the 2020 Acts of Assembly (quarterly reporting of hospital employment of certified sexual assault nurse examiners); and
- Chapters 177 and 222 of the 2005 Acts of Assembly (design and construction guidelines for hospitals).



November 7, 2022 12VAC5-410 Fast-Track Page 2

The changes also include minimum requirements for long-term care nursing units that are certified nursing facilities as required by Article 1 (§ 32.1-123 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia, updating breast milk storage requirements, removing unused terminology, improving terminology consistency, providing definitions for terms to match current clinical and industry practices, moving regulatory provisions to the appropriate part of 12VAC5-410-10 et seq., and revising provisions related to the licensing process and oversight procedures.

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.

Form: TH-04 August 2022



townhall.virginia.gov

Fast-Track Regulation Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-410-10 et seq.
VAC Chapter title(s)	Regulations for the Licensure of Hospitals in Virginia
Action title	Amend Regulation After Periodic Review
Date this document prepared	November 29, 2022

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 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.

This fast-track action is being utilized to conform 12VAC5-410-10 *et seq.* to the Code of Virginia and to update out-of-date regulatory provisions. Changes include amendments to address mandates found in:

- Chapters 80 and 81 of the 2022 Acts of Assembly (minimum standards for any hospital that voluntarily installs a newborn safety device for the reception of children);
- Chapter 218 of the 2022 Acts of Assembly (requiring hospitals that makes minors' health records available to minors through a secure website to also make the health records available to the minor's parent or guardian through the same website);
- Chapters 678 and 679 of the 2022 Acts of Assembly (minimum standards for payment plans and providing information about charity care and financial assistance policies);
- Chapter 72 of the 2021 Acts of Assembly, Special Session I (prohibition on discriminating against health insurance enrollee on the basis of the enrollee being a litigant or potential litigant due to a motor vehicle accident);

 Chapter 220 of the 2021 Acts of Assembly, Special Session I (minimum requirements for designated support persons);

Form: TH-04

- Chapters 1080 and 1081 of the 2020 Acts of Assembly (prohibition on balance billing);
- Chapter 1088 of the 2020 Acts of Assembly (quarterly reporting of hospital employment of certified sexual assault nurse examiners); and
- Chapters 177 and 222 of the 2005 Acts of Assembly (design and construction guidelines for hospitals).

The changes include including minimum requirements for long-term care nursing units that are certified nursing facilities required by Article 1 (§ 32.1-123 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia, updating breast milk storage requirements, removing unused terminology, improving terminology consistency, providing definitions for terms to match current clinical and industry practices, moving regulatory provisions to the appropriate part of 12VAC5-410-10 *et seq.*, and revising provisions related to the licensing process and oversight procedures.

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.

"ACIP" means the Advisory Committee on Immunization Practices of the CDC.

"Board" means the State Board of Health.

"CDC" means the Centers for Disease Control and Prevention.

"Commissioner" means the State Health Commissioner.

"FGI" means The Facility Guidelines Institute.

"SANE" means sexual assault nurse examiner.

"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.

The Board approved the fast-track amendments for 12VAC5-410-10 *et seq.*, Regulations for the Licensure of Hospitals in Virginia, on DATE.

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.

Form: TH-04

The Board is mandated by Va. Code § 2.2-4007.1(D) and Executive Order 14 (2020) to conduct a periodic review of its regulations. The impetus for this action is a recent periodic review that determined that this regulatory chapter needed to be amended. The rulemaking is expected to be noncontroversial because it is being utilized to conform the regulation to the statutes, legislative mandates, existing clinical and industry practices, and to accurately detail VDH's licensing procedures and practices. Additionally, VDH's subject matter experts believe that proposed changes would not jeopardize the protection of public health, safety, and welfare.

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.

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

Va. Code § 32.1-23.2 also requires VDH to designate the form and due date of reports required under Chapter 1088 (2020 Acts of Assembly). Va. Code § 32.1-127.001 requires the Board to promulgate regulations that shall include minimum standards for the design and construction of hospitals and certified nursing facilities consistent with the current edition of the FGI guidelines, per Chapter 177 and 222 of the 2005 Acts of Assembly. Chapters 80 and 81 of the 2022 Acts of Assembly created minimum standards for any hospital that voluntarily installs a newborn safety device for the reception of children. Chapters 678 and 679 of the 2022 Acts of Assembly created minimum standards for hospital payment plans and hospitals providing information about charity care and financial assistance policies. Chapter 72 of the 2021 Acts of Assembly, Special Session I prohibits hospital discrimination against health insurance enrollee on the basis of the enrollee being a litigant or potential litigant due to a motor vehicle accident. Chapter 220 of the 2021 Acts of Assembly, Special Session I created minimum requirements for designated support persons in hospitals. Chapters 1080 and 1081 of the 2020 Acts of Assembly prohibits balance billing by hospitals.

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 the regulatory change is that the regulation should incorporate all legislative mandates, current clinical and industry practices, and current licensing processes and procedures. The

regulatory change is essential to protect the health, safety, or welfare of citizens because the regulation does not currently reference the most current clinical and industry practices, including for infection prevention and control, and does not address all mandated subjects affecting patient rights. The goals of the regulatory change are consistency with the Code of Virginia and reduced confusion for patients and for hospitals; the problems it is intended to solve are removing out-of-date material that impedes hospitals from utilizing current clinical standards and ensuring that hospitals and patients are equally aware of what their rights and obligations are.

Form: TH-04

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.

Section 10. Definitions

Adds definitions for "ACIP," "activities of daily living" or "ADL," "campus," "care provider," "CDC," "certified nursing facility," "certified sexual assault nurse examiner," "CMS," "emergency department," "general hospital accrediting organization," "hospital," "inspector," "operating room," "outpatient surgical hospital accrediting organization," "person with a disability," "support and assistance necessary due to the specifics of the person's disability," and "surgery." Revises definitions for "designated support person," "full-time," "general hospital," and "nursing home." Removes definitions for "special hospital." Renames "home health care department/service/program" to "home health services," renamed "nursing care unit" to "long-term care nursing unit," "outpatient hospital" to "outpatient surgical hospital," and "Office of Licensure and Certification" to "OLC."

Section 50. Classification

Removes the "special hospital" as a classification type.

Section 60. Separate license

Changes subsection A to use a consistent and defined term when discussing the location of hospitals and the need for separate licensure.

Section 100. Name

Removes the requirement to report a hospital name change within 30 calendar days as duplicative.

Section 130. Return of license.

Section is renamed to "Surrender of license; mid-term change of license." Clarifies what is a mid-term change to a license and clarifies a hospital's obligations and the process to obtain a changed license.

Section 140. Inspection procedure

Clarifies the inspection process and a hospital's obligations during and after the inspection.

Section 150. Plan of correction

Consolidates the plan of correction language found throughout the regulatory chapter to ensure the plan of correction requirements are consistent. Revisions include minimum elements of a plan of correction and the timeline for submission and completion of a plan of correction.

Section 160. Revocation of license

Section is renamed to "Disciplinary action." Matches statutory provisions about prohibited acts and disciplinary options available.

Part II. Organization and Operation of General and Special Hospitals

Part is renamed to "Organization and Operation of General Hospitals."

Section 215. Financial assistance in general hospitals

A new section. Describes minimum requirements for providing information about charity care and financial assistance and for payment plans.

Form: TH-04

Section 225. Newborn safety devices

A new section. Describes minimum requirements for operation of a newborn safety device if a hospital has elected to install a device.

Section 230. Patient care management

Replaces reference to 22-year-old document with a reference to analogous federal requirements for patient rights. Repeals designated support person requirements and discharge requirements for a patient receiving elective surgery who may need outpatient physical therapy.

Section 235. Persons with a disability; designated support persons in general hospitals

A new section. Describes minimum requirements for providing a person with a disability access to a designated support person.

Section 237. Discharge planning

Consolidates into a single section the discharge planning requirements for inpatient admissions and for patients receiving elective surgery who may need outpatient physical therapy.

Section 370. Medical records

Removes an incorrect statutory reference, amends storage and reproduction requirements, amends subsection to address fetal death reporting, and adds subsection to address parent or guardian electronic access to minor patient's medical records.

Section 380. Nursing service

Adds language about when hospitals' quarterly reports are due and what information is to be included in the reports. Corrected out-of-date regulatory references.

Section 442. Obstetric service design and equipment criteria

Updates design and construction standards to the most current edition of the FGI guidelines for hospitals.

<u>Section 444. Newborn service medical direction; physician consultation and coverage; nursing direction, nurse staffing and coverage; policies and procedures</u>

Updates the breast milk storage times to match current CDC recommendations.

Section 445. Newborn service design and equipment criteria

Updates design and construction standards to the most current edition of the FGI guidelines for hospitals.

Section 447. Combined obstetric and clean gynecological service; infection control

Updates documents incorporated by reference for isolation or segregation of mothers, newborns, and patients.

Section 465. Long-term care nursing services

A new section. Describes the minimum statutory standards for certified nursing facilities that are operated under a general hospital's license.

Section 650. General building and physical plan information

Updates design and construction standards to the most current edition of the FGI guidelines for hospitals and outpatient facilities.

Section 760. Long-term care nursing units

Updates design and construction standards to the most current edition of the FGI guidelines for hospitals.

<u>Part IV Outpatient Surgical Hospitals: Organization, Operation, and Design Standards for Existing and New Facilities</u>

Town Hall Agency Background Document

Part is renamed to "Organization and Operation of Outpatient Surgical Hospitals."

Section 1170. Policy and procedures manual

Replaces reference to 22-year-old document with a reference to analogous federal requirements for patient rights. Repeals designated support person requirements.

Form: TH-04

Section 1171. Persons with a disability; designated support person in outpatient surgical hospitals

A new section. Describes minimum requirements for providing a person with a disability access to a designated support person.

Section 1175. Discharge planning

This section is repealed.

Section 1178. Financial assistance in outpatient surgical hospitals

A new section. Describes minimum requirements for providing information about charity care and financial assistance and for payment plans.

Section 1190 Nursing staff

Adds language about when hospitals' quarterly reports are due and what information is to be included in the reports.

Section 1260. Medical records

Removes an incorrect statutory reference and reference to VDH business unit, amends storage and reproduction requirements, and adds subsection to address parent or guardian electronic access to minor patient's medical records.

Section 1350. Local and state codes and standards

Updates design and construction standards to the most current edition of the FGI guidelines for outpatient facilities.

DIBR

Lists all documents incorporated by reference in the regulatory changes.

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 removal of language or requirements that were unclear, inconsistent, or outdated and addition of legislative mandates that had previously had not been incorporated into the regulations. The primary advantages to VDH or Commonwealth are clarity on the minimum requirements for hospitals and VDH in the administration of the hospital licensing program. There are no disadvantages to the public or the Commonwealth. Other pertinent matters of interest to the regulated community, government officials and the public would include the discovery during the periodic review that the hospital regulations failed to address or incorporate the minimum requirements for certified nursing facilities that are mandated by Article 1 (§ 32.1-123 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia. Eight general hospitals in the Commonwealth operate long-term care nursing units that are certified to participate in Medicare, Medicaid, or both; these units fall under the definition of "certified nursing facility" found in Va. Code § 32.1-123. The Board is addressing the omission in this regulatory change and is promulgating requirements for these long-term care nursing units that are in conformity with the statutory minimums. At this time, the Board is exercising its discretion to include only those statutory minimums.

Requirements More Restrictive than Federal

Form: TH-04

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.

VDH is not aware of any applicable federal requirements about:

- minimum standards for any hospital that voluntarily installs a newborn safety device for the reception of children, which is the subject of the mandates in Chapters 80 and 81 of the 2022 Acts of Assembly;
- requiring hospitals that makes minors' health records available to minors through a secure website
 to also make the health records available to the minor's parent or guardian through the same
 website, which is the subject of the mandate in Chapter 218 of the 2022 Acts of Assembly;
- minimum standards for payment plans and providing information about charity care and financial assistance policies, which is the subject of the mandates in Chapters 678 and 679 of the 2022 Acts of Assembly;
- discriminating against health insurance enrollee on the basis of the enrollee being a litigant or potential litigant due to a motor vehicle accident, which is the subject of the mandate in Chapter 72 of the 2021 Acts of Assembly, Special Session I;
- quarterly reporting of hospital employment of certified sexual assault nurse examiners, which is the subject of Chapter 1088 of the 2020 Acts of Assembly;
- storage of breast milk;
- isolation or segregation of mothers, newborns, and patients in obstetric and newborn services;
- licensing of hospitals or any processes or procedures related to licensing of hospitals;
- access to designated support persons by persons with disabilities

The regulatory change regarding the prohibition on balance billing derived from Chapters 1080 and 1081 of the 2020 Acts of Assembly do not exceed applicable federal requirements.

42 CFR § 483.80(d)(1) and (2) requires certified nursing facilities to offer influenza and pneumococcal vaccination to residents unless medically contradicted or the resident refuses vaccination. The legislative mandate in Chapter 762 of the 2004 Acts of Assembly is more specific than federal requirements about the clinical guidance informing vaccination, though the mandate does not exceed and is not more restrictive than applicable federal requirements.

The regulatory change regarding the design and construction guidelines for hospitals may be more restrictive than federal requirements, specifically 42 CFR §§ 482.41 and 483.90; however, Chapters 177 and 222 of the 2005 Acts of Assembly mandate 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.

The regulatory changes regarding training of certified nursing facility employees on mandated reporting, regarding the sex offender registry, information and notices about the family council, liability insurance, and visitation during public health emergencies related to COVID-19 may be more restrictive than federal requirements in 42 CFR Part 483 Subpart B; however, Va. Code § 32.-127 mandates the minimum requirements for certified nursing facilities 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.

Form: TH-04

Other State Agencies Particularly Affected

Virginia Commonwealth University (VCU) Health Systems Authority will be required to comply with the regulatory changes.

Localities Particularly Affected

Lee County Hospital Authority and Chesapeake Hospital Authority will be required to comply with the regulatory changes.

Other Entities Particularly Affected

The 106 licensed general hospitals (including those operated by VCU Hospital Systems Authority, Lee County Hospital Authority, and Chesapeake Hospital Authority) and 67 outpatient surgical hospitals will be required to comply with the regulatory change.

Economic Impact

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

Impact on State Agencies

For your agency: projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	There are no projected costs, savings, fees or revenues resulting from the regulatory change.
For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	There are no known projected savings, fees, or revenues resulting from the regulatory change. VCU Health System Authority would have one-time costs associated with updating policies and procedures related to designated support persons, certified nursing facilities, parent or guardian electronic access to minor patient's records, discharge planning, financial assistance, and infection control and prevention. For its existing policies and procedures, VDH is estimating it would cost \$1,250 one-time to amend their policies on each topic to conform to the regulatory minimums. It may be the case that no

amendments are needed if the policies and procedures meet or exceed the proposed regulatory minimums, in which case no cost is expected to be incurred. If VCU Hospital Systems Authority does not already have policies and procedures on these topics, VDH is estimating it would cost \$5,000 one-time to develop these policies and procedures per topic. There may be some ongoing recordkeeping and administrative costs because Chapter 1088 of the 2020 Acts of Assembly mandates that hospitals file quarterly reports with VDH about its SANE employment. VDH estimates these costs are not likely to exceed \$5,000 per year. There may be some ongoing recordkeeping and administrative costs associated with payment plans. VDH is unable to estimate at this time what the changes, if any, would be needed for VCU Hospital Systems Authority to implement the new requirements or what those changes may cost, as no information about this was reported in the Fiscal Impact Statement for Chapters 678 and 679 of the 2022 Acts of Assembly. The regulatory change is designed to conform the For all agencies: Benefits the regulatory change is designed to produce. regulation to the Code of Virginia, and to promote the health, safety, and welfare of hospital patients by incorporating current clinical and industry practices as well as by requiring reasonable timely information from hospitals, access to information to ensure hospital compliance, remedial action within a reasonable and consistently applied

Form: TH-04

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.

timeframe if noncompliance does occur.

Projected costs, savings, fees or revenues resulting from the regulatory change.	There are no known projected savings, fees, or revenues resulting from the regulatory change.
	Lee County Hospital Authority and Chesapeake Hospital Authority would have one-time costs associated with updating policies and procedures related to designated support persons, certified nursing facilities, parent or guardian electronic access to minor patient's records, discharge planning, financial assistance, and infection control and prevention. For their existing policies and procedures, VDH is estimating it would cost \$1,250 one-time to amend their policies on each topic to conform to the regulatory minimums. It may be the case that no amendments are needed

if the policies and procedures meet or exceed the proposed regulatory minimums, in which case no cost is expected to be incurred. If Lee County Hospital Authority and Chesapeake Hospital Authority do not already have policies and procedures on these topics, VDH is estimating it would cost \$5,000 one-time to develop these policies and procedures per topic. There may be some ongoing recordkeeping and administrative costs because Chapter 1088 of the 2020 Acts of Assembly mandates that hospitals file quarterly reports with VDH about its SANE employment. VDH estimates these costs are not likely to exceed \$5,000 per year. There may be some ongoing recordkeeping and administrative costs associated with payment plans. VDH is unable to estimate at this time what the changes, if any, would be needed for Lee County Hospital Authority and Chesapeake Hospital Authority to implement the new requirements or what those changes may cost. The regulatory change is designed to conform the Benefits the regulatory change is designed to regulation to the Code of Virginia, and to promote produce. the health, safety, and welfare of hospital patients by incorporating current clinical and industry practices as well as by requiring reasonable timely information from hospitals, access to information to ensure hospital compliance, remedial action within a reasonable and consistently applied timeframe if noncompliance does occur.

Form: TH-04

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.	Licensed hospitals and applicants for hospital licensure.
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 106 licensed general hospitals (including those operated by VCU Hospital Systems Authority, Lee County Hospital Authority, and Chesapeake Hospital Authority) and 67 outpatient surgical hospitals will be required to comply with the regulatory change. Applicants for hospital licensure are infrequent and difficult to estimate. VDH estimates three of the outpatient surgical hospitals may meet the definition of "small business"

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 known projected savings, fees, or revenues resulting from the regulatory change.

Form: TH-04

Hospitals would have one-time costs associated with updating policies and procedures related to designated support persons, certified nursing facilities, parent or guardian electronic access to minor patient's records, discharge planning, financial assistance, and infection control and prevention. For their existing policies and procedures, VDH is estimating it would cost \$1,250 one-time to amend their policies on each topic to conform to the regulatory minimums. It may be the case that no amendments are needed if the policies and procedures meet or exceed the proposed regulatory minimums, in which case no cost is expected to be incurred. If hospitals do not already have policies and procedures on these topics, VDH is estimating it would cost \$5,000 onetime to develop these policies and procedures per

There may be some ongoing recordkeeping and administrative costs because Chapter 1088 of the 2020 Acts of Assembly mandates that hospitals file quarterly reports with VDH about its SANE employment. VDH estimates these costs are not likely to exceed \$5,000 per year.

There may be some ongoing recordkeeping and administrative costs associated with payment plans. VDH is unable to estimate at this time what the changes, if any, would be needed for hospitals to implement the new requirements or what those changes may cost.

Benefits the regulatory change is designed to produce.

The regulatory change is designed to conform the regulation to the Code of Virginia, and to promote the health, safety, and welfare of hospital patients by incorporating current clinical and industry practices as well as by requiring reasonable timely information from hospitals, access to information to ensure hospital compliance, remedial action within a reasonable and consistently applied timeframe if noncompliance does occur.

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 was considered because the General Assembly required the Board to adopt regulations governing the licensure of hospitals and amending the regulation is the least burdensome, least intrusive, and less costly method to accomplish the purpose of this action.

Form: TH-04

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.

The Board is required to regulate the licensure of hospitals consistent with the provisions of Article 1 (§ 32.1-123 *et seq.*) of Chapter 5 of Title 32.1 of the Code of Virginia. Initiation of this regulatory action is the least burdensome method to conform the Regulations for the Licensure of Hospitals in Virginia (12VAC5-410-10 *et seq.*) to the statute.

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	New chapter-section	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
number	number, if		
410-10	applicable N/A	12VAC5-410-10. Definitions.	CHANGE: The Board is proposing the
		As used in this chapter, the	following change:
		following words and terms shall have the following meanings	12VAC5-410-10. Definitions.
		unless the context clearly	As used in this chapter, the following
		indicates otherwise:	words and terms shall have the following meanings unless the context clearly
			indicates otherwise:
		"Designated support person" means a person who is	"ACIP" means the Advisory
		knowledgeable about the needs of a person with a disability, and	Committee on Immunization Practices of the CDC.
		who is designated, orally or in	"Activity of daily living" or "ADL" has
		writing, by the individual with a	the same meaning as ascribed to the term
		disability, the individual's guardian, or the individual's care	in subsection A of § 32.1-137.08 of the Code of Virginia.
		provider to provide support and	* * *
		assistance, including physical assistance, emotional support,	"Business day" means any day that is not a Saturday, Sunday, legal holiday,
		assistance with communication	or day on which the OLC is closed. For
		or decision-making, or any other	the purposes of this chapter, any day on
		assistance necessary as a result of the person's disability, to the	which the Governor authorizes the closing of the state government shall be
		person with a disability at any	considered a legal holiday.
		time during which health care	"Campus" means the physical area
		services are provided.	that is immediately adjacent to the
		"Full-time" means a 37-1/2 to	hospital's main buildings, other areas and structures that are not strictly contiguous
		40 hour work week.	to the main buildings but are located
		"General hospital" means	within 250 yards of the main buildings,
		institutions as defined by § 32.1-	and any other physical areas determined
		123 of the Code of Virginia with	on an individual case basis, by the OLC in accordance with 42 C.F.R. § 413.65, to be
		an organized medical staff; with permanent facilities that include	part of the hospital's campus.
		inpatient beds; and with medical	"Care provider" has the same
		services, including physician	meaning as ascribed to the term in
		services, dentist services and	subsection A of § 32.1-137.08 of the Code of Virginia.
		continuous nursing services, to provide diagnosis and treatment	or virginia.

for patients who have a variety of medical and dental conditions that may require various types of care, such as medical, surgical, and maternity.

"Home health care department/service/program" means a formally structured organizational unit of the hospital that is designed to provide health services to patients in their place of residence and meets Part II (12VAC5-381-150 et seq.) of the regulations adopted by the board for the licensure of home care organizations in Virginia.

"Nursing care unit" means an organized jurisdiction of nursing service in which nursing services are provided on a continuous basis.

"Office of Licensure and Certification" or "OLC" means the Office of Licensure and Certification of the Virginia Department of Health.

"Outpatient hospital" means institutions as defined by § 32.1-123 of the Code of Virginia that primarily provide facilities for the performance of surgical procedures on outpatients. Such patients may require treatment in medical environment exceeding the normal capability found in a physician's office, but not require inpatient hospitalization.

"Special hospital" means institutions as defined by § 32.1-123 of the Code of Virginia that provide care for a specialized group of patients or limit admissions to provide diagnosis and treatment for patients who have specific conditions (e.g.,

"CDC" means the Centers for Disease Control and Prevention.

Form: TH-04

"Certified nursing facility" has the same meaning as ascribed to the term in § 32.1-123 of the Code of Virginia.

"Certified sexual assault nurse examiner" means a nurse who is board certified by the International Association of Forensic Nurses as either a Sexual Nurse Examiner-Pediatric Assault (SANE-P) or a Sexual Assault Nurse Examiner-Adult/Adolescent (SANE-A).

"CMS" means the Centers for Medicare and Medicaid Services.

"Designated support person" or means a person who is knowledgeable about the needs of a person with a disability, and who is designated, orally or in writing, by the individual with a disability, the individual's quardian, or the individual's care provider to provide support and assistance, including physical assistance, emotional support, assistance with communication or decision-making, or any other assistance necessary as a result of the person's disability, to the person with a disability at any time during which health care services are provided has the same meaning as ascribed to the term in subsection A of § 32.1-137.08 of the Code of Virginia and is not a visitor.

"Emergency department" means a department of the hospital that provides emergency services and is located on, or within a 35-mile radius of, the campus of the hospital.

"Full-time" means a 37-1/2 to 40 hour work week.

"General hospital" means institutions a hospital as defined by § 32.1-123 of the Code of Virginia with an organized medical staff; with permanent facilities that include inpatient beds; and with medical services, including physician services, dentist services and continuous nursing services, to provide diagnosis and tuberculosis, orthopedic, pediatric, maternity).

treatment for patients who have a variety of medical and dental conditions that may require various types of care, such as medical, surgical, and maternity.

Form: TH-04

"General hospital accrediting organization" means the Accreditation Commission for Health Care, the Center for Improvement in Healthcare Quality, DNV - Healthcare, The Joint Commission, or any accrediting organization that has been granted deeming authority for hospitals by CMS.

"Home health care department/service/program" "Home health services" means a formally structured organizational unit of the hospital that is designed to provide health services to patients in their place of residence and meets Part II (12VAC5-381-150 et seq.) of the regulations adopted by the board for the licensure of home care organizations in Virginia.

"Hospital" has the same meaning ascribed to the term in § 32.1-123 of the Code of Virginia and includes general hospitals and outpatient surgical hospitals.

"Inspector" means an individual employed by or contracted by the Virginia Department of Health and designated by the commissioner to conduct inspections, investigations, or evaluations.

"Long-term care nursing unit" means an organized jurisdiction of nursing service in which nursing services are provided on a continuous basis.

"Nursing care unit" means an organized jurisdiction of nursing service in which nursing services are provided on a continuous basis.

"Nursing home" means an institution or any identifiable component of any institution as defined by has the same meaning as ascribed to the term in § 32.1-123 of the Code of Virginia with permanent facilities that include inpatient beds and whose primary function is the provision, on a continuing basis, of nursing and health related services for the treatment of patients who may require

various types of long term care, such as skilled care and intermediate care.

Form: TH-04

* * *

"Office of Licensure and Certification" or "OLC" means the Office of Licensure and Certification of the Virginia Department of Health.

"Operating room" means a room in a hospital designated for the performance of surgery.

* * *

"Outpatient <u>surgical</u> hospital" means <u>institutions</u> <u>a hospital</u> as defined by § 32.1-123 of the Code of Virginia that primarily <u>provide provides</u> facilities for the performance of surgical procedures on outpatients. Such patients may require treatment in a medical environment exceeding the normal capability found in a physician's office, but do not require inpatient hospitalization.

"Outpatient surgical hospital accrediting organization" means the Accreditation Commission for Ambulatory Health Care, the Accreditation Commission for Health Care, the American Association for Accreditation of Ambulatory Surgery Facilities, The Joint Commission, or any accrediting organization that has been granted deeming authority for ambulatory surgical centers by CMS.

"Person with a disability" has the same meaning as ascribed to the term in subsection A of § 32.1-137.08 of the Code of Virginia.

* * *

"Special hospital" means institutions as defined by § 32.1-123 of the Code of Virginia that provide care for a specialized group of patients or limit admissions to provide diagnosis and treatment for patients who have specific conditions (e.g., tuberculosis, orthopedic, pediatric, maternity).

* * *

"Support and assistance necessary due to the specifics of the person's disability" has the same meaning as

ascribed to the term in subsection 32.1-137.08 of the Code of Virginia "Surgery" has the same mean ascribed to the term in subsection 54.1-2400.01:1 of the Code of Virg INTENT: The intent of the chang create, remove, and update definiti terms that have been cause for con RATIONALE: The rationale for change is that commonly used term may have multiple meanings dep on the speaker should be defined all audiences have a general	a. hing as A of § inia. e is to ons for fusion. or the ms that ending
create, remove, and update definition terms that have been cause for con RATIONALE: The rationale for change is that commonly used term may have multiple meanings depon the speaker should be defined as	ons for fusion. or the ms that ending
change is that commonly used term may have multiple meanings dep on the speaker should be defined s	ns that ending
all audiences have a con understanding of the terms' in meaning.	sistent
LIKELY IMPACT: The likely impact change is reduced confusion hospitals, VDH, and the public.	
410-50 N/A 12VAC5-410-50. Classification. CHANGE: The Board is proposing following change:	the
be classified as general hospitals, special hospitals or 12VAC5-410-50. Classification.	
outpatient hospitals defined by 12VAC5-410-10. Hospitals to be licensed should be classified as general hospitals, the hospitals or outpatient surgical hospitals or outpatient surgical hospitals.	special
INTENT: The intent of the chang remove "special hospital" a classification of hospital	e is to as a
RATIONALE: The rationale for change is that the Board has not uthis hospital classification and has regulatory provisions specific to shospitals.	utilized nas no
LIKELY IMPACT: The likely impact change is reduced confusion hospitals.	
410-60 N/A 12VAC5-410-60. Separate following change:	the
A. A separate license shall be required by hospitals 12VAC5-410-60. Separate license	∍.
maintained on separate premises even though they are operated under the same management. Separate license though they are operated under the	

		is not required for separate buildings on the same grounds or within the same complex of buildings. * * * *	management. Separate license is not required for separate buildings on the same grounds campus or within the same complex of buildings or for an emergency department of a general hospital. * * * INTENT: The intent of the change is to use consistent, defined terminology in regulation. RATIONALE: The rationale for the change is that a single defined term should be created and used instead of multiple undefined terms when discussing recurring subjects within the regulation. LIKELY IMPACT: The likely impact of the change is reduced confusion for hospitals.
410-100	N/A	12VAC5-410-100. Name. Every hospital shall be designated by a permanent and appropriate name which shall appear on the application for license. Any change of name shall be reported to the OLC within 30 days.	CHANGE: The Board is proposing the following change: 12VAC5-410-100. Name. Every hospital shall be designated by a permanent and appropriate name which that shall appear on the application for license. Any change of name shall be reported to the OLC within 30 days. INTENT: The intent of the change is to remove conflicting or duplicative regulatory provisions. RATIONALE: The rationale for the change is that changes affecting a hospital license are already addressed in a separate regulatory section and should not be addressed here, too. LIKELY IMPACT: The likely impact of the change is reduced confusion for hospitals about reporting name names.
410-130	N/A	12VAC5-410-130. Return of license. The OLC shall be notified in writing at least within 30 working days in advance of any proposed change in location or ownership of the facility. A license shall not be transferred from one owner to	CHANGE: The Board is proposing the following change:

another or from one location to another. The license issued by the commissioner shall be returned to the OLC for correction or reissuance when any of the following changes occur during the licensing year:

- 1. Revocation;
- 2. Change of location;
- 3. Change of ownership;
- 4. Change of name;
- 5. Change of bed capacity, except as provided in 12VAC5-410-110 C; or
- 6. Voluntary closure.

12VAC5-410-130. Return of license Surrender of license; mid-term change of license.

Form: TH-04

A. Upon revocation or suspension of a license, the hospital shall surrender its license to the OLC.

B. The hospital shall notify the director of the OLC shall be notified in writing by submitting a mid-term change application at least within 30 working days no less than 30 calendar days in advance of any proposed change in location or ownership of the facility. A license shall not be transferred from one owner to another or from one location to another. The license issued by the commissioner shall be returned to the OLC for correction or reissuance when any of the following changes occur during the licensing year implementing any:

1. Revocation;

- 2. 1. Change of location of the hospital, including change of location of any emergency department not located on the hospital's campus;
- 3. 2. Change of ownership of the hospital;
- 3. Change of operator of the hospital;
- 4. Change of name of the hospital;
- 5. Change of bed capacity, except as provided in 12VAC5-410-110 C; which shall be accompanied by an approved Certificate of Public Need if the requested change is for an increase in bed capacity; er
- 6. Change of services being provided, including any proposed addition or discontinuation, regardless of whether licensure is required for the service; or
- 6. Voluntary closure 7. Closure of the hospital.

C. The OLC shall:

1. Consider the submission date of a mid-term change application to be the date it is postmarked or

the date it is received, whichever is earlier: and

- 2. Notify in writing the licensee if the commissioner will issue a changed license.
- D. The commissioner's issuance of a changed license to the hospital shall satisfy the requirements of subdivision C 2 of this section.
- E. Upon receipt of the changed license, the licensee shall return its prior license issued by the commissioner to the OLC and destroy any copies of the prior license.
- F. A license may not be transferred or assigned. The commissioner may not issue a changed license in response to a change of operator of the hospital, but shall instead require the hospital to obtain a new license. If the hospital intends to implement a change of operator, it shall:
 - 1. File for a new license, in accordance with 12VAC5-410-70, no less than 30 calendar days in advance of any change of operator; and
 - 2. Upon receipt of the new license, surrender its prior license issued by the commissioner to the OLC and destroy any copies of the prior license.
- G. If the hospital is closing or will otherwise no longer be operational, it shall:
 - 1. Notify patients, legal representatives, and the OLC no fewer than seven calendar days prior to closing or ceasing operations where all clinical records are to be located following closure or cessation of operations; and
 - 2. Surrender its license to the OLC and destroy all copies of its license no more than five calendar days after the hospital closes or ceases operations.
- H. The OLC shall determine if any changes listed in subsection B affect the terms of the license or the continuing eligibility for a license. An inspector may

410-140	N/A	12VAC5-410-140. Inspection procedure. A. The OLC may presume that a hospital accredited by the Joint Commission on	inspect the hospital during the process of evaluating a proposed change. INTENT: The intent of the change is to create a consistent list of what changes VDH needs to be aware of, when those changes are reportable, and what changes can result in a changed license versus a new license. RATIONALE: The rationale for the change is that transfer or assignment of licenses are prohibited by law, that certain license changes may require a new license, a new inspection (in the case of a change of location), or both, and that VDH needs to be aware of hospitals' active service lines for disaster preparedness planning and implementation. LIKELY IMPACT: The likely impact of the change is reduced confusion for hospitals and VDH about when and what changes are reportable, and what changes warrant a new license. CHANGE: The Board is proposing the following change: 12VAC5-410-140. Inspection procedure. A. The OLC shall make periodic
		Accreditation of Healthcare Organizations (JCAHO) and certified for participation in Title XVIII of the Social Security Act (Medicare) generally meets the requirements of Part II (12VAC5-410-170 et seq.) of this chapter provided the following conditions are met:	unannounced on-site inspections of a hospital as necessary but not less often than biennially. The OLC may make onsite inspections of applicants for licensure. Compliance with all standards shall be determined by the OLC. B. The hospital or applicant shall:
		1. The hospital provides to the OLC, upon request, a copy of the most current accreditation survey findings made by the Joint Commission on Accreditation of Healthcare	1. Make available to the inspector any requested records; 2. Permit an inspector to enter upon and into its property to inspect or investigate as the inspector reasonably deems necessary in order to determine the state of compliance with the provisions of this chapter and all laws administered by the board.
		Organizations; and 2. The hospital notifies the OLC within 10 days after receipt of any	laws administered by the board; and 3. Allow the inspector access to interview the agents, employees, independent contractors,

- notice of revocation or denial of accreditation by the Joint Commission on Accreditation of Healthcare Organizations.
- B. The OLC may presume that a unit or part of a hospital licensed or certified by another state agency, or another section, bureau or division of the OLC meets the requirements of Part II of this chapter for that specific unit or part provided the following conditions are met:
 - 1. The hospital provides the OLC, upon request, a copy of the most current inspection report made by the other state agency; and
 - 2. The hospital notifies the OLC within 10 days after receipt of any notice of revocation or suspension by the other state agency.
- C. Notwithstanding any other provision of this chapter to the contrary, if the licensing agency finds, after inspection, violations pertaining to environmental health or life safety, the hospital shall receive a written licensing report of such findings. The hospital shall be required to submit a plan of correction in accordance with provisions of 12VAC5-410-150.

patients, legal representatives, patients' family members, and any person under the hospital's or applicant's control, direction, or supervision.

- C. After the on-site inspection, the inspector shall:
 - 1. Discuss the findings of the inspection with the chief executive officer or his designee; and
 - <u>2. Provide a written inspection</u> report to the chief executive officer or his designee.
- D. If the OLC cites one or more licensing violations in the written inspection report, the chief executive officer or his designee shall submit a plan of correction in accordance with 12VAC5-410-150.
- A. E. The OLC may presume that a general hospital accredited deemed by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) a general hospital accrediting organization and certified for participation in Title XVIII of the Social Security Act (Medicare) (42 U.S.C. § 301 et seq.) generally meets the requirements of Part II (12VAC5-410-170 et seq.) of this chapter provided the following conditions are met:
 - 1. The <u>general</u> hospital provides to the OLC, upon request, a copy of the most current accreditation survey findings made by the Joint Commission on Accreditation of Healthcare Organizations general hospital accrediting organization; and
 - 2. The <u>general</u> hospital notifies the OLC within 10 days after receipt of any notice of revocation or denial of accreditation by the <u>Joint Commission on Accreditation of Healthcare Organizations general hospital accrediting organization</u>.
- F. The OLC may presume that an outpatient surgical hospital deemed by an outpatient surgical hospital accrediting organization and certified for participation

in Title XVIII of the Social Security Act (42 U.S.C. § 301 et seq.) generally meets the requirements of Part IV (12VAC5-410-1150 et seq.) of this chapter provided the following conditions are met:

1. The outpatient surgical hospital provides to the OLC, upon request, a copy of the most current accreditation survey findings made by the outpatient surgical hospital accrediting organization; and

- 2. The outpatient surgical hospital notifies the OLC within 10 days after receipt of any notice of revocation or denial of accreditation by the outpatient surgical hospital accrediting organization.
- B. G. The OLC may presume that a unit or part of a general hospital licensed or certified by another state agency, or another section, bureau or division of the OLC meets the requirements of Part II (12VAC5-410-170 et seq.) of this chapter for that specific unit or part provided the following conditions are met:
 - 1. The <u>general</u> hospital provides the OLC, upon request, a copy of the most current inspection report made by the other state agency; and
 - 2. The <u>general</u> hospital notifies the OLC within 10 days after receipt of any notice of revocation or suspension by the other state agency.
- H. The OLC may presume that a unit or part of an outpatient surgical hospital licensed or certified by another state agency, or another section, bureau or division of the OLC meets the requirements of Part IV (12VAC5-410-1150 et seq.) of this chapter for that specific unit or part provided the following conditions are met:
 - 1. The outpatient surgical hospital provides the OLC, upon request, a copy of the most current inspection report made by the other state agency; and

410-150	N/A	12VAC5-410-150. Plan of correction. A. Upon receipt of a written licensing report each hospital shall prepare a plan for correcting any licensing violations cited at the time of inspection. The plan of correction shall be to the OLC within the specified time limit set forth in the licensing report. The plan of correction shall contain at least	surgical hospitals from a rebuttable presumption of compliance. LIKELY IMPACT: The likely impact of the change is reduced confusion for hospitals and more efficient inspection procedures for VDH if it can utilize similar rebuttable compliance presumptions for all hospital types on routine inspections. CHANGE: The Board is proposing the following change: 12VAC5-410-150. Plan of correction. A. Upon receipt of a written licensing inspection report, the chief executive officer or his designee each hospital shall prepare a written plan for correcting of correction addressing any each licensing violations violation cited at the time of inspection. The plan of correction shall be to the OLC within the specified time limit
			RATIONALE: The rationale for the change is hospitals are better able to anticipate what may be needed during inspection process if parameters are specified in regulation and that there is not rationale reason to exclude outpatient
			INTENT: The intent of the change is to more clearly specify what is expected of a hospital and VDH when an inspection occurs and to create a rebuttable compliance presumption for outpatient surgical hospitals.
			2. The outpatient surgical hospital notifies the OLC within 10 days after receipt of any notice of revocation or suspension by the other state agency. C. I. Notwithstanding any other provision of this chapter to the contrary, if the licensing agency OLC finds, after inspection, violations pertaining to environmental health or life safety, the hospital shall receive a written licensing report of such findings. The hospital shall be required to submit a plan of correction in accordance with provisions of 12VAC5-410-150.

- 1. The methods implemented to correct any violations of this chapter; and
- 2. The date on which such corrections are expected to be completed.
- B. The OLC shall notify the hospital, in writing, whenever any item in the plan of correction is determined to be unacceptable.
- of correction shall contain at least the following information:

- B. The chief executive officer or his designee shall submit to the OLC a written plan of correction no more than 15 business days after receipt of the inspection report. The plan of correction shall contain for each licensing violation cited:
 - 1. The methods implemented to correct any violations of this chapter A description of the corrective action or actions to be taken and the position title of the employees to implement the corrective action. If employees share the same position title, the chief executive officer or his designee shall assign the employees a unique identifier to distinguish them; and
 - 2. The expected correction date, on which such corrections are expected to be completed not to exceed 45 business days from the exit date of the inspection-; and
 - 3. A description of the measures implemented to prevent a recurrence of each licensing violation.
- C. The chief executive officer or his designee shall ensure that the person responsible for the validity of the plan of correction signs, dates, and indicates their title on the plan of correction.
- B. D. The OLC shall notify the hospital chief executive officer or his designee, in writing, whenever if the OLC determines any item in the plan of correction is determined to be unacceptable.
- E. The OLC may conduct an inspection to verify any portion of a plan of correction has been implemented.
- F. The chief executive officer or his designee shall ensure the plan of correction is implemented and monitored so that compliance is maintained.
- G. The commissioner may deny licensure or renewal of licensure if the chief executive officer or his designee

410-160	N/A	12VAC5-410-160. Revocation	fails to submit an acceptable plan of correction or fails to implement an acceptable plan of correction. H. The OLC shall consider the submission date of a plan of correction to be the date it is postmarked or the date it is received, whichever is earlier. INTENT: The intent of the change is to standardize the plan of correction process to make it more similar to federal plan of correction processes. RATIONALE: The rationale for the change is that documentation of remedial action and completion of remedial action should be consistently applied to all hospitals. LIKELY IMPACT: The likely impact of the change is improved clarity about what should be in a plan of correction, when it is due, and when it should be completed. CHANGE: The Board is proposing the following change:
		revoke or suspend the license to operate a hospital in accordance with § 32.1-135 of the Code of Virginia for the following reasons: 1. Violation of any provision of these rules and regulations. Violations which in the judgment of the commissioner jeopardize the health or safety of patients shall be sufficient cause for immediate revocation or suspension; or 2. Willfully permitting, aiding, or abetting the commission of any illegal act in the hospital.	12VAC5-410-160. Revocation of license Disciplinary action. The commissioner may revoke or suspend the license to operate a hospital in accordance with § 32.1-135 of the Code of Virginia for the following reasons: 1. Violation of any provision of these rules and regulations. Violations which in the judgment of the commissioner jeopardize the health or safety of patients shall be sufficient cause for immediate revocation or suspension; or 2. Willfully permitting, aiding, or abetting the commission of any illegal act in the hospital. A. A hospital may not: 1. Violate the provisions of this chapter or Article 1 (§ 32.1-123 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia; 2. Permit, aid, or abet the commission of any illegal act in the hospital;

Engage in a pattern of violations pursuant to § 38.2-3445.01 of the Code of Virginia; 4. Engage in a pattern of violations of subdivision B 13 of § 38.2-3407.15 of the Code of Virginia. B. The commissioner may: 1. For each violation of subsection A of this section: a. Deny, revoke, or suspend the license to operate a hospital, in accordance with the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia); b. Refer a hospital for criminal prosecution pursuant to subsection A of § 32.1-27 of the Code of Virginia; or c. Petition an appropriate court for an injunction, mandamus, or other appropriate remedy or imposition of a civil penalty against a hospital pursuant to subsection B or C of § 32.1-27 of the Code of Virginia; 2. For each violation of subsection A of this section by or occurring in a long-term care nursing unit of a general hospital if that unit is a certified nursing facility: a. Restrict or prohibit new admissions to the long-term care nursing unit in accordance with the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia); b. Petition an appropriate court for imposition of a civil monetary penalty against a hospital pursuant to subsection A of § 32.1-27.1 of the Code of Virginia; or c. Petition an appropriate court for appointment of a

Form: TH-04 receiver for the long-term care nursing unit pursuant to subsection B of § 32.1-27.1 of the Code of Virginia; and For each violation of subdivision A 3 of this section, levy a fine upon the hospital in an amount not to exceed \$1,000 per violation, in accordance with the Administrative Process Acts (§ 2.2-4000 et seq. of the Code of Virginia). C. Suspension of a license shall in all cases be for an indefinite time. D. For each violation of subsection A of this section and with the consent of the person who has violated subsection A of this section, the board may provide, in an order issued by the board, for the payment of civil charges for past violations in specific sums, which may not exceed the limits specified in § 32.1-27 of the Code of Virginia or if applicable, the limits specified in § 32.1-27.1 of the Code of Virginia. E. Upon receipt of a completed application and a nonrefundable service charge, the commissioner may issue a new license to a hospital that has had its license revoked if the commissioner determines that: 1. The conditions upon which revocation was based have been corrected; and 2. The applicant is in compliance with this chapter, Article 1 (§ 32.1-123 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia, and all other applicable state and federal law and regulations. F. Upon receipt of a completed application, the commissioner may partially or completely restore a suspended license to a hospital if the commissioner determines that:

1. The conditions upon which suspension was based have been completely or partially

corrected; and

		2. The interests of the public will not be jeopardized by resumption of operation. G. The commissioner may not require an additional service charge for restoring a license pursuant to subsection F of this section. H. The hospital shall submit evidence relevant to subdivisions E 1, E 2, F 1, and F 2 of this subsection that is satisfactory to the commissioner or his designee. The commissioner or his designee may conduct an inspection prior to making a determination. INTENT: The intent of the change is to describe the grounds upon which the
		commissioner may take disciplinary action against a hospital, the options available to the commissioner for disciplinary action, and how a hospital may obtain a license after suspension or revocation.
		RATIONALE: The rationale for the change is that the regulation should conform to Chapter 72 of the 2021 Acts of Assembly, Special Session I, Chapters 1080 and 1081 of the 2020 Acts of Assembly, and to Va. Code §§ 32.1-27, 32.1-27.1, and 32.1-135.
		LIKELY IMPACT: The likely impact of the change is improved clarity for hospitals about what acts are not permitted and what consequences may follow if a prohibited act occurs.
410-215	None	CHANGE: The Board is proposing the following change:
		Part II
		Organization and Operation of General and Special Hospitals
		12VAC5-410-215. Financial assistance in general hospitals.
		A. As used in this section, "patient" and "uninsured patient" have the same meanings as ascribed to these terms in subsection A of § 32.1-137.010 of the Code of Virginia.
	410-215	410-215 None

B. A general hospital shall make reasonable efforts to screen every uninsured patient to determine whether the individual is eligible for medical assistance pursuant to the state plan for medical assistance or for financial assistance under the general hospital's financial assistance policy.

- C. A general hospital shall inform every uninsured patient who receives services at the general hospital and who is determined to be eligible for assistance under the general hospital's financial assistance policy of the option to enter into a payment plan with the general hospital.
 - 1. A payment plan entered into pursuant to this subsection shall be provided to the patient in writing or electronically and shall provide for repayment of the cumulative amount owed to the general hospital.
 - 2. The amount of monthly payments and the term of the payment plan shall be determined based upon the patient's ability to pay.
 - 3. Any interest on amounts owed pursuant to the payment plan shall not exceed the maximum judgment rate of interest pursuant to § 6.2-302 of the Code of Virginia.
 - 4. The general hospital may not charge any fees related to the payment plan.
 - 5. The payment plan shall allow prepayment of amounts owed without penalty.
- D. A general hospital shall develop a process by which either an uninsured patient who agrees to a payment plan pursuant to subsection C of this section or the general hospital may request and shall be granted the opportunity to renegotiate the payment plan.
 - 1. Renegotiation shall include opportunity for a new screening in accordance with subsection B of this section.

<u>, </u>	
	A general hospital may not
	charge any fees for renegotiation
	of a payment plan pursuant to this
	subsection.
	E. A general hospital shall provide
	written information about:
	1. Its charity care policies,
	including:
	a. Policies related to free and
	discounted care;
	b. Specific eligibility criteria
	for charity care; and
	c. Procedures for applying for
	<u>charity care;</u>
	
	The availability of a payment plan for the payment of debt
	owed to the general hospital
	pursuant to subsection C of this
	section; and
	3. The renegotiation process
	described in subsection D of this
	section.
	F. To provide the information required
	by subsection E of this section, a general
	hospital shall:
	1. Post the information
	conspicuously in public areas of
	the general hospital, including
	admissions or registration areas,
	emergency departments, and
	associated waiting rooms;
	2. Make the information available
	<u>to:</u>
	a. A patient at the time of
	admission or discharge, or at
	the time services are
	provided; and
	b. Persons with limited
	English proficiency in
	accordance with the U.S.
	Department of Health and
	Human Services' Guidance
	<u>to Federal Financial</u>
	Assistance Recipients
	Regarding Title VI Prohibition
	Against National Origin
	Discrimination Affecting
	Limited English Proficient
	Persons (August 8, 2003, 68
	FR 47311), if the general

	hospital is subject to the requirements of Title VI of the Civil Rights Act of 1964 (Pub. L. No. 88-352), as amended;
	<u>and</u> 3. Include the information:
	a. With any billing statements
	sent to uninsured patients; and
	<u>b. On any website</u> <u>maintained by the general</u>
	hospital.
	G. Notwithstanding any other provision of law, a general hospital may not engage in any action described in § 501(r)(6) of the Internal Revenue Code, as it was in effect on January 1, 2020, to
	recover a debt for medical services against any patient unless the general hospital has made all reasonable efforts to determine whether the patient:
	 Qualifies for medical assistance pursuant to the state plan for medical assistance; or
	 Is eligible for financial assistance under the general hospital's financial assistance policy.
	H. Nothing in this section shall be construed to:
	 Prohibit a general hospital, as part of its financial assistance policy, from requiring a patient to:
	a. Provide necessary information needed to
	<u>determine eligibility for</u> financial assistance under
	the general hospital's
	financial assistance policy, medical assistance pursuant
	to Title XVIII or XIX of the
	Social Security Act (42
	<u>U.S.C.</u> § 301 et seq.), 10 <u>U.S.C.</u> § 1071 et seq., or
	other programs of insurance;
	<u>or</u>
	 b. Undertake good faith efforts to apply for and enroll
	in the programs of insurance
	for which the patient may be
	<u>eligible as a condition of</u>

			eligibility for the general hospital's financial assistance policy; or b. A patient has not
			undertaken good faith efforts to comply with any payment plan pursuant to this section; or
			3. Prohibit the coordination of benefits as required by state or federal law.
			INTENT: The intent of the change is to remove "special hospitals" from the name of this Part and to describe the minimum requirements for information disclosure about financial assistance, for payment plans, and for renegotiation of payment plans.
			RATIONALE: The rationale for the change is that the Board does not intend to use "special hospitals" as a classification of hospital and that the regulation should conform to Chapters 678 and 679 of the 2022 Acts of Assembly.
			LIKELY IMPACT: The likely impact of the change is reduced confusion for outpatient surgical hospitals about the minimum requirements for providing information about financial assistance and providing financial assistance to patients.
N/A	410-225	None	CHANGE: The Board is proposing the following change:

<u>12VAC5-410-225.</u> Newborn safety devices.

- A general hospital that voluntarily installs a newborn safety device for the reception of children shall ensure that:
 - 1. The device is located inside the hospital in an area that is conspicuous and visible to employees or personnel;

Form: TH-04

- 2. The device is staffed 24 hours a day by a health care provider;
- 3. The device is climate controlled and serves as a safe sleep environment for an infant;
- 4. The device is equipped with a dual alarm system that sounds 60 seconds after a child is placed in the device and automatically places a call to 911 if the alarm is not deactivated within 60 seconds from within the hospital;
- 5. The dual alarm system is visually checked at least two times per day and tested at least one time per week to ensure the alarm system is in working order;
- 6. The device automatically locks when a child is placed in the device; and
- 7. The device is identifiable by appropriate signage that shall include written and pictorial operational instructions.

INTENT: The intent of the change is to describe the minimum standards a general hospital must meet if it choose to install a newborn safety device.

RATIONALE: The rationale for the change is that the regulation should be consistent with Chapters 80 and 81 of the 2022 Acts of Assembly

LIKELY IMPACT: The likely impact of the change is reduced confusion for general hospitals about the minimum requirements if they choose to install a newborn safety device.

CHANGE: The Board is proposing the 410-230 N/A 12VAC5-410-230. Patient care following change: management. 12VAC5-410-230. **Patient** C. Each hospital shall management. establish a protocol relating to the rights and responsibilities of C. Each hospital shall establish a patients based on Joint protocol relating to the rights and Commission on Accreditation of responsibilities of patients based on 42 Healthcare Organizations' 2000 C.F.R. § 482.13 Joint Commission on Hospital Accreditation of___ Accreditation -Standards, January 2000. The Organizations' 2000 protocol shall include a process Accreditation Standards, January 2000. reasonably designed to inform The protocol shall include a process patients of their rights and reasonably designed to inform patients of responsibilities. Patients shall be their rights and responsibilities. Patients given a copy of their rights and shall be given a copy of their rights and responsibilities upon admission. responsibilities upon admission. G. If the Governor has G. If the Governor has declared a declared public health а public health emergency related to the emergency related to the novel novel coronavirus (COVID-19), each coronavirus (COVID-19), each hospital shall allow a person with a hospital shall allow a person with who requires disability who requires assistance as a disability result of such disability to be assistance as a result of such accompanied by a designated support disability to be accompanied by a person at any time during which health designated support person at care services are provided. any time during which health care services are provided. 1. In any case in which health care services are provided in an 1. In any case in which inpatient setting, and the duration health care services are of health care services in such provided in an inpatient inpatient setting is anticipated to setting, and the duration last more than 24 hours, the of health care services in person with a disability may such inpatient setting is designate more than one anticipated to last more designated support person. than 24 hours, However, no hospital shall be person with a disability required to allow more than one designate mav more designated support person to be one than designated present with a person with a support person. disability at any time. However, no hospital shall be required to allow 2. A designated support person than shall not be subject to any more one designated support restrictions on visitation adopted person to be present by such hospital. However, such with a person with a designated support person may disability at any time.

Form: TH-04

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Healthcare 1 4 1

be required to comply with all reasonable requirements of the

hospital adopted to protect the

health and safety of patients and

staff of the hospital.

Hospital

not

be

any

2. A designated support

shall

restrictions on visitation

to

person

subject

- adopted bν such hospital. However, such designated support person may be required comply with reasonable requirements the adopted hospital to protect the health and safety of patients and staff of the hospital.
- 3. Every hospital shall establish policies applicable to designated support persons and shall:
 - a. Make such policies available to the public on a website maintained by the hospital; and
 - b. Provide such policies, in writing, to the patient at such time as health care services are provided.
- H. Each hospital that is equipped to provide lifesustaining treatment shall develop a policy to determine the medical or ethical appropriateness of proposed medical care. which shall include:
 - Α 1. process for obtaining а second opinion regarding the medical and ethical appropriateness proposed medical care in cases in which a physician has determined proposed care to be medically or ethically inappropriate;
 - 2. Provisions for review of the determination that proposed medical care is medically or ethically inappropriate by an interdisciplinary medical

3. Every hospital shall establish policies applicable to designated support persons and shall:

- a. Make such policies available to the public on a website maintained by the hospital; and
- b. Provide such policies, in writing, to the patient at such time as health care services are provided.
- H. G. Each hospital that is equipped to provide life-sustaining treatment shall develop a policy to determine the medical or ethical appropriateness of proposed medical care, which shall include:
 - 1. A process for obtaining a second opinion regarding the medical and ethical appropriateness of proposed medical care in cases in which a physician has determined proposed care to be medically or ethically inappropriate;
 - 2. Provisions for review of the determination that proposed medical care is medically or ethically inappropriate by an interdisciplinary medical review committee and a determination by the interdisciplinary medical review committee regarding the medical and ethical appropriateness of the proposed health care of the patient;
 - 3. Requirements for a written explanation of the decision of the interdisciplinary medical review committee, which shall be included in the patient's medical record; and
 - 4. Provisions to ensure the patient, the patient's agent, or the person authorized to make the patient's medical decisions in accordance with § 54.1-2986 of the Code of Virginia is informed of the patient's right to obtain the patient's medical record and the right to obtain an independent medical opinion and afforded reasonable opportunity to

review committee and a determination by the interdisciplinary medical review committee regarding the medical and ethical appropriateness of the proposed health care of the patient;

- 3. Requirements for a written explanation of the decision of the interdisciplinary medical review committee, which shall be included in the patient's medical record; and
- 4. Provisions to ensure the patient, the patient's agent, or the person authorized to make the patient's medical decisions in accordance with § 54.1-2986 of the Code of Virginia is informed of the patient's right to obtain the patient's medical record and the right to obtain an independent medical opinion and afforded reasonable opportunity to participate in the medical review committee meeting.

The policy shall not prevent the patient, the patient's agent, or the person authorized to make the patient's medical decisions from obtaining legal counsel to represent the patient or from seeking other legal remedies, including court review, provided that the patient, the patient's agent, person authorized to make the patient's medical decisions, or legal counsel provide written notice to the chief executive officer of the hospital within 14 days of the date of the physician's determination that proposed medical treatment is medically or ethically participate in the medical review committee meeting.

Form: TH-04

The policy shall not prevent the patient, the patient's agent, or the person authorized to make the patient's medical decisions from obtaining legal counsel to represent the patient or from seeking other legal remedies, including court review, provided that the patient, the patient's agent, person authorized to make the patient's medical decisions, or legal counsel provide written notice to the chief executive officer of the hospital within 14 days of the date of the physician's determination that proposed medical treatment is medically or ethically inappropriate as documented in the patient's medical record.

- H. H. Each hospital shall establish a protocol requiring that, before a health care provider arranges for air medical transportation services for a patient who does not have an emergency medical condition as defined in 42 USC § 1395dd(e)(1), the hospital shall provide the patient or the patient's authorized representative with written or electronic notice that the patient (i) may have a choice of transportation by an air medical transportation provider or medically appropriate ground transportation by an emergency medical services provider and (ii) will be responsible for charges incurred for such transportation in the event that the provider is not a contracted network provider of the patient's health insurance carrier or such charges are not otherwise covered in full or in part by the patient's health insurance plan.
- J. I. Each hospital shall provide written information about the patient's ability to request an estimate of the payment amount for which the participant will be responsible pursuant to § 32.1-137.05 of the Code of Virginia. The written information shall be posted conspicuously in public areas of the hospital, including admissions or registration areas, and included on any website maintained by the hospital.

K. Each hospital shall establish protocols to ensure that any patient

inappropriate as documented in the patient's medical record.

- Each hospital shall establish a protocol requiring that, before a health care provider arranges for air medical transportation services for a patient who does not have an emergency medical condition as defined 42 in USC 1395dd(e)(1), the hospital shall provide the patient or the patient's authorized representative with written or electronic notice that the patient (i) may have a choice of transportation by an air medical transportation provider medically appropriate ground transportation by an emergency medical services provider and (ii) will be responsible for charges incurred for such transportation in the event that the provider is contracted not a network provider of the patient's health insurance carrier or such charges are not otherwise covered in full or in part by the patient's health insurance plan.
- J. Each hospital shall provide written information about the patient's ability to request an estimate of the payment amount for which the participant will be responsible pursuant to § 32.1-137.05 of the Code of Virginia. The written information shall be posted conspicuously in public areas of the hospital, including admissions or registration areas, and included on any website maintained by the hospital.
- K. Each hospital shall establish protocols to ensure that any patient scheduled to receive an elective surgical procedure for which the patient can reasonably be expected to require outpatient physical therapy as a follow-up treatment after discharge is informed that the patient:

scheduled to receive an elective surgical procedure for which the patient can reasonably be expected to require outpatient physical therapy as a follow-up treatment after discharge is informed that the patient:

1. Is expected to require outpatient physical therapy as a follow-up treatment; and

Form: TH-04

2. Will be required to select a physical therapy provider prior to being discharged from the hospital.

INTENT: The intent of the change is to use a more relevant basis for patient rights protocols and to create two new sections of regulation that separately address discharge planning and designated support persons.

RATIONALE: The rationale for the change is that a document from 2000 is an out-of-date basis for patient rights, that all general hospitals in Virginia are already complying with 42 C.F.R. § 482.13 as a condition of participation in Medicare, and that discharge planning and designated support persons are topics requiring significantly more detail that, if both were to continue to be addressed in the present section of regulation, would make the section more difficult to read.

LIKELY IMPACT: The likely impact of the change is improved readability of this regulatory section and improved ease in locating provisions addressing discharge planning and designated support persons.

		1. Is expected to require outpatient physical therapy as a follow-up treatment; and 2. Will be required to select a physical therapy provider prior to being discharged from the hospital.	
410-	410-235	See row above regarding	CHANGE: The Board is proposing the
230(G)		changes proposed for 410-230.	following change:
			12VAC5-410-235. Persons with a disability; designated support person in general hospital. A. For the purposes of this section: 1. "Admission" means accepting a person for bed occupancy and care that is anticipated to span at least two midnights or for observation: 2. "General hospital" means a general hospital other than one that is certified as a long-term acute care hospital or specialty rehabilitation hospital. B. A general hospital shall allow a person with a disability who requires support and assistance necessary due to the specifics of the person's disability to be accompanied by a DSP who will provide support and assistance necessary due to the specifics of the person's disability to the person with a disability during an admission. 1. In any case in which the duration of the admission lasts more than 24 hours, the person with a disability may designate more than one DSP. 2. No general hospital shall be required to allow more than one DSP to be present with a person with a disability at any time. C. A general hospital may: 1. Not subject a DSP to any restrictions on visitation; 2. Require a DSP to comply with all reasonable requirements of a general hospital adopted to

protect the health and safety of the person with a disability; the DSP; the staff and other patients of, or visitors to, a general hospital; and the public; and

Form: TH-04

- 3. Restrict a DSP's access to specified areas of and movement on the premises of a general hospital when such restrictions are determined by a general hospital to be reasonably necessary to protect the health and safety of the person with a disability; the DSP; the staff and other patients of, or visitors to, a general hospital; and the public.
- D. A general hospital may request that a person with a disability provide documentation indicating that he is a person with a disability.
 - 1. If the person with a disability fails, refuses, or is unable to provide documentation requested pursuant to subsection D of this section, a general hospital may perform an objective assessment of the person to determine whether he is a person with a disability.
 - 2. If a general hospital fails to perform an objective assessment pursuant to subdivision D 1 of this section, a general hospital may not prohibit a DSP from accompanying a person with a disability for the purpose of providing support and assistance necessary due to the specifics of the person's disability.

E. A general hospital shall

1. Establish protocols to inform patients, at the time of admission, of the right of a person with a disability who requires support and assistance necessary due to the specifics of the person's disability to be accompanied by a DSP for the purpose of providing support and assistance necessary due to the specifics of the person's disability;

2. Develop and make available to a patient or his guardian, authorized representative, or care provider upon request written information regarding the right of a person with a disability who requires support and assistance necessary due to the specifics of the person's disability to be accompanied by a DSP and any policies related to that right; and

Form: TH-04

3. Make the written information described in subdivision E 2 of this section available to the public on its website.

G. This section may not:

1. Alter the obligation of a general hospital to provide patients with effective communication support or other required services, regardless of the presence of a DSP or other reasonable accommodation, consistent with applicable federal or state law or regulations; and

2. Be interpreted to:

- a. Prevent a general hospital from complying, or interfere with the ability of a general hospital to comply, with or cause a general hospital to violate any federal or state law or regulation;
- b. Deem a DSP to be acting under the direction or control of a general hospital or as an agent of a general hospital; or c. Require a general hospital to allow a DSP to perform any
- to allow a DSP to perform any action or provide any support or assistance necessary due to the specifics of the person's disability when a general hospital reasonably determines that the performance of the action or provision would be:
- (1) Medically or therapeutically contraindicated; or

		(2) A threat to the health and safety of the person with a disability, the DSP, or the
		staff or other patients of, or visitors to, a general hospital.
		INTENT: The intent of the change is to describe the minimum requirements for access to designated support persons by persons with disabilities in general hospitals.
		RATIONALE: The rationale for the change is that the regulation should be in conformity with Chapter 220 of the 2021 Acts of Assembly, Special Session I.
		LIKELY IMPACT: The likely impact of the change is reduced confusion for general hospitals about what the minimum requirements for designated support persons are outside of a Governor-declared public health emergency related to COVID-19.
p	proposed changes to 410-230 and row below regarding	CHANGE: The Board is proposing the following change: 12VAC5-410-237. Discharge planning. A. A general hospital shall provide each patient admitted as an inpatient or his legal guardian the opportunity to designate: 1. An individual who will care for or assist the patient in his residence following discharge from a general hospital; and 2. To whom a general hospital shall provide information regarding the patient's discharge plan and any follow-up care, treatment, and services that the patient may require. B. Upon admission, a general hospital shall record in the patient's medical record: 1. The name of the individual designated by the patient; 2. The relationship between the patient and the person; and 3. The person's telephone
0		See row above regarding proposed changes to 410-230 and row below regarding proposed changes to 410-1175

C. If the patient fails or refuses to designate an individual to receive information regarding his discharge plan and any follow-up care, treatment, and services, a general hospital shall record the patient's failure or refusal in the patient's medical record.

- D. A patient may change the designated individual at any time prior to the patient's release, and a general hospital shall record the changes, including the information referenced in subsection B of this section, in the patient's medical record within 24 hours of such a change.
- E. Prior to discharging a patient who has designated an individual pursuant to subsections A or D of this section, a general hospital shall:
 - 1. Notify the designated individual of the patient's discharge,
 - 2. Provide the designated individual with a copy of the patient's discharge plan and instructions and information regarding any follow-up care, treatment, or services that the designated individual will provide; and
 - 3. Consult with the designated individual regarding the designated individual's ability to provide the care, treatment, or services.
- F. The discharge plan prescribed in subdivision E 2 of this section shall include:
 - 1. The name and contact information of the designated individual;
 - 2. A description of follow-up care, treatment, and services that the patient requires; and
 - 3. Information, including contact information, about any health care, long-term care, or other community-based services and supports necessary for the implementation of the patient's discharge plan.

G. A general hospital shall include a copy of the discharge plan and any instructions or information provided to the designated individual in the patient's medical record.

Form: TH-04

- H. A general hospital shall provide each individual designated pursuant to subsection A or D of this section the opportunity for a demonstration of specific follow-up care tasks that the designated individual will provide to the patient in accordance with the patient's discharge plan prior to the patient's discharge, including opportunity for the designated individual to ask questions regarding the performance of follow-up care tasks in a culturally competent manner and in the designated individual's native language.
- I. A general hospital shall establish protocols to ensure that any patient scheduled to receive an elective surgical procedure for which the patient can reasonably be expected to require outpatient physical therapy as a follow-up treatment after discharge is informed that the patient:
 - 1. Is expected to require outpatient physical therapy as a follow-up treatment; and
 - 2. Will be required to select a physical therapy provider prior to being discharged from a general hospital.

INTENT: The intent of the change is to have all of the inpatient discharge planning information located in the part of the regulatory chapter where inpatient services are addressed.

RATIONALE: The rationale for the change is that the regulation should be in conformity with statutory/legislative mandates and that many of these requirements were incorrectly located in the part of the regulatory chapter for hospitals that do not provide inpatient services.

LIKELY IMPACT: The likely impact of the change is reduced confusion for general hospitals about inpatient discharge

	ı		was wine was unto an all whom the sylvery language.
			requirements and where they are located in 12VAC5-410.
410-370	N/A	12VAC5-410-370. Medical records. * * * E. Provisions shall be made for the safe storage of medical records er accurate and legible reproductions thereof according to § 32.1-127.1:03 of the Code of Virginia and the Health Insurance Portability and Accountability Act, or HIPAA (42 USC § 1320d et seq.). F. All medical records either original or accurate reproductions shall be preserved for a minimum of five years following discharge of the patient. 1. Records of minors shall be kept for at least five years after such minor has reached the age of 18 years. 2. Birth and death information shall be retained for 10 years in accordance with § 32.1-274 of the Code of Virginia.	CHANGE: The Board is proposing the following change: 12VAC5-410-370. Medical records. * * * E. Provisions shall be made for the safe storage of medical records er and the accurate and legible reproductions thereof of medical records according to § 32.1-127.1:03 of the Code of Virginia and the Health Insurance Portability and Accountability Act, or HIPAA (42 USC § 1320d et seq.) (Pub. L. No. 104-191). F. All medical records either original or accurate reproductions shall be preserved for a minimum of five years following discharge of the patient. 1. Records of minors shall be kept for at least five years after such minor has reached the age of 18 years. 2. Birth and death information shall be retained for 10 years in accordance with § 32.1-274 of the Code of Virginia. 3. Record of abortions and proper information for the issuance of a fetal death certificate shall be furnished the Office of Vital Records, Virginia Department of Health, as required by law. G. A general hospital that makes health records, as defined in § 32.1-127.1:03 of the Code of Virginia, of patients who are minors available to the patient's parent or guardian through the secure website, unless the general hospital cannot make the health record available: 1. In a manner that prevents disclosure of information, the disclosure of which has been denied pursuant to subsection F of § 32.1-127.1:03 of the Code of Virginia; or

			2. Because the consent required in accordance with subsection E of § 54.1-2969 of the Code of Virginia has not been provided.
			INTENT: The intent of the change is to correct an erroneous statutory citation, to require that hospitals are capable of both safe storage and accurate reproduction of medical records, to update the regulatory text to match the style guidelines, to mirror fetal death reporting provisions for outpatient surgical hospitals, and to describe minimum standards for giving parent's or guardian's electronic access to their minor's medical records.
			RATIONALE: The rationale for the change is that statutory references should be accurate, that fetal death reporting should not be different between general hospitals and outpatient surgical hospitals, that hospitals should not have the discretion to choose between whether to provide safe storage or accurate reproduction of medical records, that the style guidelines ensure more intelligible regulatory text, and that the regulation should be in conformity with Chapter 218 of the 2022 Acts of Assembly.
			LIKELY IMPACT: The likely impact of the change is reduced confusion for general hospitals regarding parental/guardian electronic access to a minor patient's medical records.
410-380	N/A	12VAC5-410-380. Nursing service.	CHANGE: The Board is proposing the following change:
		C. All nursing services shall be directly provided by an appropriately qualified registered nurse or licensed practical nurse, except for those nursing tasks that may be delegated by a registered nurse according to 18VAC90-20-420 through 18VAC90-20-460 of the regulation of the Virginia Board of Nursing with a plan developed and implemented by the hospital. D. Nursing personnel shall be assigned to patient care units	12VAC5-410-380. Nursing service. * * * C. All nursing services shall be directly provided by an appropriately qualified registered nurse or licensed practical nurse, except for those nursing tasks that may be delegated by a registered nurse according to 18VAC90-20-420 18VAC90-19-240 through 18VAC90-20-460 18VAC90-19-280 of the regulation of the Virginia Board of Nursing with a plan developed and implemented by the hospital.

	in a manner that minimizes the risk of cross infection and accidental contamination.	D. Nursing personnel shall be assigned to patient care units in a manner that minimizes the risk of cross infection and accidental contamination. E. Each hospital shall quarterly report to the department no later than 30 calendar days after January 1st, April 1st, July 1st, and October 1st:
		1. The total number of certified sexual assault nurse examiners employed by the hospital; and 2. The location, including street address, and contact information for each location at which such certified sexual assault nurse examiner provides services. Each hospital shall report the information required by this subsection to the Office of Family Health Services, Virginia Department of Health.
		INTENT: The intent of the change is to update regulatory references and to describe what hospitals should report, when they should report, and to whom they should report data regarding SANEs they employ.
		RATIONALE: The rationale for the change is that regulatory references should be accurate and the regulations should be in conformity with Chapter 1088 of the 2020 Acts of Assembly.
		LIKELY IMPACT: The likely impact of the change is reduced confusion for hospitals about their reporting responsibilities and what regulations apply to them and improved consistency in the data being reported.
410-442 N/A	12VAC5-410-442. Obstetric service design and equipment	CHANGE: The Board is proposing the following change:
	criteria. A. Renovation or construction of a hospital's obstetric unit shall be consistent with (i) section 2.2-2.9 of Part 2 of the 2018 Guidelines for Design and Construction of Hospitals of the Facility Guidelines Institute pursuant to § 32.1-127.001 of the Code of Virginia and (ii) the	12VAC5-410-442. Obstetric service design and equipment criteria. A. Renovation or construction of a hospital's obstetric unit shall be consistent with (i) section 2.2-2.9 2.2-2.10 of Part 2 of the 2018 Guidelines for Design and Construction of Hospitals, 2022 Edition of the (The Facility Guidelines Institute) pursuant to § 32.1-127.001 of the Code of

		Virginia Uniform Statewide Building Code (13VAC5-63).	Virginia and (ii) the Virginia Uniform Statewide Building Code (13VAC5-63).
			INTENT: The intent of the change is to update the design and construction guidelines to the recently published 2022 edition.
			RATIONALE: The rationale for the change is that the regulation should be in conformity with the mandates in Chapters 177 and 222 of the 2005 Acts of Assembly.
			LIKELY IMPACT: The likely impact of the change is reduced confusion about which edition of the FGI guidelines general hospitals should reference.
410-444	N/A	12VAC5-410-444. Newborn service medical direction;	CHANGE: The Board is proposing the following change:
		service medical direction; physician consultation and coverage; nursing direction, nurse staffing and coverage; policies and procedures. * * * B. The duties and responsibilities of the medical directors of all levels of newborn service shall include, but not be limited to the: * * * F. The nursing direction, staff and coverage required for the general level newborn service shall be as follows: * * * 2. The nursing director's responsibilities shall include, but not be limited to: * * * H. The nursing direction, staff and coverage for the specialty level newborn service	following change: 12VAC5-410-444. Newborn service medical direction; physician consultation and coverage; nursing direction, nurse staffing and coverage; policies and procedures. * * * * B. The duties and responsibilities of the medical directors of all levels of newborn service shall include, but not be limited to the: * * * * F. The nursing direction, staff and coverage required for the general level newborn service shall be as follows: * * * 2. The nursing director's responsibilities shall include, but not be limited to: * * * H. The nursing direction, staff and coverage for the specialty level newborn service shall be the same as the lower level newborn service levels with the
		shall be the same as the lower level newborn service levels with the following exceptions:	following exceptions: 1The responsibilities of the nurse manager shall include, but not be limited to:

1. ...The responsibilities of the nurse manager shall include, but not be limited to:

* * *

K. The policies and procedures for the general level nursery and all higher levels of newborn services shall include, but not be limited to:

* * *

3. ...The collaboration agreements shall include, but not be limited to:

* * *

- 17. The management of mothers who utilize breast milk with their newborns. Breast milk shall be collected in aseptic containers. dated, stored under refrigeration and consumed or disposed of within 24-48 hours of collection if the breast milk has not been frozen. This policy pertains to breast milk collected while in the hospital or at home for hospital use.
- 18. Preparation and use of formula including, but not limited to:

* * *

L. The additional policies and procedures required for the intermediate level newborn service shall include, but not be limited to:

* * *

M. The additional policies and procedures required for the specialty level newborn service shall include, but not be limited to:

* * *

N. The additional policies and procedures required for the

* * *

K. The policies and procedures for the general level nursery and all higher levels of newborn services shall include, but not be limited to:

* * *

3. ...The collaboration agreements shall include, but not be limited to:

Form: TH-04

* * *

- 17. The management of mothers who utilize breast milk with their newborns. Breast milk shall be collected in aseptic containers, dated, stored under refrigeration and consumed or disposed of within 24-48 96 hours of collection if the breast milk has not been frozen. This policy pertains to breast milk collected while in the hospital or at home for hospital use.
- 18. Preparation and use of formula including, but not limited to:

* * *

L. The additional policies and procedures required for the intermediate level newborn service shall include, but not be limited to:

* * *

M. The additional policies and procedures required for the specialty level newborn service shall include, but not be limited to:

* * *

N. The additional policies and procedures required for the subspecialty level newborn service shall include, but not be limited to:

* * *

INTENT: The intent of the change is to update breast milk storage requirements to match current recommendations from the CDC and to update the regulatory text to match the style guidelines.

RATIONALE: The rationale for the change is that regulation should reference

		subspecialty level newborn service shall include, but not be limited to: * * *	current clinical practices as recommended by subject matter experts and that the style guidelines ensure more intelligible regulatory text.
			LIKELY IMPACT: The likely impact of the change is reduced confusion for general hospitals regarding breast milk storage.
410-445	N/A	12VAC5-410-445. Newborn service design and equipment criteria.	CHANGE: The Board is proposing the following change:
		A. Construction or renovation of a hospital's nursery	12VAC5-410-445. Newborn service design and equipment criteria.
		shall be consistent with (i) section 2.2-2.10 of Part 2 of the 2018 Guidelines for Design and Construction of Hospitals of the Facility Guidelines Institute pursuant to § 32.1-127.001 of the Code of Virginia and (ii) the Virginia Uniform Statewide Building Code (13VAC5-63). Hospitals with higher-level nurseries shall comply with section 2.2-2.8 of Part 2 of the 2018 edition of the guidelines as applicable.	A. Construction or renovation of a hospital's nursery shall be consistent with (i) section 2.2-2.10 2.2-2.11 of Part 2 of the 2018 Guidelines for Design and Construction of Hospitals, 2022 Edition of the (The Facility Guidelines Institute) pursuant to § 32.1-127.001 of the Code of Virginia and (ii) the Virginia Uniform Statewide Building Code (13VAC5-63). Hospitals with higher-level nurseries shall comply with section 2.2-2.8 2.2-2.9 of Part 2 of the 2018 2022 edition of the guidelines as applicable. * * * INTENT: The intent of the change is to update the design and construction
			guidelines to the recently published 2022 edition.
			RATIONALE: The rationale for the change is that the regulation should be in conformity with the mandates in Chapters 177 and 222 of the 2005 Acts of Assembly.
			LIKELY IMPACT: The likely impact of the change is reduced confusion about which edition of the FGI guidelines general hospitals should reference.
410-447	N/A	12VAC5-410-447. Combined obstetric and clean gynecological service;	CHANGE: The Board is proposing the following change:
		infection control. A. A hospital may combine obstetric and clean	12VAC5-410-447. Combined obstetric and clean gynecological service; infection control.
		gynecological servicesThe policies and procedures shall be	A. A hospital may combine obstetric and clean gynecological servicesThe

approved by the medical and nursing staff of these services and adopted by the governing body and shall include, but not limited to the following requirements:

* * *

B. In addition to the infection control requirements specified in 12VAC5-410-490...The policies and procedures shall be adopted by the governing body and shall include, but not be limited to, the following:

* * *

- 2. Written criteria for the isolation or segregation mothers of and newborns. in accordance with Guidelines for Perinatal Care (American Academy Pediatrics/American College of Obstetricians and Gynecologists) and Control Communicable Diseases in Man (American Public Health Association) to include at least the following categories:
- 3. Written policies and procedures for the isolation of patients in accordance with Guidelines for Perinatal Care (AAP/ACOG) and Control Communicable Diseases Man (American Public Health Association) including, but not limited to, the following:
- 7. Techniques of patient care, including handwashing and the

policies and procedures shall be approved by the medical and nursing staff of these services and adopted by the governing body and shall include, but not limited to the following requirements:

Form: TH-04

* * *

B. In addition to the infection control requirements specified in 12VAC5-410-490...The policies and procedures shall be adopted by the governing body and shall include, but not be limited to, the following:

* * *

2. Written criteria for the isolation or segregation of mothers and newborns, in accordance with Guidelines for Perinatal Care. 8th Edition, 2017, (American Academy of Pediatrics/American College of Obstetricians and Gynecologists) and Control of Communicable Diseases in Man Manual, 21st Edition, 2022 (American Public Health Association) to include at least the following categories:

* * * *
Written polici

policies procedures for the isolation of patients in accordance with Guidelines for Perinatal Care, 8th Edition. 2017 (AAP/ACOG) (American Academy of Pediatrics/American College of Obstetricians and Gynecologists) and Control of Communicable Diseases in Man Manual, 21st Edition, 2022 (American Public Health Association) including, but not limited to, the following:

* * *

7. Techniques of patient care, including handwashing and the use of protective clothing such as gowns, masks, and gloves; and 8. Infection control in the nursery, including but not limited to:

* * *

INTENT: The intent of the change to update the regulatory text to match the

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		use of protective clothing such as gowns, masks, and gloves; and * * *	style guidelines and to cite the current editions of the relevant clinical texts. RATIONALE: The rationale for the change is that the style guidelines ensure more intelligible regulatory text, that the regulation should be in conformity with the Virginia Code Commission's regulation on documents incorporated by reference, and that general hospitals should be relying on current clinical texts about infection prevention and control. LIKELY IMPACT: The likely impact of the change is general hospitals being able to utilize current clinical texts about infection prevention and control while remaining in compliance with the applicable regulations.
N/A	410-465	None	CHANGE: The Board is proposing the following change: 12VAC5-410-465. Long-term care nursing services. A. The provisions of this section shall apply to a general hospital's long-term care nursing unit if that unit is a certified nursing facility. The general hospital shall be responsible for ensuring its long-term care nursing unit meets the requirements of this section. B. For the purposes of this section, "resident" means any person admitted to a general hospital's long-term care nursing unit. C. A long-term care nursing unit shall fully disclose to the applicant for admission the unit's admissions policies, including any preferences given. D. A long-term care nursing unit shall train, or arrange for training of, all employees who work in the long-term care unit and who are mandated to report adult abuse, neglect, or exploitation pursuant to § 63.2-1606 of the Code of Virginia on such reporting procedures and the consequences for failing to make a required report. E. A long-term care nursing unit shall register with the Department of State Police to receive notice of the registration, reregistration, or verification of

registration information of any person required to register with the Sex Offender and Crimes Against Minors Registry pursuant to Chapter 9 (§ 9.1-900 et seq.) of Title 9.1 of the Code of Virginia within the same or a contiguous zip code area in which the long-term care nursing unit is located, pursuant to § 9.1-914 of the Code of Virginia.

Form: TH-04

F. If a long-term care nursing unit anticipates a potential resident will have a length of stay greater than three days or in fact stays longer than three days, the long-term care nursing unit shall ascertain, prior to admission, whether the potential resident is required to register with the Sex Offender and Crimes Against Minors Registry pursuant to Chapter 9 (§ 9.1-900 et seq.) of Title 9.1 of the Code of Virginia.

G. Upon the request of the unit's family council, a long-term care nursing unit shall send notices and information about the family council mutually developed by the family council and the administration of the unit, and provided to the unit for such purpose, to the listed responsible party or a contact person of the resident's choice up to six times per year.

- 1. Such notices may be included together with a monthly billing statement or other regular communication.
- 2. Notices and information shall also be posted in a designated location within the unit.
- 3. No family member of a resident or other resident representative shall be restricted from participating in meetings in the unit with the families or resident representatives of other residents in the unit.

H. A general hospital shall maintain for its long-term care unit liability insurance coverage in a minimum amount of \$1 million, and professional liability coverage in an amount at least equal to the recovery limit set forth in § 8.01-581.15 of the Code of Virginia, to compensate residents or individuals for

Form: TH-04 injuries and losses resulting from the negligent or criminal acts of the unit. I. During a public health emergency related to COVID-19, a long-term care unit shall establish a protocol to allow each resident to receive visits, consistent with guidance from the CDC and as directed by CMS and the board, which shall include: 1. Provisions describing: a. The conditions, including conditions related to the presence of COVID-19 in the long-term care nursing unit and community, under which in-person visits will be allowed and under which inperson visits will not be allowed and visits will be required to be virtual; b. The requirements with which in-person visitors will be required to comply to protect the health and safety of the residents and staff of the long-term care nursing unit; c. The types of technology, including interactive audio or video technology, and the staff support necessary to ensure visits are provided as required by this subsection; <u>and</u> d. The steps the long-term care unit will take in the event of a technology failure, service interruption, or documented emergency that prevents visits from occurring required by this subsection; 2. A statement of the frequency with which visits, including virtual and in-person, appropriate, will be allowed, which shall be at least once every 10 calendar days for each resident;

3. A provision authorizing a

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		personal representative to waive or limit visitation, provided that such waiver or limitation is included in the resident's health record; and
		4. A requirement that the general hospital publish on its website or communicate to each resident or the resident's authorized representative, in writing or via electronic means, the long-term care unit's plan for providing visits to residents as required by this
		subsection. J. Unless the vaccination is medically contraindicated or the resident declines the offer of vaccination, a general hospital shall provide, or arrange for, the administration to the residents of an annual influenza vaccination and a pneumococcal vaccination in accordance with the following recommendations of
		ACIP: 1. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2022–23 Influenza Season, MMWR 71 (1), 2022,
		CDC; 2. Use of 15-Valent Pneumococcal Conjugate Vaccine and 20-Valent Pneumococcal Conjugate Vaccine Among U.S. Adults: Updated Recommendations of ACIP — United States, MMWR 71 (4), 2022, CDC;
		3. Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults Aged >65 Years: Updated Recommendations of ACIP, MMWR 68 (46), 2019, CDC;
		4. Intervals Between PCV13 and PPSV23 Vaccines: Recommendations of ACIP, MMWR 64 (15), 2015, CDC;

	<u>5. Use of 13-Valent</u>
	<u>Pneumococcal</u> <u>Conjugate</u>
	<u>Vaccine</u> and 23-Valent
	Pneumococcal Polysaccharide
	Vaccine Among Adults Aged >65
	Years: Recommendations of
	ACIP, MMWR 63 (37), 2014,
	CDC;
	6. Use of 13-Valent
	Pneumococcal Conjugate
	Vaccine and 23-Valent
	Pneumococcal Polysaccharide
	Vaccine Among Children Aged
	6–18 Years with
	Immunocompromising
	Conditions: Recommendations of
	ACIP, MMWR 62 (25), 2013,
	CDC;
	7. Use of 13-Valent
	Pneumococcal Conjugate
	Vaccine and 23-Valent
	Pneumococcal Polysaccharide
	Vaccine for Adults with
	<u>Immunocompromising</u>
	Conditions: Recommendations of
	ACIP, MMWR 61 (40), 2012,
	CDC;
	8. Prevention of Pneumococcal
	<u>Disease Among Infants and</u>
	<u>Children</u> — Use of 13-Valent
	<u>Pneumococcal</u> <u>Conjugate</u>
	Vaccine and 23-Valent
	Pneumococcal Polysaccharide
	Vaccine: Recommendations of
	ACIP, MMWR 59 (RR-11), 2010,
	CDC; and
	9. Updated Recommendations
	for Prevention of Invasive
	Pneumococcal Disease Among
	Adults Using the 23-Valent
	Pneumococcal Polysaccharide
	Vaccine (PPSV23), MMWR 59
	(34), 2010, CDC.
	NTENT: The intent of the change is to
	update the general hospital requirements
	with the minimum requirements required
	by Virginia law for those general hospitals
	operating a long-term care nursing unit hat is a certified nursing facility.
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			RATIONALE: The rationale for the change is that the regulation should be in conformity with Va. Code § 32.1-127.
			LIKELY IMPACT: The likely impact of the change is increased or new awareness by general hospitals that their long-term care nursing units that are certified nursing facilities have state-specific requirements they must meet.
410-650	N/A	12VAC5-410-650. General building and physical plant information. A. All construction of new buildings and additions, renovations, alterations or repairs of existing buildings for occupancy as a hospital shall conform to state and local codes, zoning ordinances, and the Virginia Uniform Statewide Building Code (13VAC5-63). In addition, hospitals shall be designed and constructed consistent with Part 1 and Part 2 of the 2018 Guidelines for Design and Construction of Hospitals of the Facility Guidelines Institute pursuant to § 32.1-127.001 of the Code of Virginia. B. Architectural drawings and specifications for all new construction or for additions, alterations, or renovations to any existing building shall be dated, stamped with professional seal, and signed by the architect. The architect shall certify that the drawings and specifications were prepared to conform to the Virginia Uniform Statewide Building Code (13VAC5-63) and be consistent with Part 1 and Part 2 of the 2018 Guidelines for Design and Construction of Hospitals of the Facility Guidelines Institute.	CHANGE: The Board is proposing the following change: 12VAC5-410-650. General building and physical plant information. A. All construction of new buildings and additions, renovations, or alterations or repairs of existing buildings for occupancy as a hospital shall conform to state and local codes, zoning ordinances, and the Virginia Uniform Statewide Building Code (13VAC5-63). In addition, hospitals shall be designed and constructed consistent with Part 1 and Part 2 of the 2018 Guidelines for Design and Construction of Hospitals, 2022 Edition of the (The Facility Guidelines Institute), as amended by the November 2022 Errata for Guidelines for Design and Construction of Hospitals, 2022 Edition (The Facility Guidelines Institute), and if applicable, Chapter 2.8 of Part 2 of the Guidelines for Design and Construction of Outpatient Facilities, 2022 Edition (The Facility Guidelines Institute), as amended by the November 2022 Errata for Guidelines for Design and Construction of Outpatient Facilities, 2022 Edition (The Facility Guidelines Institute), as amended by the November 2022 Errata for Guidelines for Design and Construction of Outpatient Facilities, 2022 Edition (The Facility Guidelines Institute) pursuant to § 32.1-127.001 of the Code of Virginia. B. Architectural drawings and specifications for all new construction or for additions, alterations, or renovations to any existing building shall be dated, stamped with professional seal, and signed by the architect. The architect shall certify that the drawings and specifications were prepared to conform
			to the Virginia Uniform Statewide Building Code (13VAC5-63) and be consistent with Part 1 and Part 2 of the 2018

			Cuidalinas fan Dasiana and Construction (
			Guidelines for Design and Construction of Hospitals, 2022 Edition of the (The
			Facility Guidelines Institute), as amended
			by the November 2022 Errata for
			Guidelines for Design and Construction of
			Hospitals, 2022 Edition (The Facility
			Guidelines Institute), and if applicable,
			Chapter 2.8 of the Guidelines for Design
			and Construction of Outpatient Facilities,
			2022 Edition (The Facility Guidelines
			Institute), as amended by the November
			2022 Errata for Guidelines for Design and Construction of Outpatient Facilities, 2022
			Edition (The Facility Guidelines Institute).
			<u>Edition (The Facility Odidelines institute)</u> .
			INTENT: The intent of the change is to update the design and construction guidelines to the recently published 2022 editions, including the move of provisions related to freestanding emergency departments from the hospital guidelines to the outpatient facility guidelines.
			RATIONALE: The rationale for the change is that the regulation should be in conformity with the mandates in Chapters 177 and 222 of the 2005 Acts of
			Assembly.
			LIKELY IMPACT: The likely impact of the change is reduced confusion about which
			editions of the FGI guidelines general hospitals should reference.
410-760	N/A	12VAC5-410-760. Long-term	CHANGE: The Board is proposing the
		care nursing units.	following change:
		Construction and renovation of long-term care nursing units,	12VAC5-410-760. Long-term care nursing units.
		including intermediate and	Construction and renovation of long-
		skilled nursing care nursing units, shall be designed and	term care nursing units, including
		constructed consistent with	intermediate and skilled nursing care
		section 2.2-2.13 of Part 2 of the	nursing units, shall be designed and
		2018 Guidelines for Design and	constructed consistent with section 2.2-
		Construction of Hospitals of the	2.13 2.2-2.15 of Part 2 of the 2018
		Facility Guidelines Institute	Guidelines for Design and Construction of
		pursuant to § 32.1-127.001 of the	Hospitals, 2022 Edition of the (The
		Code of Virginia.	Facility Guidelines Institute) pursuant to §
		The architect shall certify	32.1-127.001 of the Code of Virginia.
		that the drawings and	The architect shall certify that the
		specifications were prepared to	drawings and specifications were prepared to conform to the Virginia
		conform to the Virginia Uniform Statewide Building Code	Uniform Statewide Building Code
	l	Statewide Building Code	Children Stateward Ballating Code

		(13VAC5-63) and be consistent with section 2.2-2.13 of Part 2 of the 2018 Guidelines for Design and Construction of Hospitals of the Facility Guidelines Institute	(13VAC5-63) and be consistent with section 2.2-2.13 2.2-2.15 of Part 2 of the 2018 Guidelines for Design and Construction of Hospitals, 2022 Edition of the (The Facility Guidelines Institute). INTENT: The intent of the change is to update the design and construction guidelines to the recently published 2022 edition. RATIONALE: The rationale for the change is that the regulation should be in conformity with the mandates in Chapters 177 and 222 of the 2005 Acts of Assembly. LIKELY IMPACT: The likely impact of the change is reduced confusion about which edition of the FGI guidelines general hospitals should reference.
410-1170	N/A	Part IV Outpatient Surgical Hospitals: Organization, Operation, and Design Standards for Existing and New Facilities 12VAC5-410-1170. Policy and procedures manual. * * * B. A copy of approved policies and procedures and revisions thereto shall be made available to the OLC upon request. C. Each outpatient surgical hospital shall establish a protocol relating to the rights and responsibilities of patients based on Joint Commission on Accreditation of Healthcare Organizations' Standards for Ambulatory Care (2000 Hospital Accreditation Standards, January 2000). The protocol shall include a process reasonably designed to inform patients of their rights and responsibilities. Patients shall be given a copy of their rights and responsibilities upon admission.	CHANGE: The Board is proposing the following change: Part IV Organization and Operation of Outpatient Surgical Hospitals: Organization, Operation, and Design Standards for Existing and New Facilities 12VAC5-410-1170. Policy and procedures manual. * * * B. An outpatient surgical hospital shall provide A a copy of approved policies and procedures and any subsequent revisions—thereto shall be made available to the OLC upon request. C. Each outpatient surgical hospital shall establish a protocol relating to the rights and responsibilities of patients based on 42 C.F.R. § 416.50 Joint Commission—on—Accreditation—of Healthcare Organizations' Standards for Ambulatory—Care—(2000—Hospital Accreditation Standards, January 2000). The protocol shall include a process reasonably designed to inform patients of their rights and responsibilities. Patients shall be given a copy of their rights and responsibilities.

- D. If the Governor has declared a public health emergency related to the novel coronavirus (COVID-19), each outpatient surgical hospital shall allow a person with a disability who requires assistance as a result of such disability to be accompanied by a designated support person at any time during which health care services are provided.
 - 1. A designated support person shall not be subject to anv restrictions on visitation adopted such bν outpatient surgical hospital. However, such support designated person may be required comply with reasonable requirements of the outpatient surgical hospital adopted protect the health and safety of patients and staff of the outpatient surgical hospital.
 - 2. Every outpatient surgical hospital shall establish policies applicable to designated support persons and shall:
 - a. Make such policies available to the public on a website maintained by the outpatient surgical hospital; and
 - b. Provide such policies, in writing, to the patient at such time as health care services are provided.
- E. Each outpatient surgical hospital shall obtain a criminal history record check pursuant to

D. If the Governor has declared a public health emergency related to the novel coronavirus (COVID-19), each outpatient surgical hospital shall allow a person with a disability who requires assistance as a result of such disability to be accompanied by a designated support person at any time during which health care services are provided.

- 1. A designated support person shall not be subject to any restrictions on visitation adopted by such outpatient surgical hospital. However, such designated support person may be required to comply with all reasonable requirements of the outpatient surgical hospital adopted to protect the health and safety of patients and staff of the outpatient surgical hospital.
- 2. Every outpatient surgical hospital shall establish policies applicable to designated support persons and shall:
 - a. Make such policies available to the public on a website maintained by the outpatient surgical hospital; and
 - b. Provide such policies, in writing, to the patient at such time as health care services are provided.
- E. D. Each outpatient surgical hospital shall obtain a criminal history record check pursuant to § 32.1-126.02 of the Code of Virginia on any compensated employee not licensed by the Board of Pharmacy whose job duties provide access to controlled substances within the outpatient surgical hospital pharmacy.
- **INTENT:** The intent of the change is to update the Part's name to match Part II and not be confused with Part V, to use a more relevant basis for patient rights protocols, and to create a new section of regulation that separately addresses designated support persons.

		§ 32.1-126.02 of the Code of Virginia on any compensated employee not licensed by the Board of Pharmacy whose job duties provide access to controlled substances within the outpatient surgical hospital pharmacy.	RATIONALE: The rationale for the change is that the current Part name gives the incorrect impression it addresses design and construction standards when it does not, that a document from 2000 is an out-of-date basis for patient rights, that over 95% of outpatient surgical hospitals in Virginia are already complying with 42 C.F.R. § 416.50 as a condition for coverage participation in Medicare, and that designated support persons is a topics requiring significantly more detail that, if it were to continue to be addressed in the present section of regulation, would make the section more difficult to read. LIKELY IMPACT: The likely impact of the change is improved readability of this regulatory section and improved ease in locating provisions addressing designated support persons and design and constructions for outpatient surgical hospitals.
410- 1170(D)	410-1171	See row above about proposed changes to 410-1170	CHANGE: The Board is proposing the following change: 12VAC5-410-1171. Persons with a disability; designated support person in outpatient surgical hospital. A. For the purposes of this section, "admission" means accepting a person for observation. B. An outpatient surgical hospital shall allow a person with a disability who requires support and assistance necessary due to the specifics of the person's disability to be accompanied by a DSP who will provide support and assistance necessary due to the specifics of the person's disability to the person with a disability during an admission. 1. In any case in which the duration of the admission lasts more than 24 hours, the person with a disability may designate more than one DSP. 2. No outpatient surgical hospital shall be required to allow more than one DSP to be present with a person with a disability at any time.

- C. An outpatient surgical hospital may:
 - 1. Not subject a DSP to any restrictions on visitation;

- 2. Require a DSP to comply with all reasonable requirements of an outpatient surgical hospital adopted to protect the health and safety of the person with a disability; the DSP; the staff and other patients of, or visitors to, an outpatient surgical hospital; and the public; and
- 3. Restrict a DSP's access to specified areas of and movement on the premises of an outpatient surgical hospital when such restrictions are determined by an outpatient surgical hospital to be reasonably necessary to protect the health and safety of the person with a disability; the DSP; the staff and other patients of, or visitors to, an outpatient surgical hospital; and the public.
- D. An outpatient surgical hospital may request that a person with a disability provide documentation indicating that he is a person with a disability.
 - 1. If the person with a disability fails, refuses, or is unable to provide documentation requested pursuant to subsection D of this section, an outpatient surgical hospital may perform an objective assessment of the person to determine whether he is a person with a disability.
 - 2. If an outpatient surgical hospital fails to perform an objective assessment pursuant to subdivision D 1 of this section, an outpatient surgical hospital may not prohibit a DSP from accompanying a person with a disability for the purpose of providing support and assistance necessary due to the specifics of the person's disability.
- E. An outpatient surgical hospital shall

1. Establish protocols to inform patients, at the time of admission, of the right of a person with a disability who requires support and assistance necessary due to the specifics of the person's disability to be accompanied by a DSP for the purpose of providing support and assistance necessary due to the specifics of the person's disability;

Form: TH-04

- 2. Develop and make available to a patient or his guardian, authorized representative, or care provider upon request written information regarding the right of a person with a disability who requires support and assistance necessary due to the specifics of the person's disability to be accompanied by a DSP and any policies related to that right; and
- 3. Make the written information described in subdivision E 2 of this section available to the public on its website.

G. This section may not:

1. Alter the obligation of an outpatient surgical hospital to provide patients with effective communication support or other required services, regardless of the presence of a DSP or other reasonable accommodation, consistent with applicable federal or state law or regulations; and

2. Be interpreted to:

a. Prevent an outpatient surgical hospital from complying, or interfere with the ability of an outpatient surgical hospital to comply, with or cause an outpatient surgical hospital to violate any federal or state law or regulation;

b. Deem a DSP to be acting under the direction or control of an outpatient surgical hospital or as an agent of an

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			outpatient surgical hospital;
			<u>or</u>
			<u>c. Require an outpatient</u>
			surgical hospital to allow a
			DSP to perform any action or
			<u>provide any support or</u>
			assistance necessary due to
			the specifics of the person's
			disability when an outpatient
			<u>surgical hospital reasonably</u> determines that the
			determines that the performance of the action or
			provision would be:
			(1) Medically or
			<u>therapeutically</u>
			<u>contraindicated; or</u>
			(2) Would pose a threat to the
			<u>health and safety of the</u>
			person with a disability, the
			DSP, or the staff or other
			patients of, or visitors to, an
			outpatient surgical hospital.
			INTENT: The intent of the change is to
			INTENT: The intent of the change is to describe the minimum requirements for
			access to designated support persons by
			persons with disabilities in outpatient
			surgical hospitals.
			RATIONALE: The rationale for the
			change is that the regulation should be in
			conformity with Chapter 220 of the 2021 Acts of Assembly, Special Session I.
			LIKELY IMPACT: The likely impact of the
			change is reduced confusion for
			outpatient surgical hospitals about what the minimum requirements for designated
			support persons are outside of a
			Governor-declared public health
			emergency related to COVID-19.
410-	N/A	12VAC5-410-1175. Discharge	CHANGE: The Board is proposing to
1175		planning.	repeal this section.
		A. Every hospital shall	INTENT: The intent of the change is to
		provide each patient admitted as	remove provisions about discharge
		an inpatient or his legal guardian	planning in an inpatient setting from the
		the opportunity to designate an	provisions about outpatient surgical
		individual who will care for or	hospitals.
		assist the patient in his residence	
		following discharge from the	RATIONALE: The rationale for the
		hospital and to whom the hospital	change is that these discharge planning

shall provide information regarding the patient's discharge plan and any follow-up care, treatment, and services that the patient may require.

- B. Every hospital upon admission shall record in the patient's medical record:
 - 1. The name of the individual designated by the patient;
 - 2. The relationship between the patient and the person; and
 - 3. The person's telephone number and address.
- C. If the patient fails or refuses to designate an individual to receive information regarding his discharge plan and any follow-up care, treatment, and services, the hospital shall record the patient's failure or refusal in the patient's medical record.
- D. A patient may change the designated individual at any time prior to the patient's release, and the hospital shall record the changes, including the information referenced in subsection B of this section, in the patient's medical record within 24 hours of such a change.
- E. Prior to discharging a patient who has designated an individual pursuant to subsection A or D of this section, the hospital shall (i) notify the designated individual of the patient's discharge, (ii) provide designated individual with a copy of the patient's discharge plan and instructions and information regarding any follow-up care, treatment, or services that the designated individual provide, and (iii) consult with the designated individual regarding the designated individual's ability to provide the care, treatment, or

provisions were inadvertently placed in the wrong Part of this regulation and should be moved to the Part for general hospitals.

Form: TH-04

LIKELY IMPACT: The likely impact of the change is reduced confusion for hospitals and improved ease of locating the discharge planning requirements.

		services. Such discharge plan shall include:	
		The name and contact information of the designated individual;	
		A description of follow- up care, treatment, and services that the patient requires; and	
		3. Information, including contact information, about any health care, long-term care, or other community-based services and supports necessary for the implementation of the patient's discharge plan.	
		A copy of the discharge plan and any instructions or information provided to the designated individual shall be included in the patient's medical record.	
		F. The hospital shall provide each individual designated pursuant to subsection A or D of this section the opportunity for a demonstration of specific follow-up care tasks that the designated individual will provide to the patient in accordance with the patient's discharge plan prior to the patient's discharge, including opportunity for the designated individual to ask questions regarding the performance of follow-up care tasks. Such opportunity shall be provided in a culturally competent manner and in the designated individual's native language.	
N/A	410-1178	None	CHANGE: The Board is proposing the following change:
			12VAC5-410-1178. Financial assistance in outpatient surgical hospitals. A. As used in this section, "patient" and "uninsured patient" have the same meanings as ascribed to these terms in

subsection A of § 32.1-137.010 of the Code of Virginia.

- B. An outpatient surgical hospital shall make reasonable efforts to screen every uninsured patient to determine whether the individual is eligible for medical assistance pursuant to the state plan for medical assistance or for financial assistance under the outpatient surgical hospital's financial assistance policy.
- C. An outpatient surgical hospital shall inform every uninsured patient who receives services at the outpatient surgical hospital and who is determined to be eligible for assistance under the outpatient surgical hospital's financial assistance policy of the option to enter into a payment plan with the outpatient surgical hospital.
 - 1. A payment plan entered into pursuant to this subsection shall be provided to the patient in writing or electronically and shall provide for repayment of the cumulative amount owed to the outpatient surgical hospital.
 - 2. The amount of monthly payments and the term of the payment plan shall be determined based upon the patient's ability to pay.
 - 3. Any interest on amounts owed pursuant to the payment plan shall not exceed the maximum judgment rate of interest pursuant to § 6.2-302 of the Code of Virginia.
 - 4. The outpatient surgical hospital may not charge any fees related to the payment plan.
 - 5. The payment plan shall allow prepayment of amounts owed without penalty.
- D. An outpatient surgical hospital shall develop a process by which either an uninsured patient who agrees to a payment plan pursuant to subsection C of this section or the outpatient surgical hospital may request and shall be granted the opportunity to renegotiate the payment plan.

	1. Renegotiation shall include
	opportunity for a new screening in
	accordance with subsection B of
	this section.
	2. An outpatient surgical hospital
	may not charge any fees for
	renegotiation of a payment plan pursuant to this subsection.
	E. An outpatient surgical hospital shall provide written information about:
	 Its charity care policies, including:
	a. Policies related to free and discounted care;
	b. Specific eligibility criteria
	for charity care; and
	c. Procedures for applying for charity care;
	2. The availability of a payment
	plan for the payment of debt
	owed to the outpatient surgical
	hospital pursuant to subsection C of this section; and
	3. The renegotiation process described in subsection D of this
	section.
	F. To provide the information required
	by subsection F of this section, an
	outpatient hospital shall:
	1. Post the information conspicuously in public areas of
	the outpatient surgical hospital,
	including admissions or
	registration areas and associated waiting rooms;
	2. Make the information available
	to:
	a. A patient at the time of
	admission or discharge, or at
	the time services are provided; and
	b. Persons with limited
	English proficiency in
	accordance with the U.S.
	Department of Health and
	Human Services' Guidance
	to Federal Financial Assistance Recipients
	Regarding Title VI Prohibition
	Against National Origin

Discrimination Affecting Limited English Proficient Persons (August 8, 2003, 68 FR 47311), if the outpatient surgical hospital is subject to the requirements of Title VI of the Civil Rights Act of 1964 (Pub. L. No. 88-352), as amended; and 3. Include the information: a. With any billing statements sent to uninsured patients; and b. On any website maintained by the outpatient surgical hospital hospital hospital hospital hospital hospital hospital hospital hospital may not engage in any action described in §, 501(r)(6) of the Internal Revenue Code, as it was in effect on January 1, 2020, to recover a debt for medical services against any patient unless the outpatient surgical hospital has made all reasonable efforts to determine whether the patient: 1. Qualifies for medical assistance pursuant to the state plan for medical assistance pursuant to the state plan for medical assistance core 2. Is eligible for financial assistance policy. H. Nothing in this section shall be construed to: 1. Prohibit an outpatient surgical hospital, as part of its financial assistance policy, from requiring a patient to: a. Provide necessary information needed to determine eligibility for financial assistance pursuant to Title VIII or XIX of the Social Security Act (42 U.S.C. § 301.		
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Security Act (42 U.S.C. § 301		assistance pursuant to Title
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et seq.) 01-10-0.3.C. § 1071		et seq.) or 10 U.S.C. § 1071

et seq., or other programs of insurance; or b. Undertake good faith efforts to apply for and enroll in the programs of insurance for which the patient may be eligible as a condition of awarding financial assistance; 2. Require an outpatient surgical hospital to grant or continue to grant any financial assistance or payment plan pursuant to this section when: a. A patient has provided false, inaccurate, or information incomplete required for determining eligibility for the outpatient surgical hospital's financial assistance policy; or b. A patient has not undertaken good faith efforts to comply with any payment plan pursuant to this section; 3. Prohibit the coordination of benefits as required by state or federal law. **INTENT:** The intent of the change is to describe the minimum requirements for information disclosure about financial assistance, for payment plans, and for renegotiation of payment plans. **RATIONALE:** The rationale for the change is that the regulation should conform to Chapters 678 and 679 of the 2022 Acts of Assembly.

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LIKELY IMPACT: The likely impact of the change is reduced confusion for outpatient surgical hospitals about the minimum requirements for providing information about financial assistance and providing financial assistance to

patients.

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410- 1190	N/A	12VAC5-410-1190. Nursing	CHANGE: The Board is proposing the following change:
1190		staff.	Tollowing change.
		The total number of nursing personnel will vary depending	12VAC5-410-1190. Nursing staff.
		upon the number and types of	A. The total number of nursing
		patients to be admitted and the	personnel will vary depending upon the
		types of operative procedures to	number and types of patients to be
		be performed or the services	admitted and the types of operative procedures to be performed or the
		programmed.	services programmed.
		~ * *	* * *
			B. Each outpatient surgical hospital
			shall quarterly report to the department no
			later than 30 calendar days after January
			1st, April 1st, July 1st, and October 1st:
			1. The total number of certified
			sexual assault nurse examiners
			employed by the outpatient surgical hospital; and
			2. The location, including street
			address, and contact information
			for each location at which such
			<u>certified sexual assault nurse</u>
			examiner provides services.
			Each outpatient surgical hospital shall report the information required by this
			subsection to the Office of Family Health
			Services, Virginia Department of Health.
			INTENT: The intent of the change is to describe what hospitals should report,
			when they should report, and to whom
			they should report data regarding SANEs
			they employ.
			RATIONALE: The rationale for the
			change is that the regulation should be in
			conformity with Chapter 1088 of the 2020 Acts of Assembly.
			,
			LIKELY IMPACT: The likely impact of the change is reduced confusion for hospitals
			about their reporting responsibilities and
			improved consistency about the data
			being reported.
410-	N/A	12VAC5-410-1260. Medical	CHANGE: The Board is proposing the
1260		records.	following change:
		A. Medical records. An	12VAC5-410-1260. Medical records.
		accurate and complete clinical record or chart shall be	A. Medical records. An accurate and
		maintained on each patient. The	complete clinical record or chart shall be

record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. It shall include, when applicable, but not be limited to the following:

* * *

4. Confirmation of pregnancy, if applicable;

13. Patient instructions, preoperative and postoperative;

* *

- B. Provisions shall be made for the safe storage of medical records or accurate and legible reproductions thereof according to § 32.1-127.1:03 of the Code of Virginia and the Health Insurance Portability and Accountability Act, or HIPAA (42 USC § 1320d et seq.).
- C. All medical records, either original or accurate reproductions, shall be preserved for a minimum of five years following discharge of the patient.

* * *

3. Record of abortions and proper information for the issuance of a fetal death certificate shall be furnished the Division of Vital Records, Virginia Department of Health, within 10 days after the abortion.

maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. It shall include, when applicable, but not be limited to the following:

* * *

4. Confirmation of pregnancy, if applicable;

Form: TH-04

13. Patient instructions, preoperative and postoperative; and

* * *

- B. Provisions shall be made for the safe storage of medical records er and the accurate and legible reproductions thereof of medical records according to § 32.1-127.1:03 of the Code of Virginia and the Health Insurance Portability and Accountability Act, or HIPAA (42 USC § 1320d et seq.) (Pub. L. No. 104-191).
- C. All medical records, either original or accurate reproductions, shall be preserved for a minimum of five years following discharge of the patient.

3. Record of abortions and proper information for the issuance of a fetal death certificate shall be furnished to the Division Office of Vital Records, Virginia Department of Health, within 10 days after the abortion as required by law.

D. An outpatient surgical hospital that makes health records, as defined in § 32.1-127.1:03 of the Code of Virginia, of patients who are minors available to patients through a secure website shall make the health records available to the patient's parent or guardian through the secure website, unless the hospital cannot make the health record available:

1. In a manner that prevents disclosure of information, the disclosure of which has been denied pursuant to subsection F of § 32.1-127.1:03 of the Code of Virginia; or

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			2. Because the consent required in accordance with subsection E of § 54.1-2969 of the Code of Virginia has not been provided.
			INTENT: The intent of the change is to correct an erroneous statutory citation, to update the name of a business unit within VDH, to require that hospitals are capable of both safe storage and accurate reproduction of medical records, to update the regulatory text to match the style guidelines, and to describe minimum standards for giving parent's or guardian's electronic access to their minor's medical records.
			RATIONALE: The rationale for the change is that statutory references should be accurate, that VDH business units should be referred to by their current names, that hospitals should not have the discretion to choose between whether to provide safe storage or accurate reproduction of medical records, that the style guidelines ensure more intelligible regulatory text, and that the regulation should be in conformity with Chapter 218 of the 2022 Acts of Assembly.
			LIKELY IMPACT: The likely impact of the change is reduced confusion for general hospitals regarding parental/guardian electronic access to a minor patient's medical records.
410- 1350	N/A	12VAC5-410-1350. Local and state codes and standards.	CHANGE: The Board is proposing the following change:
		A. All construction of new buildings and additions, alterations, or repairs to existing buildings for occupancy as a "free-standing" outpatient hospital shall conform to state and local codes, zoning ordinances, and the Virginia Uniform Statewide Building Code (13VAC5-63). In addition, hospitals shall be designed and constructed consistent with Part 1 and sections 2.1 and 2.7 of Part 2 of the 2018 Guidelines for Design and Construction of Outpatient	12VAC5-410-1350. Local and state codes and standards. A. All construction of new buildings and additions, renovations, or alterations, or repairs to existing buildings for occupancy as a "free-standing" outpatient hospital shall conform to state and local codes, zoning ordinances, and the Virginia Uniform Statewide Building Code (13VAC5-63). In addition, hospitals shall be designed and constructed consistent with Part 1 and sections Chapters 2.1 and 2.7 of Part 2 of the 2018 Guidelines for Design and Construction of Outpatient

D	nearest regional office of the Department of Environmental Quality. * * * *	INTENT: The intent of the change is to update the design and construction guidelines to the recently published 2022 edition. RATIONALE: The rationale for the change is that the regulation should be in conformity with the mandates in Chapters 177 and 222 of the 2005 Acts of Assembly. LIKELY IMPACT: The likely impact of the change is reduced confusion about which edition of the FGI guidelines outpatient surgical hospitals should reference.
	Oocuments Incorporated by Reference (12VAC5-410)	CHANGE: The Board is proposing the following change:
E Ir	Guidelines for Design and Construction of Hospitals, 2018 Edition, Facility Guidelines nstitute, Washington D.C., http://www.fgiguidelines.org	Documents Incorporated by Reference (12VAC5-410) Control of Communicable Diseases Manual, American Public Health

Guidelines for Design and Association. 21st Edition, 2022. Construction of Outpatient https://www.apha.org Facilities, 2018 Edition, Facility Errata for Guidelines for Design and Guidelines Institute, Washington, Construction of Hospitals, The Facility D.C., https://fgiguidelines.org Guidelines Institute, 2022 Edition, https://fgiquidelines.org/quidelines/errataaddenda/ (eff. 11/2022). Errata for Guidelines for Design and Construction of Outpatient Facilities, The Facility Guidelines Institute, 2022 Edition. https://fgiquidelines.org/quidelines/errataaddenda/ (eff. 11/2022). Guidelines for Design Construction of Hospitals, 2018 Edition, Guidelines Facility Institute. Washington D.C. 2022 Edition, http://www.fgiguidelines.org https://fgiguidelines.org. Guidelines for Design and Construction of Outpatient Facilities, 2018 Edition, The Facility Guidelines Institute, Washington, D.C. 2022 Edition, https://fgiguidelines.org. Guidelines for Perinatal Care. American Academy of Pediatric/American College of Obstetricians and 2017, Gynecologists, 8th Edition, https://www.aap.org and https://www.acog.org. Intervals Between PCV13 and PPSV23 Vaccines: Recommendations of ACIP, MMWR 64 (15), 2015, CDC. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2022-23 Influenza Season, MMWR 71 (1), 2022, CDC. Prevention of Pneumococcal Disease Among Infants and Children — Use of 13-Valent Pneumococcal Conjugate Vaccine 23-Valent Pneumococcal and Polysaccharide Vaccine: Recommendations of ACIP, MMWR 59 (RR-11), 2010, CDC. Updated Recommendations Prevention of Invasive Pneumococcal Disease Among Adults Using the 23-Valent Pneumococcal Polysaccharide Vaccine (PPSV23), MMWR 59 (34), 2010, CDC.

Form: TH-04 Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults Aged >65 Years: Recommendations of ACIP, MMWR 63 (37), 2014, CDC. Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults Aged >65 Years: Updated Recommendations of ACIP, MMWR 68 (46), 2019, CDC. Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine for Adults with Immunocompromising Conditions: Recommendations of ACIP. MMWR 61 (40), 2012, CDC. Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Children Aged 6-18 Years with Immunocompromising Conditions: Recommendations of ACIP, MMWR 62 (25), 2013, CDC. Use of 15-Valent Pneumococcal Conjugate Vaccine and 20-Valent Pneumococcal Conjugate Vaccine Among U.S. Adults: Updated Recommendations of ACIP — United States, MMWR 71 (4), 2022, CDC. **INTENT:** The intent of these proposed changes is to ensure documents incorporated by reference are current and accurate. **RATIONALE:** The rationale behind these proposed changes is that hospitals should be held to current standards and quidelines.

LIKELY IMPACT: The likely impact of these proposed changes is improved patient health and safety at hospitals.

Project 6374 - Fast-Track

Department of Health

Amend Regulation After Periodic Review

12VAC5-410-10. Definitions.

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

"ACIP" means the Advisory Committee on Immunization Practices of the CDC.

"Activity of daily living" or "ADL" has the same meaning as ascribed to the term in subsection A of § 32.1-137.08 of the Code of Virginia.

"Board" means the State Board of Health.

"Business day" means any day that is not a Saturday, Sunday, legal holiday, or day on which the OLC 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.

"Campus" means the physical area that is immediately adjacent to the hospital's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other physical areas determined on an individual case basis, by the OLC in accordance with 42 C.F.R. § 413.65, to be part of the hospital's campus.

"Care provider" has the same meaning as ascribed to the term in subsection A of § 32.1-137.08 of the Code of Virginia.

"CDC" means the Centers for Disease Control and Prevention.

"Certified nursing facility" has the same meaning as ascribed to the term in § 32.1-123 of the Code of Virginia.

"Certified sexual assault nurse examiner" means a nurse who is board certified by the International Association of Forensic Nurses as either a Sexual Assault Nurse Examiner-Pediatric (SANE-P) or a Sexual Assault Nurse Examiner-Adult/Adolescent (SANE-A).

"Chief executive officer" means a job descriptive term used to identify the individual appointed by the governing body to act in its behalf in the overall management of the hospital. Job titles may include administrator, superintendent, director, executive director, president, vice-president, and executive vice-president.

"CMS" means the Centers for Medicare and Medicaid Services.

"Commissioner" means the State Health Commissioner.

"Consultant" means one who provides services or advice upon request.

"Department" means an organized section of the hospital.

"Designated support person" or "DSP" means a person who is knowledgeable about the needs of a person with a disability, and who is designated, orally or in writing, by the individual with a disability, the individual's guardian, or the individual's care provider to provide support and assistance, including physical assistance, emotional support, assistance with communication or decision making, or any other assistance necessary as a result of the person's disability, to the person with a disability at any time during which health care services are provided has the same meaning as ascribed to the term in subsection A of § 32.1-137.08 of the Code of Virginia and is not a visitor.

"Direction" means authoritative policy or procedural guidance for the accomplishment of a function or activity.

<u>"Emergency department" means a department of the hospital that provides emergency</u> services and is located on, or within a 35-mile radius of, the campus of the hospital.

"Facilities" means building(s), equipment, and supplies necessary for implementation of services by personnel.

"Full-time" means a 37-1/2 to 40 hour work week.

"General hospital" means institutions a hospital as defined by § 32.1-123 of the Code of Virginia with an organized medical staff; with permanent facilities that include inpatient beds; and with medical services, including physician services, dentist services and continuous nursing services, to provide diagnosis and treatment for patients who have a variety of medical and dental conditions that may require various types of care, such as medical, surgical, and maternity.

"General hospital accrediting organization" means the Accreditation Commission for Health Care, the Center for Improvement in Healthcare Quality, DNV - Healthcare, The Joint Commission, or any accrediting organization that has been granted deeming authority for hospitals by CMS.

"Home health care department/service/program" "Home health services" means a formally structured organizational unit of the hospital that is designed to provide health services to patients in their place of residence and meets Part II (12VAC5-381-150 et seq.) of the regulations adopted by the board for the licensure of home care organizations in Virginia.

"Hospital" has the same meaning ascribed to the term in § 32.1-123 of the Code of Virginia and includes general hospitals and outpatient surgical hospitals.

"Inspector" means an individual employed by or contracted by the Virginia Department of Health and designated by the commissioner to conduct inspections, investigations, or evaluations.

"Long-term care nursing unit" means an organized jurisdiction of nursing service in which nursing services are provided on a continuous basis.

"Medical" means pertaining to or dealing with the healing art and the science of medicine.

"Nursing care unit" means an organized jurisdiction of nursing service in which nursing services are provided on a continuous basis.

"Nursing home" means an institution or any identifiable component of any institution as defined by has the same meaning as ascribed to the term in § 32.1-123 of the Code of Virginia with permanent facilities that include inpatient beds and whose primary function is the provision, on a continuing basis, of nursing and health related services for the treatment of patients who may require various types of long term care, such as skilled care and intermediate care.

"Nursing services" means patient care services pertaining to the curative, palliative, restorative, or preventive aspects of nursing that are prepared or supervised by a registered nurse.

"Office of Licensure and Certification" or "OLC" means the Office of Licensure and Certification of the Virginia Department of Health.

"Operating room" means a room in a hospital designated for the performance of surgery.

"Organized" means administratively and functionally structured.

"Organized medical staff" means a formal organization of physicians and dentists with the delegated responsibility and authority to maintain proper standards of medical care and to plan for continued betterment of that care.

"Outpatient <u>surgical</u> hospital" means <u>institutions</u> <u>a hospital</u> <u>as defined by § 32.1-123 of the Code of Virginia</u> that primarily <u>provide provides</u> facilities for the performance of surgical procedures on outpatients. Such patients may require treatment in a medical environment exceeding the normal capability found in a physician's office, but do not require inpatient hospitalization.

"Outpatient surgical hospital accrediting organization" means the Accreditation Commission for Ambulatory Health Care, the Accreditation Commission for Health Care, the American Association for Accreditation of Ambulatory Surgery Facilities, The Joint Commission, or any accrediting organization that has been granted deeming authority for ambulatory surgical centers by CMS.

"Ownership/person" means any individual, partnership, association, trust, corporation, municipality, county, governmental agency, or any other legal or commercial entity that owns or controls the physical facilities and/or manages or operates a hospital.

"Person with a disability" has the same meaning as ascribed to the term in subsection A of § 32.1-137.08 of the Code of Virginia.

"Rural hospital" means any general hospital in a county classified by the federal Office of Management and Budget (OMB) as rural, any hospital designated as a critical access hospital, any general hospital that is eligible to receive funds under the federal Small Rural Hospital Improvement Grant Program, or any general hospital that notifies the commissioner of its desire to retain its rural status when that hospital is in a county reclassified by the OMB as a metropolitan statistical area as of June 6, 2003.

"Service" means a functional division of the hospital. Also used to indicate the delivery of care.

"Special hospital" means institutions as defined by § 32.1-123 of the Code of Virginia that provide care for a specialized group of patients or limit admissions to provide diagnosis and treatment for patients who have specific conditions (e.g., tuberculosis, orthopedic, pediatric, maternity).

"Special care unit" means an appropriately equipped area of the hospital where there is a concentration of physicians, nurses, and others who have special skills and experience to provide optimal medical care for patients assigned to the unit.

"Staff privileges" means authority to render medical care in the granting institution within well-defined limits, based on the individual's professional license and the individual's experience, competence, ability, and judgment.

"Support and assistance necessary due to the specifics of the person's disability" has the same meaning as ascribed to the term in subsection A of § 32.1-137.08 of the Code of Virginia.

"Surgery" has the same meaning as ascribed to the term in subsection A of § 54.1-2400.01:1 of the Code of Virginia.

"Unit" means a functional division or facility of the hospital.

124 Statutory Authority

125 §§ 32.1-12 and 32.1-127 of the Code of Virginia.

126 Historical Notes

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- Derived from VR355-33-500 § 1.1, eff. July 28, 1993; amended, Virginia Register Volume 11,
- 128 Issue 8, eff. April 1, 1995; Volume 11, Issue 16, eff. June 1, 1995; Volume 21, Issue 12, eff. May
- 9, 2005; Volume 23, Issue 10, eff. March 1, 2007; Volume 29, Issue 19, eff. June 20, 2013;
- 130 Volume 37, Issue 14, eff. March 31, 2021.

131 12VAC5-410-50. Classification.

Hospitals to be licensed shall be classified as general hospitals, special hospitals or outpatient surgical hospitals defined by 12VAC5-410-10.

134 Statutory Authority

135 §§ 32.1-12 and 32.1-127 of the Code of Virginia.

136 Historical Notes

- 137 Derived from VR355-33-500 § 1.5, eff. July 28, 1993; amended, Virginia Register Volume 11, 138 Issue 8, eff. April 1, 1995.
- 139 12VAC5-410-60. Separate license.
- A. A separate license shall be required by hospitals maintained on separate premises campuses even though they are operated under the same management. Separate license is not required for separate buildings on the same grounds campus or within the same complex of buildings or for an emergency department of a general hospital.
- B. Hospitals which have separate organized sections, units, or buildings to provide services of a classification covered by provisions of other state statutes or regulations may be required to have an additional applicable license for that type or classification of service (e.g., psychiatric, nursing home, home health services, and outpatient surgery).
- 148 Statutory Authority
- 149 §§ 32.1-12 and 32.1-127 of the Code of Virginia.
- 150 Historical Notes
- Derived from VR355-33-500 § 1.6, eff. July 28, 1993; amended, Virginia Register Volume 11,
- 152 Issue 8, eff. April 1, 1995; Volume 29, Issue 19, eff. June 20, 2013.
- 153 12VAC5-410-100. Name.
- Every hospital shall be designated by a permanent and appropriate name which that shall appear on the application for license. Any change of name shall be reported to the OLC within 30 days.
- 157 Statutory Authority
- **158** §§ 32.1-12 and 32.1-127 of the Code of Virginia.
- 159 Historical Notes

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- Derived from VR355-33-500 § 1.10, eff. July 28, 1993; amended, Virginia Register Volume 11,
- 161 Issue 8, eff. April 1, 1995; Volume 23, Issue 10, eff. March 1, 2007.
- 162 12VAC5-410-130. Return of license Surrender of license; mid-term change of license.
- 163 <u>A. Upon revocation or suspension of a license, the hospital shall surrender its license to the OLC.</u>
 - B. The <u>hospital shall notify the director of the</u> OLC <u>shall be notified</u> in writing <u>by submitting a mid-term change application</u> at least within 30 working days <u>no less than 30 calendar days</u> in advance of <u>any proposed change in location or ownership of the facility. A license shall not be transferred from one owner to another or from one location to another. The license issued by the commissioner shall be returned to the OLC for correction or reissuance when any of the following changes occur during the licensing year <u>implementing any</u>:</u>
 - 1. Revocation;
 - 2. 1. Change of location of the hospital, including change of location of any emergency department not located on the hospital's campus;
- 3. 2. Change of ownership of the hospital;
- 3. Change of operator of the hospital;
 - Change of name of the hospital;
- 5. Change of bed capacity, except as provided in 12VAC5-410-110 C;, which shall be accompanied by an approved Certificate of Public Need if the requested change is for an increase in bed capacity; er
- 6. Change of services being provided, including any proposed addition or discontinuation,
 regardless of whether licensure is required for the service; or

- 6. Voluntary closure 7. Closure of the hospital.
- 183 C. The OLC shall:

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- 1. Consider the submission date of a mid-term change application to be the date it is postmarked or the date it is received, whichever is earlier; and
- 2. Notify in writing the licensee if the commissioner will issue a changed license.
- <u>D.</u> The commissioner's issuance of a changed license to the hospital shall satisfy the requirements of subdivision C 2 of this section.
- E. Upon receipt of the changed license, the licensee shall return its prior license issued by the commissioner to the OLC and destroy any copies of the prior license.
- F. A license may not be transferred or assigned. The commissioner may not issue a changed license in response to a change of operator of the hospital, but shall instead require the hospital to obtain a new license. If the hospital intends to implement a change of operator, it shall:
 - 1. File for a new license, in accordance with 12VAC5-410-70, no less than 30 calendar days in advance of any change of operator; and
 - <u>2. Upon receipt of the new license, surrender its prior license issued by the commissioner to the OLC and destroy any copies of the prior license.</u>
 - G. If the hospital is closing or will otherwise no longer be operational, it shall:
 - 1. Notify patients, legal representatives, and the OLC no fewer than seven calendar days prior to closing or ceasing operations where all clinical records are to be located following closure or cessation of operations; and
 - 2. Surrender its license to the OLC and destroy all copies of its license no more than five calendar days after the hospital closes or ceases operations.
- H. The OLC shall determine if any changes listed in subsection B affect the terms of the license or the continuing eligibility for a license. An inspector may inspect the hospital during the process of evaluating a proposed change.
- 207 Statutory Authority
- 208 §§ 32.1-12, and 32.1-127, and 32.1-132 of the Code of Virginia.
- 209 Historical Notes
- 210 Derived from VR355-33-500 § 1.13, eff. July 28, 1993; amended, Virginia Register Volume 11,
- 211 Issue 8, eff. April 1, 1995; Volume 11, Issue 16, eff. June 1, 1995; Volume 23, Issue 10, eff. March
- 212 1, 2007; Volume 35, Issue 24, eff. August 23, 2019.
- 213 12VAC5-410-140. Inspection procedure.
 - A. The OLC shall make periodic unannounced on-site inspections of a hospital as necessary but not less often than biennially. The OLC may make on-site inspections of applicants for licensure. Compliance with all standards shall be determined by the OLC.
 - B. The hospital or applicant shall:
 - 1. Make available to the inspector any requested records;
 - 2. Permit an inspector to enter upon and into its property to inspect or investigate as the inspector reasonably deems necessary in order to determine the state of compliance with the provisions of this chapter and all laws administered by the board; and
 - 3. Allow the inspector access to interview the agents, employees, independent contractors, patients, legal representatives, patients' family members, and any person under the hospital's or applicant's control, direction, or supervision.
 - C. After the on-site inspection, the inspector shall:

1. Discuss the findings of the inspection with the chief executive officer or his designee;
 and

- 2. Provide a written inspection report to the chief executive officer or his designee.
- <u>D. If the OLC cites one or more licensing violations in the written inspection report, the chief executive officer or his designee shall submit a plan of correction in accordance with 12VAC5-410-150.</u>
- A. E. The OLC may presume that a <u>general</u> hospital <u>accredited deemed</u> by the <u>Joint Commission on Accreditation of Healthcare Organizations (JCAHO) a general hospital accrediting organization and certified for participation in Title XVIII of the Social Security Act (Medicare) (42 U.S.C. § 301 et seq.) generally meets the requirements of Part II (12VAC5-410-170 et seq.) of this chapter provided the following conditions are met:</u>
 - 1. The <u>general</u> hospital provides to the OLC, upon request, a copy of the most current accreditation survey findings made by the <u>Joint Commission on Accreditation of Healthcare Organizations</u> general hospital accrediting organization; and
 - 2. The <u>general</u> hospital notifies the OLC within 10 days after receipt of any notice of revocation or denial of accreditation by the Joint Commission on Accreditation of Healthcare Organizations general hospital accrediting organization.
- F. The OLC may presume that an outpatient surgical hospital deemed by an outpatient surgical hospital accrediting organization and certified for participation in Title XVIII of the Social Security Act (42 U.S.C. § 301 et seq.) generally meets the requirements of Part IV (12VAC5-410-1150 et seq.) of this chapter provided the following conditions are met:
 - 1. The outpatient surgical hospital provides to the OLC, upon request, a copy of the most current accreditation survey findings made by the outpatient surgical hospital accrediting organization; and
 - 2. The outpatient surgical hospital notifies the OLC within 10 days after receipt of any notice of revocation or denial of accreditation by the outpatient surgical hospital accrediting organization.
- B. G. The OLC may presume that a unit or part of a <u>general</u> hospital licensed or certified by another state agency, or another section, bureau or division of the OLC meets the requirements of Part II (12VAC5-410-170 et seq.) of this chapter for that specific unit or part provided the following conditions are met:
 - 1. The <u>general</u> hospital provides the OLC, upon request, a copy of the most current inspection report made by the other state agency; and
 - 2. The <u>general</u> hospital notifies the OLC within 10 days after receipt of any notice of revocation or suspension by the other state agency.
- H. The OLC may presume that a unit or part of an outpatient surgical hospital licensed or certified by another state agency, or another section, bureau or division of the OLC meets the requirements of Part IV (12VAC5-410-1150 et seq.) of this chapter for that specific unit or part provided the following conditions are met:
 - 1. The outpatient surgical hospital provides the OLC, upon request, a copy of the most current inspection report made by the other state agency; and
 - 2. The outpatient surgical hospital notifies the OLC within 10 days after receipt of any notice of revocation or suspension by the other state agency.
- C. I. Notwithstanding any other provision of this chapter to the contrary, if the licensing agency OLC finds, after inspection, violations pertaining to environmental health or life safety, the hospital shall receive a written licensing report of such findings. The hospital shall be required to submit a plan of correction in accordance with provisions of 12VAC5-410-150.

273 Statutory Authority

274 §§ 32.1-12 and 32.1-127 of the Code of Virginia.

275 Historical Notes

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Derived from VR355-33-500 § 1.14, eff. July 28, 1993; amended, Virginia Register Volume 11, Issue 8, eff. April 1, 1995; Volume 11, Issue 16, eff. June 1, 1995; Volume 23, Issue 10, eff. March 1, 2007.

12VAC5-410-150. Plan of correction.

A. Upon receipt of a written <u>licensing inspection</u> report, the chief executive officer or <u>his designee each hospital</u> shall prepare a <u>written plan for correcting of correction addressing any each licensing violations violation cited at the time of inspection. The plan of correction shall be to the OLC within the specified time limit set forth in the licensing report. The plan of correction shall contain at least the following information:</u>

- B. The chief executive officer or his designee shall submit to the OLC a written plan of correction no more than 15 business days after receipt of the inspection report. The plan of correction shall contain for each licensing violation cited:
 - 1. The methods implemented to correct any violations of this chapter A description of the corrective action or actions to be taken and the position title of the employees to implement the corrective action. If employees share the same position title, the chief executive officer or his designee shall assign the employees a unique identifier to distinguish them; and
 - 2. The <u>expected correction</u> date, on which such corrections are expected to be completed not to exceed 45 business days from the exit date of the inspection.; and
 - 3. A description of the measures implemented to prevent a recurrence of each licensing violation.
- <u>C. The chief executive officer or his designee shall ensure that the person responsible for the</u> validity of the plan of correction signs, dates, and indicates their title on the plan of correction.
- B. D. The OLC shall notify the hospital chief executive officer or his designee, in writing, whenever if the OLC determines any item in the plan of correction is determined to be unacceptable.
- E. The OLC may conduct an inspection to verify any portion of a plan of correction has been implemented.
- F. The chief executive officer or his designee shall ensure the plan of correction is implemented and monitored so that compliance is maintained.
- G. The commissioner may deny licensure or renewal of licensure if the chief executive officer or his designee fails to submit an acceptable plan of correction or fails to implement an acceptable plan of correction.
- H. The OLC shall consider the submission date of a plan of correction to be the date it is postmarked or the date it is received, whichever is earlier.

310 Statutory Authority

311 §§ 32.1-12 and 32.1-127 of the Code of Virginia.

312 Historical Notes

- 313 Derived from VR355-33-500 § 1.15, eff. July 28, 1993; amended, Virginia Register Volume 11,
- 314 Issue 8, eff. April 1, 1995; Volume 11, Issue 16, eff. June 1, 1995; Volume 23, Issue 10, eff. March
- **315** 1, 2007.

316 12VAC5-410-160. Revocation of license Disciplinary action.

The commissioner may revoke or suspend the license to operate a hospital in accordance with § 32.1-135 of the Code of Virginia for the following reasons:

- 1. Violation of any provision of these rules and regulations. Violations which in the judgment of the commissioner jeopardize the health or safety of patients shall be sufficient cause for immediate revocation or suspension; or

 2. Willfully permitting, aiding, or abetting the commission of any illegal act in the hospital.

 A. A hospital may not:
 - 1. Violate the provisions of this chapter or Article 1 (§ 32.1-123 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia;
 - 2. Permit, aid, or abet the commission of any illegal act in the hospital;
 - 3. Engage in a pattern of violations pursuant to § 38.2-3445.01 of the Code of Virginia; or
 - 4. Engage in a pattern of violations of subdivision B 13 of § 38.2-3407.15 of the Code of Virginia.
 - B. The commissioner may:

- 1. For each violation of subsection A of this section:
 - a. Deny, revoke, or suspend the license to operate a hospital, in accordance with the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia);
 - b. Refer a hospital for criminal prosecution pursuant to subsection A of § 32.1-27 of the Code of Virginia; or
 - c. Petition an appropriate court for an injunction, mandamus, or other appropriate remedy or imposition of a civil penalty against a hospital pursuant to subsection B or C of § 32.1-27 of the Code of Virginia;
- 2. For each violation of subsection A of this section by or occurring in a long-term care nursing unit of a general hospital if that unit is a certified nursing facility:
 - a. Restrict or prohibit new admissions to the long-term care nursing unit in accordance with the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia);
 - b. Petition an appropriate court for imposition of a civil monetary penalty against a hospital pursuant to subsection A of § 32.1-27.1 of the Code of Virginia; or
 - c. Petition an appropriate court for appointment of a receiver for the long-term care nursing unit pursuant to subsection B of § 32.1-27.1 of the Code of Virginia; and
- 3. For each violation of subdivision A 3 of this section, levy a fine upon the hospital in an amount not to exceed \$1,000 per violation, in accordance with the Administrative Process Acts (§ 2.2-4000 et seq. of the Code of Virginia).
- C. Suspension of a license shall in all cases be for an indefinite time.
- D. For each violation of subsection A of this section and with the consent of the person who has violated subsection A of this section, the board may provide, in an order issued by the board, for the payment of civil charges for past violations in specific sums, which may not exceed the limits specified in § 32.1-27 of the Code of Virginia or if applicable, the limits specified in § 32.1-27.1 of the Code of Virginia.
- E. Upon receipt of a completed application and a nonrefundable service charge, the commissioner may issue a new license to a hospital that has had its license revoked if the commissioner determines that:
 - 1. The conditions upon which revocation was based have been corrected; and
 - 2. The applicant is in compliance with this chapter, Article 1 (§ 32.1-123 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia, and all other applicable state and federal law and regulations.
- F. Upon receipt of a completed application, the commissioner may partially or completely restore a suspended license to a hospital if the commissioner determines that:

- 365 <u>1. The conditions upon which suspension was based have been completely or partially</u>
 366 corrected; and
 - 2. The interests of the public will not be jeopardized by resumption of operation.
 - G. The commissioner may not require an additional service charge for restoring a license pursuant to subsection F of this section.
 - H. The hospital shall submit evidence relevant to subdivisions E 1, E 2, F 1, and F 2 of this subsection that is satisfactory to the commissioner or his designee. The commissioner or his designee may conduct an inspection prior to making a determination.

373 Statutory Authority

- 374 §§ 32.1-12, 32.1-27, 32.1-27.1, and 32.1-127, 32.1-135, 32.1-137.07, and 38.2-3407.15 of the
- 375 Code of Virginia.

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- 376 Historical Notes
- 377 Derived from VR355-33-500 § 1.16, eff. July 28, 1993; amended, Virginia Register Volume 11, 1985.
- 379 Part II

Organization and Operation of General and Special Hospitals

12VAC5-410-215. Financial assistance in general hospitals.

- A. As used in this section, "patient" and "uninsured patient" have the same meanings as ascribed to these terms in subsection A of § 32.1-137.010 of the Code of Virginia.
- B. A general hospital shall make reasonable efforts to screen every uninsured patient to determine whether the individual is eligible for medical assistance pursuant to the state plan for medical assistance or for financial assistance under the general hospital's financial assistance policy.
- C. A general hospital shall inform every uninsured patient who receives services at the general hospital and who is determined to be eligible for assistance under the general hospital's financial assistance policy of the option to enter into a payment plan with the general hospital.
 - 1. A payment plan entered into pursuant to this subsection shall be provided to the patient in writing or electronically and shall provide for repayment of the cumulative amount owed to the general hospital.
 - 2. The amount of monthly payments and the term of the payment plan shall be determined based upon the patient's ability to pay.
 - 3. Any interest on amounts owed pursuant to the payment plan shall not exceed the maximum judgment rate of interest pursuant to § 6.2-302 of the Code of Virginia.
 - 4. The general hospital may not charge any fees related to the payment plan.
 - 5. The payment plan shall allow prepayment of amounts owed without penalty.
- D. A general hospital shall develop a process by which either an uninsured patient who agrees to a payment plan pursuant to subsection C of this section or the general hospital may request and shall be granted the opportunity to renegotiate the payment plan.
 - 1. Renegotiation shall include opportunity for a new screening in accordance with subsection B of this section.
 - <u>2. A general hospital may not charge any fees for renegotiation of a payment plan pursuant to this subsection.</u>
- **407** E. A general hospital shall provide written information about:
- 408 1. Its charity care policies, including:

409	 a. Policies related to free and discounted care;
410	b. Specific eligibility criteria for charity care; and
411	c. Procedures for applying for charity care;
412	2. The availability of a payment plan for the payment of debt owed to the general hospital
413	pursuant to subsection C of this section; and
414	3. The renegotiation process described in subsection D of this section.
415	F. To provide the information required by subsection E of this section, a general hospital shall:
416	1. Post the information conspicuously in public areas of the general hospital, including
417	admissions or registration areas, emergency departments, and associated waiting rooms;
418	2. Make the information available to:
419	a. A patient at the time of admission or discharge, or at the time services are provided;
420	<u>and</u>
421	b. Persons with limited English proficiency in accordance with the U.S. Department of
422	Health and Human Services' Guidance to Federal Financial Assistance Recipients
423 424	Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons (August 8, 2003, 68 FR 47311), if the general hospital is
425	subject to the requirements of Title VI of the Civil Rights Act of 1964 (Pub. L. No. 88-
426	352), as amended; and
427	3. Include the information:
428	a. With any billing statements sent to uninsured patients; and
429	b. On any website maintained by the general hospital.
430	G. Notwithstanding any other provision of law, a general hospital may not engage in any action
431	described in § 501(r)(6) of the Internal Revenue Code, as it was in effect on January 1, 2020, to
432	recover a debt for medical services against any patient unless the general hospital has made all
433	reasonable efforts to determine whether the patient:
434	1. Qualifies for medical assistance pursuant to the state plan for medical assistance; or
435	2. Is eligible for financial assistance under the general hospital's financial assistance
436	policy.
437	H. Nothing in this section shall be construed to:
438 439	1. Prohibit a general hospital, as part of its financial assistance policy, from requiring a patient to:
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440	 a. Provide necessary information needed to determine eligibility for financial assistance under the general hospital's financial assistance policy, medical assistance
442	pursuant to Title XVIII or XIX of the Social Security Act (42 U.S.C. § 301 et seq.), 10
443	U.S.C. § 1071 et seq., or other programs of insurance; or
444	b. Undertake good faith efforts to apply for and enroll in the programs of insurance for
445	which the patient may be eligible as a condition of awarding financial assistance;
446	2. Require a general hospital to grant or continue to grant any financial assistance or
447	payment plan pursuant to this section when:
448	a. A patient has provided false, inaccurate, or incomplete information required for
449	determining eligibility for the general hospital's financial assistance policy; or
450	b. A patient has not undertaken good faith efforts to comply with any payment plan
451	pursuant to this section; or
452	3. Prohibit the coordination of benefits as required by state or federal law.
453	Statutory Authority

§§ 32.1-12, 32.1-127, 32.1-137.01, and 32.1-137.010 of the Code of Virginia.

12VAC5-410-225. Newborn safety devices.

A general hospital that voluntarily installs a newborn safety device for the reception of children shall ensure that:

- 1. The device is located inside the hospital in an area that is conspicuous and visible to employees or personnel;
- 2. The device is staffed 24 hours a day by a health care provider:
- 3. The device is climate controlled and serves as a safe sleep environment for an infant;
- 4. The device is equipped with a dual alarm system that sounds 60 seconds after a child is placed in the device and automatically places a call to 911 if the alarm is not deactivated within 60 seconds from within the hospital;
- 5. The dual alarm system is visually checked at least two times per day and tested at least one time per week to ensure the alarm system is in working order;
- 6. The device automatically locks when a child is placed in the device; and
- 7. The device is identifiable by appropriate signage that shall include written and pictorial operational instructions.

470 Statutory Authority

§§ 8.01-226.5:2, 32.-12, and 32.1-127 of the Code of Virginia.

12VAC5-410-230. Patient care management.

- A. All patients shall be under the care of a member of the medical staff.
- B. Each hospital shall have a plan that includes effective mechanisms for the periodic review and revision of patient care policies and procedures.
- C. Each hospital shall establish a protocol relating to the rights and responsibilities of patients based on 42 C.F.R. § 482.13 Joint Commission on Accreditation of Healthcare Organizations' 2000 Hospital Accreditation Standards, January 2000. The protocol shall include a process reasonably designed to inform patients of their rights and responsibilities. Patients shall be given a copy of their rights and responsibilities upon admission.
- D. No medication or treatment shall be given except on the signed order of a person lawfully authorized by state statutes.
 - 1. Hospital personnel, as designated in medical staff bylaws, rules and regulations, or hospital policies and procedures, may accept emergency telephone and other verbal orders for medication or treatment for hospital patients from physicians and other persons lawfully authorized by state statute to give patient orders.
 - 2. As specified in the hospital's medical staff bylaws, rules and regulations, or hospital policies and procedures, emergency telephone and other verbal orders shall be signed within a reasonable period of time not to exceed 72 hours, by the person giving the order, or, when such person is not available, cosigned by another physician or other person authorized to give the order.
- E. Each hospital shall have a reliable method for identification of each patient, including newborn infants.
- F. Each hospital shall include in its visitation policy a provision allowing each adult patient to receive visits from any individual from whom the patient desires to receive visits, subject to other restrictions contained in the visitation policy including the patient's medical condition and the number of visitors permitted in the patient's room simultaneously.
- G. If the Governor has declared a public health emergency related to the novel coronavirus (COVID-19), each hospital shall allow a person with a disability who requires assistance as a

result of such disability to be accompanied by a designated support person at any time during which health care services are provided.

- 1. In any case in which health care services are provided in an inpatient setting, and the duration of health care services in such inpatient setting is anticipated to last more than 24 hours, the person with a disability may designate more than one designated support person. However, no hospital shall be required to allow more than one designated support person to be present with a person with a disability at any time.
- 2. A designated support person shall not be subject to any restrictions on visitation adopted by such hospital. However, such designated support person may be required to comply with all reasonable requirements of the hospital adopted to protect the health and safety of patients and staff of the hospital.
- 3. Every hospital shall establish policies applicable to designated support persons and shall:
 - a. Make such policies available to the public on a website maintained by the hospital;
 - b. Provide such policies, in writing, to the patient at such time as health care services are provided.
- H. G. Each hospital that is equipped to provide life-sustaining treatment shall develop a policy to determine the medical or ethical appropriateness of proposed medical care, which shall include:
 - 1. A process for obtaining a second opinion regarding the medical and ethical appropriateness of proposed medical care in cases in which a physician has determined proposed care to be medically or ethically inappropriate;
 - 2. Provisions for review of the determination that proposed medical care is medically or ethically inappropriate by an interdisciplinary medical review committee and a determination by the interdisciplinary medical review committee regarding the medical and ethical appropriateness of the proposed health care of the patient;
 - 3. Requirements for a written explanation of the decision of the interdisciplinary medical review committee, which shall be included in the patient's medical record; and
 - 4. Provisions to ensure the patient, the patient's agent, or the person authorized to make the patient's medical decisions in accordance with § 54.1-2986 of the Code of Virginia is informed of the patient's right to obtain the patient's medical record and the right to obtain an independent medical opinion and afforded reasonable opportunity to participate in the medical review committee meeting.

The policy shall not prevent the patient, the patient's agent, or the person authorized to make the patient's medical decisions from obtaining legal counsel to represent the patient or from seeking other legal remedies, including court review, provided that the patient, the patient's agent, person authorized to make the patient's medical decisions, or legal counsel provide written notice to the chief executive officer of the hospital within 14 days of the date of the physician's determination that proposed medical treatment is medically or ethically inappropriate as documented in the patient's medical record.

I. H. Each hospital shall establish a protocol requiring that, before a health care provider arranges for air medical transportation services for a patient who does not have an emergency medical condition as defined in 42 USC § 1395dd(e)(1), the hospital shall provide the patient or the patient's authorized representative with written or electronic notice that the patient (i) may have a choice of transportation by an air medical transportation provider or medically appropriate ground transportation by an emergency medical services provider and (ii) will be responsible for charges incurred for such transportation in the event that the provider is not a contracted network

provider of the patient's health insurance carrier or such charges are not otherwise covered in full or in part by the patient's health insurance plan.

- J. I. Each hospital shall provide written information about the patient's ability to request an estimate of the payment amount for which the participant will be responsible pursuant to § 32.1-137.05 of the Code of Virginia. The written information shall be posted conspicuously in public areas of the hospital, including admissions or registration areas, and included on any website maintained by the hospital.
- K. Each hospital shall establish protocols to ensure that any patient scheduled to receive an elective surgical procedure for which the patient can reasonably be expected to require outpatient physical therapy as a follow-up treatment after discharge is informed that the patient:
 - 1. Is expected to require outpatient physical therapy as a follow-up treatment; and
 - 2. Will be required to select a physical therapy provider prior to being discharged from the hospital.

Statutory Authority

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

Historical Notes

- Derived from VR355-33-500 § 2.7, eff. July 28, 1993; amended, Virginia Register Volume 11, Issue 8, eff. April 1, 1995; Volume 19, Issue 1, eff. November 1, 2002; Errata, 19:3 VA.R. 549 October 21, 2002; amended, Virginia Register Volume 24, Issue 11, eff. March 5, 2008; Volume 35, Issue 4, eff. November 14, 2018; Volume 35, Issue 21, eff. July 10, 2019; Volume 35, Issue 24, eff. August 23, 2019; Volume 36, Issue 23, eff. August 6, 2020; Volume 37, Issue 14, eff. March 31, 2021.
- 569 <u>12VAC5-410-235. Persons with a disability; designated support person in general</u> 570 <u>hospitals.</u>
 - A. For the purposes of this section:
 - 1. "Admission" means accepting a person for bed occupancy and care that is anticipated to span at least two midnights or for observation;
 - <u>2. "General hospital" means a general hospital other than one that is certified as a long-term acute care hospital or specialty rehabilitation hospital.</u>
 - B. A general hospital shall allow a person with a disability who requires support and assistance necessary due to the specifics of the person's disability to be accompanied by a DSP who will provide support and assistance necessary due to the specifics of the person's disability to the person with a disability during an admission.
 - 1. In any case in which the duration of the admission lasts more than 24 hours, the person with a disability may designate more than one DSP.
 - 2. No general hospital shall be required to allow more than one DSP to be present with a person with a disability at any time.
 - C. A general hospital may:
 - 1. Not subject a DSP to any restrictions on visitation;
 - 2. Require a DSP to comply with all reasonable requirements of a general hospital adopted to protect the health and safety of the person with a disability; the DSP; the staff and other patients of, or visitors to, a general hospital; and the public; and
 - 3. Restrict a DSP's access to specified areas of and movement on the premises of a general hospital when such restrictions are determined by a general hospital to be reasonably necessary to protect the health and safety of the person with a disability; the DSP; the staff and other patients of, or visitors to, a general hospital; and the public.

- 593 <u>D. A general hospital may request that a person with a disability provide documentation</u> 594 indicating that he is a person with a disability.
 - 1. If the person with a disability fails, refuses, or is unable to provide documentation requested pursuant to subsection D of this section, a general hospital may perform an objective assessment of the person to determine whether he is a person with a disability.
 - 2. If a general hospital fails to perform an objective assessment pursuant to subdivision D 1 of this section, a general hospital may not prohibit a DSP from accompanying a person with a disability for the purpose of providing support and assistance necessary due to the specifics of the person's disability.

E. A general hospital shall

- 1. Establish protocols to inform patients, at the time of admission, of the right of a person with a disability who requires support and assistance necessary due to the specifics of the person's disability to be accompanied by a DSP for the purpose of providing support and assistance necessary due to the specifics of the person's disability;
- 2. Develop and make available to a patient or his guardian, authorized representative, or care provider upon request written information regarding the right of a person with a disability who requires support and assistance necessary due to the specifics of the person's disability to be accompanied by a DSP and any policies related to that right; and
- 3. Make the written information described in subdivision E 2 of this section available to the public on its website.

G. This section may not:

1. Alter the obligation of a general hospital to provide patients with effective communication support or other required services, regardless of the presence of a DSP or other reasonable accommodation, consistent with applicable federal or state law or regulations; and

2. Be interpreted to:

- a. Prevent a general hospital from complying, or interfere with the ability of a general hospital to comply, with or cause a general hospital to violate any federal or state law or regulation;
- <u>b. Deem a DSP to be acting under the direction or control of a general hospital or as</u> an agent of a general hospital; or
- c. Require a general hospital to allow a DSP to perform any action or provide any support or assistance necessary due to the specifics of the person's disability when a general hospital reasonably determines that the performance of the action or provision would be:
- (1) Medically or therapeutically contraindicated; or
- (2) A threat to the health and safety of the person with a disability, the DSP, or the staff or other patients of, or visitors to, a general hospital.

631 Statutory Authority

632 §§ 32.1-12, 32.1-127, and 32.1-137.08 of the Code of Virginia.

12VAC5-410-237. Discharge planning.

- A. A general hospital shall provide each patient admitted as an inpatient or his legal guardian the opportunity to designate:
 - 1. An individual who will care for or assist the patient in his residence following discharge from a general hospital; and

- 638 2. To whom a general hospital shall provide information regarding the patient's discharge plan and any follow-up care, treatment, and services that the patient may require. 639
 - B. Upon admission, a general hospital shall record in the patient's medical record:
 - 1. The name of the individual designated by the patient;
 - 2. The relationship between the patient and the person; and
 - 3. The person's telephone number and address.
 - C. If the patient fails or refuses to designate an individual to receive information regarding his discharge plan and any follow-up care, treatment, and services, a general hospital shall record the patient's failure or refusal in the patient's medical record.
 - D. A patient may change the designated individual at any time prior to the patient's release. and a general hospital shall record the changes, including the information referenced in subsection B of this section, in the patient's medical record within 24 hours of such a change.
 - E. Prior to discharging a patient who has designated an individual pursuant to subsections A or D of this section, a general hospital shall:
 - 1. Notify the designated individual of the patient's discharge,
 - 2. Provide the designated individual with a copy of the patient's discharge plan and instructions and information regarding any follow-up care, treatment, or services that the designated individual will provide; and
 - 3. Consult with the designated individual regarding the designated individual's ability to provide the care, treatment, or services.
 - F. The discharge plan prescribed in subdivision E 2 of this section shall include:
 - 1. The name and contact information of the designated individual;
 - 2. A description of follow-up care, treatment, and services that the patient requires; and
 - 3. Information, including contact information, about any health care, long-term care, or other community-based services and supports necessary for the implementation of the patient's discharge plan.
 - G. A general hospital shall include a copy of the discharge plan and any instructions or information provided to the designated individual in the patient's medical record.
 - H. A general hospital shall provide each individual designated pursuant to subsection A or D of this section the opportunity for a demonstration of specific follow-up care tasks that the designated individual will provide to the patient in accordance with the patient's discharge plan prior to the patient's discharge, including opportunity for the designated individual to ask questions regarding the performance of follow-up care tasks in a culturally competent manner and in the designated individual's native language.
 - I. A general hospital shall establish protocols to ensure that any patient scheduled to receive an elective surgical procedure for which the patient can reasonably be expected to require outpatient physical therapy as a follow-up treatment after discharge is informed that the patient:
 - 1. Is expected to require outpatient physical therapy as a follow-up treatment; and
 - 2. Will be required to select a physical therapy provider prior to being discharged from a general hospital.
- **Statutory Authority** 678

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- 679 §§ 32.1-12, 32.1-127, and 32.1-137.03 of the Code of Virginia.
- 680 12VAC5-410-370. Medical records.
- A. The medical record department shall be staffed and equipped to facilitate the accurate processing, checking, indexing, filing and retrieval of all medical records. 682

B. A medical record shall be established and maintained for every person treated on an inpatient, outpatient (ambulatory) or emergency basis, in any unit of the hospital. The record shall be available to all other units.

A separate medical record shall be maintained for each newborn infant. Entered on the chart of the newborn shall be notes of gestational history, including any pathology and information regarding complications of delivery and mother's medication during labor and delivery.

- C. Written policies and procedures shall be established regarding content and completion of medical records.
- D. Entries in the medical record shall be made by the responsible person in accordance with hospital policies and procedures.
- E. Provisions shall be made for the safe storage of medical records or and the accurate and legible reproductions thereof of medical records according to § 32.1-127.1:03 of the Code of Virginia and the Health Insurance Portability and Accountability Act, or HIPAA (42 USC § 1320d et seq.) (Pub. L. No. 104-191).
- F. All medical records either original or accurate reproductions shall be preserved for a minimum of five years following discharge of the patient.
 - 1. Records of minors shall be kept for at least five years after such minor has reached the age of 18 years.
 - 2. Birth and death information shall be retained for 10 years in accordance with § 32.1-274 of the Code of Virginia.
 - 3. Record of abortions and proper information for the issuance of a fetal death certificate shall be furnished to the Office of Vital Records, Virginia Department of Health, as required by law.
- G. A general hospital that makes health records, as defined in § 32.1-127.1:03 of the Code of Virginia, of patients who are minors available to patients through a secure website shall make the health records available to the patient's parent or guardian through the secure website, unless the general hospital cannot make the health record available:
 - 1. In a manner that prevents disclosure of information, the disclosure of which has been denied pursuant to subsection F of § 32.1-127.1:03 of the Code of Virginia; or
 - 2. Because the consent required in accordance with subsection E of § 54.1-2969 of the Code of Virginia has not been provided.

Statutory Authority

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

716 Historical Notes

- 717 Derived from VR355-33-500 § 2.21, eff. July 28, 1993; amended, Virginia Register Volume 11,
 718 Issue 8, eff. April 1, 1995; Volume 22, Issue 8, eff. January 25, 2006.
- 719 12VAC5-410-380. Nursing service.
 - A. Each hospital shall have an organized nursing department. A registered nurse qualified on the basis of education, experience and clinical ability shall be responsible for the direction of nursing care provided the patients.
 - B. The number and type of nursing personnel on all shifts shall be based upon the needs of the patients and the capabilities of the nursing staff assigned to the patient care unit. All registered nurses and licensed practical nurses shall hold a current license issued by the Virginia Board of Nursing or a current multistate licensure privilege to practice nursing in Virginia.
 - C. All nursing services shall be directly provided by an appropriately qualified registered nurse or licensed practical nurse, except for those nursing tasks that may be delegated by a registered

- nurse according to 18VAC90-20-420 18VAC90-19-240 through 18VAC90-20-460 18VAC90-19-280 of the regulation of the Virginia Board of Nursing with a plan developed and implemented by the hospital.
 - D. Nursing personnel shall be assigned to patient care units in a manner that minimizes the risk of cross infection and accidental contamination.
 - E. Each hospital shall quarterly report to the department no later than 30 calendar days after January 1st, April 1st, July 1st, and October 1st:
 - 1. The total number of certified sexual assault nurse examiners employed by the hospital; and
 - 2. The location, including street address, and contact information for each location at which such certified sexual assault nurse examiner provides services.

Each hospital shall report the information required by this subsection to the Office of Family
 Health Services, Virginia Department of Health.

742 Statutory Authority

743 §§ 32.1-12, 32.1-23.2, and 32.1-127 of the Code of Virginia.

744 Historical Notes

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- 745 Derived from VR355-33-500 § 2.22, eff. July 28, 1993; amended, Virginia Register Volume 11, 1946 Issue 8, eff. April 1, 1995; Volume 11, 1995; Volume 11, 1995; Volume 22, Issue 8, eff. January 25, 2006.
- 748 12VAC5-410-442. Obstetric service design and equipment criteria.
 - A. Renovation or construction of a hospital's obstetric unit shall be consistent with (i) section 2.2-2.9 2.2-2.10 of Part 2 of the 2018 Guidelines for Design and Construction of Hospitals, 2022 Edition of the (The Facility Guidelines Institute) pursuant to § 32.1-127.001 of the Code of Virginia and (ii) the Virginia Uniform Statewide Building Code (13VAC5-63).
 - B. Delivery rooms labor, deliver, and recover (LDR) rooms; labor delivery, recovery, and postpartrum (LDRP) rooms; and nurseries shall be equipped to provide emergency resuscitation for mothers and infants.
 - C. Equipment and supplies shall be assigned for exclusive use in the obstetric and newborn units.
 - D. The same equipment and supplies required for the labor room and delivery room shall be available for use in the LDR/LDRP rooms during periods of labor, delivery, and recovery.
 - E. Sterilizing equipment shall be available in the obstetric unit or in a central sterilizing department. Flash sterilizing equipment or sterile supplies and instruments shall be provided in the obstetric unit.
 - F. Daily monitoring is required of the stock of necessary equipment in the LDR rooms and LDRP rooms and nursery.
 - G. The hospital shall provide the following equipment in the labor, delivery and recovery rooms and, except where noted, in the LDR/LDRP rooms:
 - 1. Labor rooms.
 - a. A labor or birthing bed with adjustable side rails.
 - b. Adjustable lighting adequate for the examination of patients.
- c. An emergency signal and intercommunication system.
 - d. A sphygmomanometer, stethoscope and fetoscope or doppler.
 - e. Fetal monitoring equipment with internal and external attachments.
 - f. Mechanical infusion equipment.

- 774 g. Wall-mounted oxygen and suction outlets. 775 h. Storage equipment. i. Sterile equipment for emergency delivery to include at least one clamp and suction 776 bulb. 777 j. Neonatal resuscitation cart. 778 779 2. Delivery rooms. a. A delivery room table that allows variation in positions for delivery. This equipment 780 is not required for the LDR/LDRP rooms. 781 b. Adequate lighting for vaginal deliveries or cesarean deliveries. 782 783 c. Sterile instruments, equipment, and supplies to include sterile uterine packs for vaginal deliveries or cesarean deliveries, episiotomies or laceration repairs, 784 postpartum sterilizations and cesarean hysterectomies. 785 d. Continuous in-wall oxygen source and suction outlets for both mother and infant. 786 787 e. Equipment for inhalation and regional anesthesia. This equipment is not required for LDR/LDRP rooms. 788 f. A heated, temperature-controlled infant examination and resuscitation unit. 789 g. An emergency call system. 790 791 h. Plastic pharyngeal airways, adult and newborn sizes.
 - - i. Laryngoscope and endotracheal tubes, adult and newborn sizes.
- j. A self-inflating bag with manometer and adult and newborn masks that can deliver 793 100% oxygen. 794
 - k. Separate cardiopulmonary crash carts for mothers and infants.
- 796 I. Sphygmomanometer.
 - m. Cardiac monitor. This equipment is not required for the LDR/LDRP rooms.
- 798 n. Gavage tubes.

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- o. Umbilical vessel catheterization trays. This equipment is not required for LDR/LDRP 799 800 rooms.
 - p. Equipment that provides a source of continuous suction for aspiration of the pharvnx and stomach.
 - g. Stethoscope.
- 804 r. Fetoscope.
 - s. Intravenous solutions and equipment.
 - t. Wall clock with a second hand.
 - u. Heated bassinets equipped with oxygen and transport incubator.
 - v. Neonatal resuscitation cart.
 - 3. Recovery rooms.
 - a. Beds with side rails.
 - b. Adequate lighting.
- 812 c. Bedside stands, overbed tables, or fixed shelving.
- d. An emergency call signal. 813
- e. Equipment necessary for a complete physical examination. 814
- 815 f. Accessible oxygen and suction equipment.
- 816 **Statutory Authority**

817 §§ 32.1-12, 32.1-127, and 32.1-127.001 of the Code of Virginia.

Historical Notes

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- 819 Former 12VAC5-41-440 C 5 and 6 derived from VR 355-33-500 § 2.28, eff. July 28, 1993;
- amended, Virginia Register Volume 11, Issue 8, eff. April 1, 1995; Volume 11, Issue 16, eff. June
- 1, 1995; Volume 11, Issue 21, eff. August 10, 1995; amended and adopted as 12VAC5-410-442,
- Virginia Register 21, Issue 6, eff. February 14, 2005; Volume 22, Issue 8, eff. January 25, 2006;
- 823 Volume 23, Issue 10, eff. March 1, 2007; Volume 37, Issue 19, eff. June 9, 2021.
 - 12VAC5-410-444. Newborn service medical direction; physician consultation and coverage; nursing direction, nurse staffing and coverage; policies and procedures.
 - A. The governing body shall appoint a physician as medical director of the organized newborn service who meets the qualifications specified in the medical staff bylaws. In addition, the medical director must meet the qualifications specified for the medical direction of the highest level of newborn service provided by the hospital.
 - 1. If a hospital offers only general level newborn services, the medical director shall be a physician qualified to provide normal newborn care, including the ability to immediately resuscitate and stabilize a sick newborn for transfer to a higher level of service.
 - 2. If a hospital offers intermediate level newborn services, the medical director shall be a board-certified or board-eligible pediatrician with training and experience in the care of preterm neonates, including stabilization and ventilation management.
 - 3. If a hospital offers specialty level newborn services, the medical director shall be a board-certified or board-eligible neonatologist.
 - 4. If a hospital offers subspecialty level newborn services, the medical director shall be a board-certified or board-eligible neonatologist.
 - B. The duties and responsibilities of the medical directors of all levels of newborn service shall include, but not be limited to the:
 - 1. General supervision of the quality of care provided patients admitted to the service:
 - 2. Establishment of criteria for admission to the service;
 - 3. Adherence of the service to standards of professional practices, policies and procedures, the medical protocol, and the hospital's collaboration agreements adopted by the medical staff and governing body applicable to the service;
 - 4. Development of recommendations to the medical staff on standards of professional practice and staff privileges applicable to the service;
 - 5. Identification of clinical conditions and medical and surgical procedures that require physician consultation;
 - 6. Conducting conferences, at least quarterly, to review routine and emergency surgical procedures, complications and infant and maternal mortality and morbidity. Infant mortality and morbidity shall be discussed with the obstetric service staff; and
 - 7. Active participation in the service's quality assurance program.
 - C. The hospital shall provide the following physician consultation and coverage in the general level newborn nursery service and all higher level nursery services unless unique requirements are specifically imposed for the higher level nursery services:
 - 1. A physician with pediatric privileges capable of arriving on-site within 30 minutes of notification shall be on the 24-hour on-call duty roster;
 - 2. A physician or nurse skilled in neonatal cardiopulmonary resuscitation (CPR) shall be available in the hospital at all times.

- 3. A current roster of physicians, with a delineation of their newborn, pediatric, medical and surgical privileges shall be posted at each nurses' station in the newborn service unit.
 - 4. A copy of the 24-hour on-call duty schedule, including a list of on-call consulting physicians, shall be posted at each nurses' station in the newborn service unit.
 - 5. If the medical director is not a board-certified or board-eligible pediatrician, the hospital shall have a written agreement with one or more board-certified or board-eligible pediatricians to be available to provide consultation on a 24-hour basis. Consultation may be by telephone.
 - 6. If a hospital does not have a neonatologist on staff available on a 24-hour basis, it shall have a written agreement with another hospital to provide consultation, at least by telephone, on a 24-hour basis, by a board-certified or board-eligible neonatologist. The consultant shall be available to advise on the development of a protocol for the care and transport of sick newborns.
 - D. The physician consultation and coverage for the intermediate level newborn nursery service shall be the same as the general level newborn service with the following exceptions:
 - 1. Subdivision C 1 of this section shall not apply.

- 2. Physician coverage shall be provided on a 24-hour on-call basis by a board-certified or board-eligible pediatrician or pediatricians capable of arriving on-site within 30 minutes of notification.
- E. The physician consultation and coverage for the specialty level and the subspecialty level newborn services shall be the same as for the lower level newborn services with the following exceptions:
 - 1. Subdivision C 1 of this section shall not apply.
 - 2. In-house physician consultation and coverage shall be provided 24 hours a day by a:
 - a. Board-certified or board-eligible neonatologist;
 - b. Board-certified or board-eligible pediatrician;
 - c. Second year or higher level pediatric resident; or
 - d. Neonatal nurse practitioner.
 - 3. Whenever in-house coverage is provided as stated in subdivision 2 b, c, or d of this subsection, a board-certified or board-eligible neonatologist shall be on-call and available to be on-site within 20 minutes of request.
- F. The nursing direction, staff and coverage required for the general level newborn service shall be as follows:
 - 1. The neonatal nursing program shall be under the direction of a registered nurse.
 - 2. The nursing director's responsibilities shall include, but not be limited to:
 - a. Directing neonatal nursing services;
 - b. Guiding the development and implementation of neonatal nursing policies and procedures;
 - c. Collaborating with the medical staff; and
 - d. Consulting with referral hospitals with which a hospital has transfer agreements applicable to the service or services.
 - 3. Each occupied unit of the newborn service shall be under the direct supervision of a registered nurse 24 hours a day. The registered nurse shall have documented competence in neonatal nursing appropriate to the level of service provided.

- 4. If a general level newborn nursery is organized as a separate nursing unit, staffing shall be based on a formula of a minimum of one nursing personnel to every eight newborns. Staffing shall include at least one registered nurse for the unit for each duty shift to provide direct supervision for nursing care.
 - 5. If the postpartum and general level newborn units are organized as combined rooming-in or modified rooming-in units, staffing shall be based on a formula of one nursing personnel for every four mother-baby units. The rooming-in units shall always be staffed with no less than two nursing personnel assigned to each shift. One of the two nursing personnel shall be a registered nurse to provide direct supervision of nursing care.
 - 6. When infants are present in the nursery, at least one nursing personnel trained in the care of newborn infants, with duties restricted to the care of the infants, shall be assigned to the nursery at all times. This nursing personnel is in addition to the registered nurse who is required to provide supervision.
 - 7. To ensure adequate nursing staff for the nursery for normal newborns, duty schedules shall be developed and actual shift staffing shall occur according to the following minimum nurse to patient ratios:
 - a. 1:4 Recently born infants and those needing close observation.
 - b. 1:8 Newborns needing only routine care.
 - c. 1:4 Mother-newborn routine care.

- 8. Student nurses, licensed practical nurses and nursing aides who assist in the nursing care of newborn infants shall be under the direct supervision of a registered nurse.
- 9. At least one nurse on each shift who is skilled in neonatal cardiopulmonary resuscitation must be immediately available to the nursery.
- 10. All nursing personnel assigned to the newborn service shall have orientation to the nursery, including orientation to patient care appropriate for the service level provided.
- G. The nursing direction, staff and coverage required of the intermediate level newborn service shall be the same as required of the general level newborn service with the following exceptions:
 - 1. To ensure adequate nursing staff for the nursery, duty schedules shall be developed and actual shift staffing shall occur according to a ratio of at least one nurse to four neonates.
 - 2. All registered nurses assigned to the newborn service shall be trained in neonatal cardiopulmonary resuscitation (CPR).
- H. The nursing direction, staff and coverage for the specialty level newborn service shall be the same as the lower level newborn service levels with the following exceptions:
 - 1. The newborn nursery service shall have a nurse manager. The nurse manager shall be a registered nurse with advanced training and experience in the nursing management of high-risk neonates and their families. The responsibilities of the nurse manager shall include, but not be limited to:
 - a. Daily management of the nursery;
 - b. Supervision and evaluation of nursing personnel assigned to the nursery;
 - c. Assuring nursing coverage 24 hours a day; and
 - d. Implementing nursing policies and procedures at the service level.
 - 2. All registered nurses shall have advanced training and experience in the management of neonatal patients, including specialized care technology and ventilator care for

951 neonates. Only registered nurses with this advanced training and experience shall be assigned to care for neonates on ventilators. 952

- 3. To ensure adequate nursing staff for the nursery, duty schedules shall be developed and actual shift staffing shall occur according to a ratio of at least one nurse to three patients for neonates requiring specialty level care. For those neonates who have been assessed as no longer needing specialty level care, nurse to patient ratios shall be according to the neonate's appropriate level of service.
- I. The nursing direction, staff and coverage for the subspecialty level newborn service shall be the same as all lower levels of newborn services with the following exceptions:
 - 1. A neonatal clinical nurse specialist shall be assigned to the nursery, duties and responsibilities shall include staff consultation, collaboration, and teaching.
 - 2. All registered nurses shall have advanced training and experience, beyond what is required of nurses in the lower level nurseries, in the management of high-risk neonates, including the care of unstable neonates with multisystem problems.
 - 3. To ensure adequate nursing staff for the nursery, duty schedules shall be developed and actual shift staffing shall occur according to the following minimum nurse to patient ratios for neonates requiring subspecialty level care:
 - a. 1:2 Neonates requiring subspecialty level care; and
 - b. 1:1 Neonates requiring multisystem support.

For those neonates who have been assessed as no longer needing subspecialty level care, nurse to patient ratios shall be according to the neonate's appropriate level of service.

- 4. All nursing patient care shall be provided by registered nurses assigned to the subspecialty level nursery.
- J. The governing body shall adopt written policies and procedures approved by the medical and nursing staff of the service, for the medical care of newborns.
- K. The policies and procedures for the general level nursery and all higher levels of newborn services shall include. but not be limited to:
 - 1. Medical criteria for the identification of high-risk neonatal patients.
 - 2. Protocols for the management of all neonatal medical conditions that are routinely managed by the service as well as protocols for the stabilization and transfer of neonates that require a higher level of newborn service. These protocols shall be maintained in the nursery in addition to the telephone numbers of each nursery and the names of each referral newborn service medical director.
 - 3. Written collaboration agreements with hospitals with higher levels of newborn services. A hospital may enter into more than one collaboration agreement. The collaboration agreements shall specifically identify those medical conditions that require consultation and may necessitate a neonatal transfer as well as the interim treatment required prior to transfer. Nothing in the regulation shall require a birth hospital to enter into a collaboration agreement with a referral hospital that disagrees with the medical, consultation and transfer protocols adopted by the birth hospital. All neonatal transfers shall conform with Section 1867 of the Social Security Act, its amendments in force to date and implementing regulations. At the time of any transfer, the medical treatment at the referral hospital shall outweigh the risks to the neonate from affecting the transfer. The collaboration agreements shall include, but not be limited to:
 - a. Criteria for neonatal transfer to the referral nursery;
 - b. Procedures for neonatal transport;

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- c. Back transfer criteria which provides for the return of the neonate to the referring hospital when medically appropriate;
- d. Annual review by both parties of all cases of neonatal transfer;
- e. Annual review by both parties of the collaboration agreements; and

f. Annual evaluation by both parties of the collaboration agreement and modification of the agreement, as necessary, as indicated by the evaluation results.

 4. Establishment and maintenance of an ongoing, documented quality assurance program by the service that utilizes a multidisciplinary team of health practitioners and administrators for review and is integrated with the hospital's overall quality assurance program.

a. The quality assurance program shall include:

(1) Problem identification;

(2) Action plans;

(3) Evaluation; and

(4) Follow-up.

b. The quality assurance program shall include an annual review of the following:

(1) Neonatal transfer cases;

 (2) Management of in-house neonatal cases; and

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(3) Staff in-house inservice programs.

 c. Outcome statistics, including morbidity, mortality, and the appropriateness of neonatal transfers, shall be compiled in a standardized manner and reviewed quarterly by a multidisciplinary committee.

5. Immediate resuscitation and stabilization of the sick neonate in accordance with current cardiopulmonary resuscitation (CPR) standards of the American Heart Association and the American Academy of Pediatrics.

6. Care of newborns after delivery to include the following:

 a. Care of eyes, skin and umbilical cord and the provision of a single parenteral dose of Vitamin K-1, water soluble, as a prophylaxis against hemorrhagic disorder;

b. Maintenance of the newborn's airway, respiration, and body temperature; and

 c. Assessment of the newborn and recording of the one-minute and five-minute Apgar scores.

 7. Performance of prophylaxis against ophthalmia neonatorum by the administration of a 1.0% solution of silver nitrate aqueous solution, erythromycin, or tetracycline ointment or solution. This process is to be performed within one hour of delivery with documentation entered in the newborn's medical record. The process may be performed in the nursery.

8. Clamping or tying of the umbilical cord and, when indicated, collecting a sample of cord blood.

9. Performance of Rh type and Coombs' test for every newborn born to a Rh negative mother and performing major blood grouping and Coombs' tests when indicated for every newborn born to an O blood group mother or a mother with a family history of blood incompatibility. If such qualitative tests are performed, the results shall be documented in the newborn's medical record.

10. Identification and treatment of hyperbilirubinemia and hypoglycemia.

1041 11. Identification of each newborn, prior to leaving the delivery room, with two identification bands fastened on the newborn and one identification band fastened on the mother. The newborn's medical record shall accompany the infant from the delivery room.

- 12. Newborn transport, within the hospital, of all newborns who are either premature or compromised by using a heated bassinet equipped with oxygen, a transport incubator or other similar equipment.
- 13. Registered nurse or physician assessment of a newborn within one hour after delivery and documentation of the assessment in the newborn's medical record. Assessment in the delivery area is permitted if the hospital permits a newborn and its mother to remain together during the immediate post-delivery period.
- 14. Delineation of how infants are to be monitored during stays with their mothers and under what circumstances infants must be taken to the nursery immediately after delivery and not allowed to remain with their mothers.
- 15. Physician examination of the newborn consistent with guidelines of the American Academy of Pediatrics. A high-risk newborn shall be examined upon admission to the nursery.
- 16. Ensuring that every bassinet and incubator in the nursery bears the identification of the newborn's last name, sex, date and time of birth, the mother's last name, and the attending physician's name.
- 17. The management of mothers who utilize breast milk with their newborns. Breast milk shall be collected in aseptic containers, dated, stored under refrigeration and consumed or disposed of within 24-48 96 hours of collection if the breast milk has not been frozen. This policy pertains to breast milk collected while in the hospital or at home for hospital use.
- 18. Preparation and use of formula including, but not limited to:
 - a. The distribution of feeding units immediately after assembly;
 - b. The use of prepared formula only within the time period designated on the package; and
 - c. The use of presterilized formula only, except in the case of facility-defined emergencies.
- 19. Screening newborns for risk factors associated with hearing impairment as required in §§ 32.1-64.1 and 32.1-64.2 of the Code of Virginia and in accordance with the regulations of the Board of Health governing the Virginia Hearing Impairment Identification and Monitoring System (12VAC5-80).
- 20. Screening and treatment of genetic, metabolic, and other diseases identifiable in the newborn period as specified in § 32.1-65 of the Code of Virginia and in accordance with the Regulations Governing the Newborn Screening and Treatment Program (12VAC5-70).
- 21. Reporting to the Department of Health all required reportable congenital defects.
- 22. Visitor contact with the newborn, including newborns delivered by cesarean section, and premature, sick, congenitally malformed, and dying newborns.
- 23. Completion of birth certificates.
- 24. Discharge planning appropriate for the needs of the patient for at-risk infants.
- L. The additional policies and procedures required for the intermediate level newborn service shall include, but not be limited to:
 - Page **24** of **41**

- 1. Insertion and maintenance of peripheral intravenous lines and use of pediatric infusion pumps that are accurate to plus or minus one milliliter an hour;
 - 2. Insertion and maintenance of umbilical arterial lines and the use of pediatric infusion pumps accurate to plus or minus one milliliter an hour;
 - 3. Use of heated, humidified, and blended supplemental oxygen by hood with a recording of oxygen levels every hour using a calibrated constant oxygen analyzer. The policy shall address consultation with a higher level nursery identified in the collaboration agreement when oxygen levels exceed 40% and remain at 40% or greater for a period of four hours or more;
 - Administration of nasogastric or orogastric feedings;
 - 5. Use of saturation monitor (pulse oximeter or equivalent) for any newborn requiring supplemental oxygen;
 - 6. Use of assisted ventilation in preparation for transport;
 - 7. Initiation of PgE1 prior to transport; and
 - 8. Administration of blood components and a policy for provision of partial and total exchange transfusions.
 - M. The additional policies and procedures required for the specialty level newborn service shall include, but not be limited to:
 - 1. Provision of ongoing assisted ventilation;
 - Administration of surfactant;

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- 3. Preparation and administration of total parenteral nutrition (TPN);
- 4. Initiation and maintenance of pressor medications;
- 5. Provision for developmental follow up;
- 6. Insertion and maintenance of central umbilical arterial catheters or peripheral arterial lines with constant pressure monitoring;
- 7. Placement of chest tubes with water seal on an emergency basis;
 - 8. Use of heated, humidified, and blended supplemental oxygen by hood with a recording of oxygen levels every hour using a calibrated constant oxygen analyzer;
 - 9. Administration and maintenance of CPAP including the requirement for in-house physician coverage;
 - 10. Daily availability of appropriate drug peak and trough assays on one milliliter or less of blood:
 - 11. Cardioversion capability specific for newborns; and
- 1119 12. Provision for ophthalmology consult and requirements regarding the examination of high-risk newborns.
- N. The additional policies and procedures required for the subspecialty level newborn service shall include, but not be limited to:
 - 1. Provision for returning patients to the operating room within 30 minutes, if indicated;
 - 2. Provision for echocardiography evaluation;
 - 3. Provision for patient treatment on an extracorporeal membrane oxygenator (ECMO) or a written collaboration agreement with a hospital with this capability;
 - 4. Provision for maintenance of central venous pressure monitoring; and
- **1128** 5. Provision for the maintenance of neonates on prostaglandin E1 (PgE1).

1129 Statutory Authority

- **1130** §§ 32.1-12 and 32.1-127 of the Code of Virginia.
- 1131 Historical Notes
- 1132 Former 12VAC5-41-440 D 3 to 6 derived from VR 355-33-500 § 2.28, eff. July 28, 1993; amended,
- 1133 Virginia Register Volume 11, Issue 8, eff. April 1, 1995; Volume 11, Issue 16, eff. June 1, 1995;
- Volume 11, Issue 21, eff. August 10, 1995; amended and adopted as 12VAC5-410-444, Virginia
- 1135 Register 21, Issue 6, eff. February 14, 2005; Errata, 21:8 VA.R. 1016 December 27, 2004;
- amended, Virginia Register Volume 22, Issue 8, eff. January 25, 2006; Errata, 22:9 VA.R. 1437
- **1137** January 9, 2006.

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- 12VAC5-410-445. Newborn service design and equipment criteria.
- A. Construction or renovation of a hospital's nursery shall be consistent with (i) section 2.2-2.10 2.2-2.11 of Part 2 of the 2018 Guidelines for Design and Construction of Hospitals, 2022 Edition of the (The Facility Guidelines Institute) pursuant to § 32.1-127.001 of the Code of Virginia and (ii) the Virginia Uniform Statewide Building Code (13VAC5-63). Hospitals with higher-level nurseries shall comply with section 2.2-2.8 2.2-2.9 of Part 2 of the 2018 2022 edition of the guidelines as applicable.
- B. The hospital shall provide the following equipment in the general level nursery and all higher level nurseries, unless additional equipment requirements are imposed for the higher level nurseries:
 - 1. Resuscitation equipment as specified for the delivery room in 12VAC5-410-442 G 2 shall be available in the nursery at all times;
 - 2. Equipment for the delivery of 100% oxygen concentration, properly heated, blended, and humidified, with the ability to measure oxygen delivery in fractional inspired concentration (Fl02). The oxygen analyzer shall be calibrated every eight hours and serviced according to the manufacturer's recommendations by a member of the hospital's respiratory therapy department or other responsible personnel trained to perform the task;
 - 3. Saturation monitor (pulse oximeter or equivalent);
 - 4. Equipment for monitoring blood glucose;
- **1157** 5. Infant scales;
 - 6. Intravenous therapy equipment;
- 7. Equipment and supplies for the insertion of umbilical arterial and venous catheters;
 - 8. Open bassinets, self-contained incubators, open radiant heat infant care system or any combination thereof appropriate to the service level;
 - 9. Equipment for stabilization of a sick infant prior to transfer that includes a radiant heat source capable of maintaining an infant's body temperature at 99°F;
 - 10. Equipment for insertion of a thoracotomy tube; and
 - 11. Equipment for proper administration and maintenance of phototherapy.
- 1166 C. The additional equipment required for the intermediate level newborn service and for any higher service level is:
 - 1. Pediatric infusion pumps accurate to plus or minus 1 milliliter (ml) per hour;
 - 2. On-site supply of PgE1;
- 3. Equipment for 24-hour cardiorespiratory monitoring for neonatal use available for every incubator or radiant warmer:
- 4. Saturation monitor (pulse oximeter or equivalent) available for every infant given supplemental oxygen;
- 5. Portable x-ray machine; and

- 6. If a mechanical ventilator is selected to provide assisted ventilation prior to transport, it shall be approved for the use of neonates.
- D. The additional equipment required for the specialty level newborn service and a higher newborn service is as follows:
 - 1. Equipment for 24-hour cardiorespiratory monitoring with central blood pressure capability for each neonate with an arterial line;
 - 2. Equipment necessary for ongoing assisted ventilation approved for neonatal use with online capabilities for monitoring airway pressure and ventilation performance;
 - 3. Equipment and supplies necessary for insertion and maintenance of chest tube for drainage;
 - 4. On-site supply of surfactant;
 - 5. Computed axial tomography equipment (CAT) or magnetic resonance imaging equipment (MRI);
 - 6. Equipment necessary for initiation and maintenance of continuous positive airway pressure (CPAP) with ability to constantly measure delineated pressures and including alarm for abnormal pressure (i.e., vent with PAP mode); and
 - 7. Cardioversion unit with appropriate neonatal paddles and ability to deliver appropriate small watt discharges.
 - E. The hospital shall document that it has the appropriate equipment necessary for any of the neonatal surgical and special procedures it provides that are specified in its medical protocol and that are required for the specialty level newborn service.
 - F. The additional equipment requirements for the subspecialty level newborn service are:
 - 1. Equipment for emergency gastrointestinal, genitourinary, central nervous system, and sonographic studies available 24 hours a day;
 - 2. Pediatric cardiac catheterization equipment;
 - 3. Portable echocardiography equipment; and
 - 4. Computed axial tomography equipment (CAT) and magnetic resonance imaging equipment (MRI).
 - G. The hospital shall document that it has the appropriate equipment necessary for any of the neonatal surgical and special procedures it provides that are specified in the medical protocol and are required for the subspecialty level newborn service.

1206 Statutory Authority

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1207 §§ 32.1-12, 32.1-127, and 32.1-127.001 of the Code of Virginia.

1208 Historical Notes

- 1209 Former 12VAC5-41-440 D 7 and 8 derived from VR 355-33-500 § 2.28, eff. July 28, 1993;
- amended, Virginia Register Volume 11, Issue 8, eff. April 1, 1995; Volume 11, Issue 16, eff. June
- 1, 1995; Volume 11, Issue 21, eff. August 10, 1995; amended and adopted as 12VAC5-410-445.
- 1212 Virginia Register 21, Issue 6, eff. February 14, 2005; amended, Virginia Register Volume 22,
- 1213 Issue 8, eff. January 25, 2006; Volume 23, Issue 10, eff. March 1, 2007; Volume 26, Issue 22, eff.
- **1214** August 4, 2010; Volume 37, Issue 19, eff. June 9, 2021.

1215 12VAC5-410-447. Combined obstetric and clean gynecological service; infection control.

A. A hospital may combine obstetric and clean gynecological services. The hospital shall define clean gynecological cases in written hospital policy. A combined obstetric and clean gynecologic service shall be organized under written policies and procedures. The policies and procedures shall be approved by the medical and nursing staff of these services and adopted by the governing body and shall include, but not limited to the following requirements:

- 1. Cesarean section and obstetrically related surgery, other than vaginal delivery, shall be carried out in designated operating or delivery rooms. Vaginal deliveries may be performed in designated delivery or operating rooms that are used solely for obstetric or clean gynecologic procedures.
 - 2. Clean gynecological cases may be admitted to the postpartum nursing unit of the obstetric service according to procedures determined by the obstetrics and gynecologic staff and the hospital's infection control committee.
 - 3. Only members of the medical staff with approved privileges shall admit and care for patients in the combined service area. These admissions shall be subject to the medical staff bylaws.
 - 4. Hospitals with a combined service shall limit admission to the service to those patients allowed by policies adopted by the obstetric and gynecological medical staff and the hospital's infection control committee.
 - 5. Unoccupied beds shall be reserved daily in a combined service ready for use by obstetric patients.
 - 6. Patients admitted to the combined service may be taken to radiology or other hospital departments for diagnostic procedures, before or after surgery, if it is not evident that these procedures may be hazardous to the patients or to other patients on the combined service.
 - 7. Patients may receive postpartum or immediate postoperative care in the general recovery room prior to being returned to the combined service area if the following conditions prevail:
 - a. The recovery room or intensive care unit is a separate unit adjacent to or part of the general surgical operating suite or delivery suite; and
 - b. The recovery room is under the direct supervision of the chairman of the anesthesiology department of the hospital.

In separate obstetric recovery rooms, supervision shall be provided by the obstetrician in charge or by physicians approved by the medical staff of the combined service.

- 8. Nursing care of all patients shall be supervised by a registered nurse.
- 9. Nursing care of both obstetrical and gynecological patients may be given by the same nursing personnel.
- 10. Visitor regulations applicable to visitors of obstetric patients shall also apply to visitors of other patients admitted to the combined service.
- B. In addition to the infection control requirements specified in 12VAC5-410-490, the hospital's infection control committee, in cooperation with the obstetric and newborn medical and nursing staff, shall establish written policies and procedures for infection control within the obstetric and newborn services. The policies and procedures shall be adopted by the governing body and shall include, but not be limited to, the following:
 - 1. The establishment of criteria for determining infection-related maternal and newborn morbidity;
 - 2. Written criteria for the isolation or segregation of mothers and newborns, in accordance with Guidelines for Perinatal Care, 8th Edition, 2017, (American Academy of Pediatrics/American College of Obstetricians and Gynecologists) and Control of Communicable Diseases in Man Manual, 21st Edition, 2022 (American Public Health Association) to include at least the following categories:
 - a. Birth prior to admission to the facility;
 - b. Birth within the facility but prior to admission to the labor and delivery area;

- c. Readmission to the service after transfer or discharge;
- d. Presence of infection;

- e. Elevated temperature; and
- f. Presence of rash, diarrhea, or discharging skin lesions;
- 3. Written policies and procedures for the isolation of patients in accordance with Guidelines for Perinatal Care, 8th Edition, 2017 (AAP/ACOG) (American Academy of Pediatrics/American College of Obstetricians and Gynecologists) and Control of Communicable Diseases in Man Manual, 21st Edition, 2022 (American Public Health Association) including, but not limited to, the following:
 - a. Ensuring that a physician orders and documents in the patient's medical record the placement of a mother or newborn in isolation;
 - b. Ensuring that at least one labor room is available for use by a patient requiring isolation;
 - c. Provisions for the isolation of a mother and newborn together (rooming-in) or separately; and
 - d. Policies and procedures for assigning nursing personnel to care for patients in isolation;
- 4. Control of traffic, including personnel and visitors. Policies and procedures shall be established in the event that personnel from other services must work in the obstetric and newborn services or personnel from the obstetric and newborn services must work on other services. Appropriate clothing changes and handwashing shall be required of any individual prior to assuming temporary assignments or substitution from any other area or service in the hospital;
- 5. Determination of the health status of personnel, and control of personnel with symptoms of communicable infectious disease;
- 6. Review of cleaning procedures, agents, and schedules in use in the obstetric and newborn services. Incubators or bassinets shall be cleaned with detergent and disinfectant registered by the U.S. Environmental Protection Agency each time a newborn occupying it is discharged or at least every seven days;
- 7. Techniques of patient care, including handwashing and the use of protective clothing such as gowns, masks, and gloves; and
- 8. Infection control in the nursery, including but not limited to:
 - a. Closing of the nursery immediately in the event of an epidemic, as determined by the infection control director in consultation with the medical director and the Department of Health;
 - b. Assigning a newborn to a clean incubator or bassinet at least every seven days;
 - c. Using an impervious cover that completely covers the surface of the scale pan if newborns are weighed on a common scale, and changing the cover after each newborn is weighed;
 - d. Gowning in isolation cases; and
 - e. Requiring nursery personnel wear clean scrub attire in the nursery when they are handling infants. Appropriate cover garments shall be worn over scrub attire when personnel are holding infants. Personnel shall wash their hands after contact with each patient and upon entering or leaving the nursery.

1311 Statutory Authority

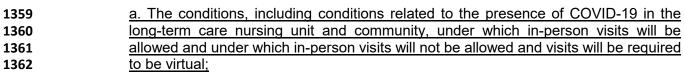
§ § 32.1-12 and 32.1-127 of the Code of Virginia.

1313 Historical Notes

- 1314 Former 12VAC5-41-440 E and F derived from VR 355-33-500 § 2.28, eff. July 28, 1993; amended,
- 1315 Virginia Register Volume 11, Issue 8, eff. April 1, 1995; Volume 11, Issue 16, eff. June 1, 1995;
- Volume 11, Issue 21, eff. August 10, 1995; amended and adopted as 12VAC5-410-447, Virginia
- 1317 Register Volume 21, Issue 6, eff. February 14, 2005.

1318 12VAC5-410-465. Long-term care nursing services.

- A. The provisions of this section shall apply to a general hospital's long-term care nursing unit if that unit is a certified nursing facility. The general hospital shall be responsible for ensuring its long-term care nursing unit meets the requirements of this section.
- B. For the purposes of this section, "resident" means any person admitted to a general hospital's long-term care nursing unit.
- <u>C. A long-term care nursing unit shall fully disclose to the applicant for admission the unit's</u> admissions policies, including any preferences given.
- D. A long-term care nursing unit shall train, or arrange for training of, all employees who work in the long-term care unit and who are mandated to report adult abuse, neglect, or exploitation pursuant to § 63.2-1606 of the Code of Virginia on such reporting procedures and the consequences for failing to make a required report.
- E. A long-term care nursing unit shall register with the Department of State Police to receive notice of the registration, reregistration, or verification of registration information of any person required to register with the Sex Offender and Crimes Against Minors Registry pursuant to Chapter 9 (§ 9.1-900 et seq.) of Title 9.1 of the Code of Virginia within the same or a contiguous zip code area in which the long-term care nursing unit is located, pursuant to § 9.1-914 of the Code of Virginia.
- F. If a long-term care nursing unit anticipates a potential resident will have a length of stay greater than three days or in fact stays longer than three days, the long-term care nursing unit shall ascertain, prior to admission, whether the potential resident is required to register with the Sex Offender and Crimes Against Minors Registry pursuant to Chapter 9 (§ 9.1-900 et seq.) of Title 9.1 of the Code of Virginia.
- G. Upon the request of the unit's family council, a long-term care nursing unit shall send notices and information about the family council mutually developed by the family council and the administration of the unit, and provided to the unit for such purpose, to the listed responsible party or a contact person of the resident's choice up to six times per year.
 - 1. Such notices may be included together with a monthly billing statement or other regular communication.
 - 2. Notices and information shall also be posted in a designated location within the unit.
 - 3. No family member of a resident or other resident representative shall be restricted from participating in meetings in the unit with the families or resident representatives of other residents in the unit.
- H. A general hospital shall maintain for its long-term care unit liability insurance coverage in a minimum amount of \$1 million, and professional liability coverage in an amount at least equal to the recovery limit set forth in § 8.01-581.15 of the Code of Virginia, to compensate residents or individuals for injuries and losses resulting from the negligent or criminal acts of the unit.
- I. During a public health emergency related to COVID-19, a long-term care unit shall establish a protocol to allow each resident to receive visits, consistent with guidance from the CDC and as directed by CMS and the board, which shall include:
 - 1. Provisions describing:



- b. The requirements with which in-person visitors will be required to comply to protect the health and safety of the residents and staff of the long-term care nursing unit;
- c. The types of technology, including interactive audio or video technology, and the staff support necessary to ensure visits are provided as required by this subsection; and
- d. The steps the long-term care unit will take in the event of a technology failure, service interruption, or documented emergency that prevents visits from occurring as required by this subsection;
- 2. A statement of the frequency with which visits, including virtual and in-person, where appropriate, will be allowed, which shall be at least once every 10 calendar days for each resident:
- 3. A provision authorizing a resident or the resident's personal representative to waive or limit visitation, provided that such waiver or limitation is included in the resident's health record; and
- 4. A requirement that the general hospital publish on its website or communicate to each resident or the resident's authorized representative, in writing or via electronic means, the long-term care unit's plan for providing visits to residents as required by this subsection.
- J. Unless the vaccination is medically contraindicated or the resident declines the offer of vaccination, a general hospital shall provide, or arrange for, the administration to the residents of an annual influenza vaccination and a pneumococcal vaccination in accordance with the following recommendations of ACIP:
 - 1. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices United States, 2022–23 Influenza Season, MMWR 71 (1), 2022, CDC;
 - 2. Use of 15-Valent Pneumococcal Conjugate Vaccine and 20-Valent Pneumococcal Conjugate Vaccine Among U.S. Adults: Updated Recommendations of ACIP United States, MMWR 71 (4), 2022, CDC;
 - 3. Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults Aged >65 Years: Updated Recommendations of ACIP, MMWR 68 (46), 2019, CDC;
 - 4. Intervals Between PCV13 and PPSV23 Vaccines: Recommendations of ACIP, MMWR 64 (15), 2015, CDC;
 - <u>5. Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults Aged >65 Years: Recommendations of ACIP, MMWR 63 (37), 2014, CDC;</u>
- 1398 <u>6. Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal</u>
 1399 <u>Polysaccharide Vaccine Among Children Aged 6–18 Years with Immunocompromising</u>
 1400 Conditions: Recommendations of ACIP, MMWR 62 (25), 2013, CDC:
- 1401 7. Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal
 1402 Polysaccharide Vaccine for Adults with Immunocompromising Conditions:
 1403 Recommendations of ACIP, MMWR 61 (40), 2012, CDC;

- 1404 8. Prevention of Pneumococcal Disease Among Infants and Children Use of 13-Valent
 1405 Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine:
 1406 Recommendations of ACIP, MMWR 59 (RR-11), 2010, CDC; and
- 1407
 9. Updated Recommendations for Prevention of Invasive Pneumococcal Disease Among
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 Adults Using the 23-Valent Pneumococcal Polysaccharide Vaccine (PPSV23), MMWR 59
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 (34), 2010, CDC.

1410 Statutory Authority

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

12VAC5-410-650. General building and physical plant information.

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

In addition, hospitals shall be designed and constructed consistent with Part 1 and Part 2 of the 2018 Guidelines for Design and Construction of Hospitals, 2022 Edition of the (The Facility Guidelines Institute), as amended by the November 2022 Errata for Guidelines for Design and Construction of Hospitals, 2022 Edition (The Facility Guidelines Institute), and if applicable, Chapter 2.8 of Part 2 of the Guidelines for Design and Construction of Outpatient Facilities, 2022 Edition (The Facility Guidelines Institute), as amended by the November 2022 Errata for Guidelines for Design and Construction of Outpatient Facilities, 2022 Edition (The Facility Guidelines Institute) pursuant to § 32.1-127.001 of the Code of Virginia.

B. Architectural drawings and specifications for all new construction or for additions, alterations, or renovations to any existing building shall be dated, stamped with professional seal, and signed by the architect. The architect shall certify that the drawings and specifications were prepared to conform to the Virginia Uniform Statewide Building Code (13VAC5-63) and be consistent with Part 1 and Part 2 of the 2018 Guidelines for Design and Construction of Hospitals, 2022 Edition of the (The Facility Guidelines Institute), as amended by the November 2022 Errata for Guidelines for Design and Construction of Hospitals, 2022 Edition (The Facility Guidelines Institute), and if applicable, Chapter 2.8 of the Guidelines for Design and Construction of Outpatient Facilities, 2022 Edition (The Facility Guidelines Institute), as amended by the November 2022 Errata for Guidelines for Design and Construction of Outpatient Facilities, 2022 Edition (The Facility Guidelines Institute).

1435 Statutory Authority

1436 §§ 32.-12, 32.1-127, and 32.1-127.001 of the Code of Virginia.

1437 Historical Notes

- 1438 Derived from VR355-33-500 § 3.1, eff. July 28, 1993; amended, Virginia Register Volume 11, 1439 Issue 8, eff. April 1, 1995; Volume 22, Issue 8, eff. January 25, 2006; Volume 23, Issue 10, eff.
- 1440 March 1, 2007; Volume 26, Issue 22, eff. August 4, 2010; Volume 37, Issue 19, eff. June 9, 2021.

1441 12VAC5-410-760. Long-term care nursing units.

Construction and renovation of long-term care nursing units, including intermediate and skilled nursing care nursing units, shall be designed and constructed consistent with section 2.2-2.13 2.2-2.15 of Part 2 of the 2018 Guidelines for Design and Construction of Hospitals, 2022 Edition of the (The Facility Guidelines Institute) pursuant to § 32.1-127.001 of the Code of Virginia.

Architectural drawings and specifications for all new construction or for additions, alterations, or renovations to any existing building shall be dated, stamped with professional seal, and signed by the architect. The architect shall certify that the drawings and specifications were prepared to conform to the Virginia Uniform Statewide Building Code (13VAC5-63) and be consistent with

- section 2.2-2.13 2.2-2.15 of Part 2 of the 2018 Guidelines for Design and Construction of
- 1451 Hospitals, 2022 Edition of the (The Facility Guidelines Institute).
- 1452 Statutory Authority
- 1453 §§ 32.1-12, 32.1-127, and 32.1-127.001 of the Code of Virginia.
- 1454 Historical Notes

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- Derived from VR355-33-500 § 3.12, eff. July 28, 1993; amended, Virginia Register Volume 11,
- 1456 Issue 8, eff. April 1, 1995; Volume 22, Issue 8, eff. January 25, 2006; Volume 23, Issue 10, eff.
- **1457** March 1, 2007; Volume 37, Issue 19, eff. June 9, 2021.
- 1458 Part IV

Organization and Operation of Outpatient Surgical Hospitals: Organization, Operation, and Design Standards for Existing and New Facilities

12VAC5-410-1170. Policy and procedures manual.

A. Each outpatient surgical hospital shall develop a policy and procedures manual that shall include provisions covering the following items:

- 1. The types of emergency and elective procedures that may be performed in the facility.
- 2. Types of anesthesia that may be used.
- 3. Admissions and discharges, including:
 - a. Criteria for evaluating the patient before admission and before discharge; and
 - b. Protocols to ensure that any patient scheduled to receive an elective surgical procedure for which the patient can reasonably be expected to require outpatient physical therapy as a follow-up treatment after discharge is informed that the patient:
 - (1) Is expected to require outpatient physical therapy as a follow-up treatment; and
 - (2) Will be required to select a physical therapy provider prior to being discharged from the hospital.
- 4. Written informed consent of patient prior to the initiation of any procedures.
- 5. Procedures for housekeeping and infection control and prevention.
- 6. Disaster preparedness.
- 7. Facility security.
- B. <u>An outpatient surgical hospital shall provide</u> A <u>a</u> copy of approved policies and procedures and <u>any subsequent</u> revisions thereto shall be made available to the OLC upon request.
- C. Each outpatient surgical hospital shall establish a protocol relating to the rights and responsibilities of patients based on <u>42 C.F.R. § 416.50</u> Joint Commission on Accreditation of Healthcare Organizations' Standards for Ambulatory Care (2000 Hospital Accreditation Standards, January 2000). The protocol shall include a process reasonably designed to inform patients of their rights and responsibilities. Patients shall be given a copy of their rights and responsibilities upon admission.
- D. If the Governor has declared a public health emergency related to the novel coronavirus (COVID-19), each outpatient surgical hospital shall allow a person with a disability who requires assistance as a result of such disability to be accompanied by a designated support person at any time during which health care services are provided.
 - 1. A designated support person shall not be subject to any restrictions on visitation adopted by such outpatient surgical hospital. However, such designated support person may be required to comply with all reasonable requirements of the outpatient surgical

- hospital adopted to protect the health and safety of patients and staff of the outpatient surgical hospital.
 - 2. Every outpatient surgical hospital shall establish policies applicable to designated support persons and shall:
 - a. Make such policies available to the public on a website maintained by the outpatient surgical hospital; and
 - b. Provide such policies, in writing, to the patient at such time as health care services are provided.
 - E. D. Each outpatient surgical hospital shall obtain a criminal history record check pursuant to § 32.1-126.02 of the Code of Virginia on any compensated employee not licensed by the Board of Pharmacy whose job duties provide access to controlled substances within the outpatient surgical hospital pharmacy.

1505 Statutory Authority

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

1507 Historical Notes

- 1508 Derived from VR355-33-500 § 4.3, eff. July 28, 1993; amended, Virginia Register Volume 11,
- 1509 Issue 8, eff. April 1, 1995; Volume 19, Issue 1, eff. November 1, 2002; Volume 23, Issue 10, eff.
- March 1, 2007; Volume 28, Issue 2, eff. November 1, 2011; Volume 36, Issue 23, eff. August 6,
- 2020; Volume 37, Issue 14, eff. March 31, 2021.
- 1512 <u>12VAC5-410-1171. Persons with a disability; designated support person in outpatient surgical hospitals.</u>
- A. For the purposes of this section, "admission" means accepting a person for observation.
 - B. An outpatient surgical hospital shall allow a person with a disability who requires support and assistance necessary due to the specifics of the person's disability to be accompanied by a DSP who will provide support and assistance necessary due to the specifics of the person's disability to the person with a disability during an admission.
 - 1. In any case in which the duration of the admission lasts more than 24 hours, the person with a disability may designate more than one DSP.
 - 2. No outpatient surgical hospital shall be required to allow more than one DSP to be present with a person with a disability at any time.
 - C. An outpatient surgical hospital may:
 - 1. Not subject a DSP to any restrictions on visitation;
 - 2. Require a DSP to comply with all reasonable requirements of an outpatient surgical hospital adopted to protect the health and safety of the person with a disability; the DSP; the staff and other patients of, or visitors to, an outpatient surgical hospital; and the public; and
 - 3. Restrict a DSP's access to specified areas of and movement on the premises of an outpatient surgical hospital when such restrictions are determined by an outpatient surgical hospital to be reasonably necessary to protect the health and safety of the person with a disability; the DSP; the staff and other patients of, or visitors to, an outpatient surgical hospital; and the public.
 - D. An outpatient surgical hospital may request that a person with a disability provide documentation indicating that he is a person with a disability.
 - 1. If the person with a disability fails, refuses, or is unable to provide documentation requested pursuant to subsection D of this section, an outpatient surgical hospital may

perform an objective assessment of the person to determine whether he is a person with a disability.

2. If an outpatient surgical hospital fails to perform an objective assessment pursuant to subdivision D 1 of this section, an outpatient surgical hospital may not prohibit a DSP from accompanying a person with a disability for the purpose of providing support and assistance necessary due to the specifics of the person's disability.

E. An outpatient surgical hospital shall

- 1. Establish protocols to inform patients, at the time of admission, of the right of a person with a disability who requires support and assistance necessary due to the specifics of the person's disability to be accompanied by a DSP for the purpose of providing support and assistance necessary due to the specifics of the person's disability;
- 2. Develop and make available to a patient or his guardian, authorized representative, or care provider upon request written information regarding the right of a person with a disability who requires support and assistance necessary due to the specifics of the person's disability to be accompanied by a DSP and any policies related to that right; and 3. Make the written information described in subdivision E 2 of this section available to the public on its website.

G. This section may not:

1. Alter the obligation of an outpatient surgical hospital to provide patients with effective communication support or other required services, regardless of the presence of a DSP or other reasonable accommodation, consistent with applicable federal or state law or regulations; and

2. Be interpreted to:

- a. Prevent an outpatient surgical hospital from complying, or interfere with the ability of an outpatient surgical hospital to comply, with or cause an outpatient surgical hospital to violate any federal or state law or regulation;
- <u>b. Deem a DSP to be acting under the direction or control of an outpatient surgical</u> hospital or as an agent of an outpatient surgical hospital; or
- c. Require an outpatient surgical hospital to allow a DSP to perform any action or provide any support or assistance necessary due to the specifics of the person's disability when an outpatient surgical hospital reasonably determines that the performance of the action or provision would be:
- (1) Medically or therapeutically contraindicated; or
- (2) A threat to the health and safety of the person with a disability, the DSP, or the staff or other patients of, or visitors to, an outpatient surgical hospital.

Statutory Authority

§ §32.1-12, 32.1-127, and 32.1-173.08 of the Code of Virginia.

12VAC5-410-1175. Discharge planning. (Repealed.)

A. Every hospital shall provide each patient admitted as an inpatient or his legal guardian the opportunity to designate an individual who will care for or assist the patient in his residence following discharge from the hospital and to whom the hospital shall provide information regarding the patient's discharge plan and any follow-up care, treatment, and services that the patient may require.

- B. Every hospital upon admission shall record in the patient's medical record:
 - 1. The name of the individual designated by the patient;
- 2. The relationship between the patient and the person; and

3. The person's telephone number and address.

C. If the patient fails or refuses to designate an individual to receive information regarding his discharge plan and any follow-up care, treatment, and services, the hospital shall record the patient's failure or refusal in the patient's medical record.

- D. A patient may change the designated individual at any time prior to the patient's release, and the hospital shall record the changes, including the information referenced in subsection B of this section, in the patient's medical record within 24 hours of such a change.
- E. Prior to discharging a patient who has designated an individual pursuant to subsection A or D of this section, the hospital shall (i) notify the designated individual of the patient's discharge, (ii) provide the designated individual with a copy of the patient's discharge plan and instructions and information regarding any follow-up care, treatment, or services that the designated individual will provide, and (iii) consult with the designated individual regarding the designated individual's ability to provide the care, treatment, or services. Such discharge plan shall include:
 - 1. The name and contact information of the designated individual;
 - 2. A description of follow-up care, treatment, and services that the patient requires; and
 - 3. Information, including contact information, about any health care, long-term care, or other community-based services and supports necessary for the implementation of the patient's discharge plan.

A copy of the discharge plan and any instructions or information provided to the designated individual shall be included in the patient's medical record.

F. The hospital shall provide each individual designated pursuant to subsection A or D of this section the opportunity for a demonstration of specific follow-up care tasks that the designated individual will provide to the patient in accordance with the patient's discharge plan prior to the patient's discharge, including opportunity for the designated individual to ask questions regarding the performance of follow-up care tasks. Such opportunity shall be provided in a culturally competent manner and in the designated individual's native language.

1610 Statutory Authority

- § 32.1-127 of the Code of Virginia.
- 1612 Historical Notes

Derived from Virginia Register Volume 32, Issue 14, eff. April 8, 2016.

12VAC5-410-1178. Financial assistance in outpatient surgical hospitals.

- A. As used in this section, "patient" and "uninsured patient" have the same meanings as ascribed to these terms in subsection A of § 32.1-137.010 of the Code of Virginia.
- B. An outpatient surgical hospital shall make reasonable efforts to screen every uninsured patient to determine whether the individual is eligible for medical assistance pursuant to the state plan for medical assistance or for financial assistance under the outpatient surgical hospital's financial assistance policy.
- C. An outpatient surgical hospital shall inform every uninsured patient who receives services at the outpatient surgical hospital and who is determined to be eligible for assistance under the outpatient surgical hospital's financial assistance policy of the option to enter into a payment plan with the outpatient surgical hospital.
 - 1. A payment plan entered into pursuant to this subsection shall be provided to the patient in writing or electronically and shall provide for repayment of the cumulative amount owed to the outpatient surgical hospital.
 - 2. The amount of monthly payments and the term of the payment plan shall be determined based upon the patient's ability to pay.

- 3. Any interest on amounts owed pursuant to the payment plan shall not exceed the maximum judgment rate of interest pursuant to § 6.2-302 of the Code of Virginia.
 4. The outpatient surgical hospital may not charge any fees related to the payment plan.
 - 5. The payment plan shall allow prepayment of amounts owed without penalty.
 - D. An outpatient surgical hospital shall develop a process by which either an uninsured patient who agrees to a payment plan pursuant to subsection C of this section or the outpatient surgical hospital may request and shall be granted the opportunity to renegotiate the payment plan.
 - 1. Renegotiation shall include opportunity for a new screening in accordance with subsection B of this section.
 - 2. An outpatient surgical hospital may not charge any fees for renegotiation of a payment plan pursuant to this subsection.
 - E. An outpatient surgical hospital shall provide written information about:
 - 1. Its charity care policies, including:

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- a. Policies related to free and discounted care;
- b. Specific eligibility criteria for charity care; and
- c. Procedures for applying for charity care;
- 2. The availability of a payment plan for the payment of debt owed to the outpatient surgical hospital pursuant to subsection C of this section; and
- 3. The renegotiation process described in subsection D of this section.
- <u>F. To provide the information required by subsection F of this section, an outpatient hospital</u> shall:
 - 1. Post the information conspicuously in public areas of the outpatient surgical hospital, including admissions or registration areas and associated waiting rooms;
 - 2. Make the information available to:
 - <u>a. A patient at the time of admission or discharge, or at the time services are provided;</u> and
 - b. Persons with limited English proficiency in accordance with the U.S. Department of Health and Human Services' Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons (August 8, 2003, 68 FR 47311), if the outpatient surgical hospital is subject to the requirements of Title VI of the Civil Rights Act of 1964 (Pub. L. No. 88-352), as amended; and
 - 3. Include the information:
 - a. With any billing statements sent to uninsured patients; and
 - b. On any website maintained by the outpatient surgical hospital.
- G. Notwithstanding any other provision of law, an outpatient surgical hospital may not engage in any action described in § 501(r)(6) of the Internal Revenue Code, as it was in effect on January 1, 2020, to recover a debt for medical services against any patient unless the outpatient surgical hospital has made all reasonable efforts to determine whether the patient:
 - 1. Qualifies for medical assistance pursuant to the state plan for medical assistance; or
 - 2. Is eligible for financial assistance under the outpatient surgical hospital's financial assistance policy.
 - H. Nothing in this section shall be construed to:
- 1. Prohibit an outpatient surgical hospital, as part of its financial assistance policy, from requiring a patient to:

- a. Provide necessary information needed to determine eligibility for financial assistance under the outpatient surgical hospital's financial assistance policy, medical assistance pursuant to Title XVIII or XIX of the Social Security Act (42 U.S.C. § 301 et seq.) or 10 U.S.C. § 1071 et seq., or other programs of insurance; or
 - b. Undertake good faith efforts to apply for and enroll in the programs of insurance for which the patient may be eligible as a condition of awarding financial assistance;
 - 2. Require an outpatient surgical hospital to grant or continue to grant any financial assistance or payment plan pursuant to this section when:
 - a. A patient has provided false, inaccurate, or incomplete information required for determining eligibility for the outpatient surgical hospital's financial assistance policy; or
 - <u>b. A patient has not undertaken good faith efforts to comply with any payment plan pursuant to this section; or </u>
 - 3. Prohibit the coordination of benefits as required by state or federal law.

1689 Statutory Authority

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1690 §§ 32.1-12, 32.1-127, 32.1-137.01, and 32.1-137.010 of the Code of Virginia.

1691 12VAC5-410-1190. Nursing staff.

<u>A.</u> The total number of nursing personnel will vary depending upon the number and types of patients to be admitted and the types of operative procedures to be performed or the services programmed.

- 1. A registered nurse qualified on the basis of education, experience, and clinical ability shall be responsible for the direction of nursing care provided the patients.
- 2. The number and type of nursing personnel, including registered nurses, licensed practical nurses, and supplementary staff, shall be based upon the needs of the patients and the types of services performed.
- 3. At least one registered nurse shall be on duty at all times while the facility is in use.
- 4. Job descriptions shall be developed for each level of nursing personnel and include functions, responsibilities, and qualifications.
- 5. Evidence of current Virginia registration required by state statute shall be on file in the facility.
- B. Each outpatient surgical hospital shall quarterly report to the department no later 30 calendar days after January 1st, April 1st, July 1st, and October 1st:
 - 1. The total number of certified sexual assault nurse examiners employed by the outpatient surgical hospital; and
 - 2. The location, including street address, and contact information for each location at which such certified sexual assault nurse examiner provides services.

Each outpatient surgical hospital shall report the information required by this subsection to the Office of Family Health Services, Virginia Department of Health.

1713 Statutory Authority

1714 §§ 32.1-12, 32.1-23.2, and 32.1-127 of the Code of Virginia.

1715 Historical Notes

- 1716 Derived from VR355-33-500 § 4.5, eff. July 28, 1993; amended, Virginia Register Volume 11,
- **1717** Issue 8, eff. April 1, 1995.

1718 12VAC5-410-1260. Medical records.

A. Medical records. An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. It shall include, when applicable, but not be limited to the following:

- 1. Patient identification:
- Admitting information, including patient history and physical examination;
- **1725** 3. Signed consent;

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- 4. Confirmation of pregnancy, if applicable;
- **1727** 5. Physician orders;
- 6. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays;
- **1729** 7. Anesthesia record;
- **1730** 8. Operative record;
- 9. Surgical medication and medical treatments;
- 1732 10. Recovery room notes;
- 1733 11. Physician and nurses' progress notes,
- 1734 12. Condition at time of discharge,
- 13. Patient instructions, preoperative and postoperative; and
- 1736 14. Names of referral physicians or agencies.
 - B. Provisions shall be made for the safe storage of medical records er and the accurate and legible reproductions thereof of medical records according to § 32.1-127.1:03 of the Code of Virginia and the Health Insurance Portability and Accountability Act, or HIPAA (42 USC § 1320d et seq.) (Pub. L. No. 104-191).
 - C. All medical records, either original or accurate reproductions, shall be preserved for a minimum of five years following discharge of the patient.
 - 1. Records of minors shall be kept for at least five years after such minor has reached the age of 18 years.
 - 2. Birth and death information shall be retained for 10 years in accordance with § 32.1-274 of the Code of Virginia.
 - 3. Record of abortions and proper information for the issuance of a fetal death certificate shall be furnished <u>to</u> the <u>Division Office</u> of Vital Records, Virginia Department of Health, <u>within 10 days after the abortion</u> as required by law.
 - D. An outpatient surgical hospital that makes health records, as defined in § 32.1-127.1:03 of the Code of Virginia, of patients who are minors available to patients through a secure website shall make the health records available to the patient's parent or guardian through the secure website, unless the hospital cannot make the health record available:
 - 1. In a manner that prevents disclosure of information, the disclosure of which has been denied pursuant to subsection F of § 32.1-127.1:03 of the Code of Virginia; or
 - 2. Because the consent required in accordance with subsection E of § 54.1-2969 of the Code of Virginia has not been provided.
- 1758 Statutory Authority
- **1759** §§ 32.1-12 and 32.1-127 of the Code of Virginia.
- 1760 Historical Notes

1761 Derived from VR355-33-500 § 4.12, eff. July 28, 1993; amended, Virginia Register Volume 11, 1762 Issue 8, eff. April 1, 1995; Volume 22, Issue 8, eff. January 25, 2006.

12VAC5-410-1350. Local and state codes and standards.

A. All construction of new buildings and additions, <u>renovations</u>, <u>or</u> alterations, <u>or repairs</u> to existing buildings for occupancy as a "free-standing" outpatient hospital shall conform to state and local codes, zoning ordinances, and the Virginia Uniform Statewide Building Code (13VAC5-63).

In addition, hospitals shall be designed and constructed consistent with Part 1 and sections Chapters 2.1 and 2.7 of Part 2 of the 2018 Guidelines for Design and Construction of Outpatient Facilities, 2022 Edition of the (The Facility Guidelines Institute) pursuant to § 32.1-127.001 of the Code of Virginia, as amended by the November 2022 Errata for the Guidelines for Design and Construction of Outpatient Facilities, 2022 Edition (The Facility Guidelines Institute).

Architectural drawings and specifications for all new construction or for additions, alterations, or renovations to any existing building shall be dated, stamped with professional seal, and signed by the architect. The architect shall certify that the drawings and specifications were prepared to conform to the Virginia Uniform Statewide Building Code (13VAC5-63) and be consistent with Part 1 and sections Chapters 2.1 and 2.7 of Part 2 of the 2018 Guidelines for Design and Construction of Outpatient Facilities, 2022 Edition of the (The Facility Guidelines Institute), as amended by the November 2022 Errata for Guidelines for Design and Construction of Outpatient Facilities, 2022 Edition (The Facility Guidelines Institute).

- B. The use of an incinerator shall require permitting from the nearest regional office of the Department of Environmental Quality.
- C. Water shall be obtained from an approved water supply system. Outpatient surgery centers shall be connected to sewage systems approved by the Department of Health or the Department of Environmental Quality.
- D. Each outpatient surgery center shall establish a monitoring program for the internal enforcement of all applicable fire and safety laws and regulations.
- E. All radiological machines shall be registered with the Office of Radiological Health of the Virginia Department of Health. Installation, calibration and testing of machines and storage facilities shall comply with 12VAC5-481, Virginia Radiation Protection Regulations.
- F. Pharmacy services shall comply with Chapter 33 (§ 54.1-3300 et seq.) of Title 54.1 of the Code of Virginia and 18VAC110-20, Regulations Governing the Practice of Pharmacy.

1793 Statutory Authority

1794 §§ 32.1-12, 32.1-127, and 32.1-127.001 of the Code of Virginia.

1795 Historical Notes

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- Derived from VR355-33-500 § 5.4, eff. July 28, 1993; amended, Virginia Register Volume 11,
- 1797 Issue 8, eff. April 1, 1995; Volume 22, Issue 8, eff. January 25, 2006; Volume 23, Issue 10, eff.
- 1798 March 1, 2007; Volume 26, Issue 22, eff. August 4, 2010; Volume 37, Issue 19, eff. June 9, 2021.

1799 Documents Incorporated by Reference (12VAC5-410)

1800 <u>Control of Communicable Diseases Manual, American Public Health Association, 21st</u>
1801 Edition, 2022, https://www.apha.org.

Errata for Guidelines for Design and Construction of Hospitals, The Facility Guidelines Institute, 2022 Edition, https://fgiguidelines.org/guidelines/errata-addenda/ (eff. 11/2022).

1804 <u>Errata for Guidelines for Design and Construction of Outpatient Facilities, The Facility</u>
1805 <u>Guidelines Institute, 2022 Edition, https://fgiguidelines.org/guidelines/errata-addenda/ (eff. 11/2022).</u>

- Guidelines for Design and Construction of Hospitals, 2018 Edition, The Facility Guidelines Institute, Washington D.C. 2022 Edition, http://www.fgiguidelines.org https://fgiguidelines.org.
- Guidelines for Design and Construction of Outpatient Facilities, 2018 Edition, The Facility Guidelines Institute, Washington, D.C. 2022 Edition, https://fgiguidelines.org.
- 1811 <u>Guidelines for Perinatal Care, American Academy of Pediatric/American College of</u>
 1812 <u>Obstetricians and Gynecologists, 8th Edition, 2017, https://www.aap.org and https://www.acog.org.</u>
- Intervals Between PCV13 and PPSV23 Vaccines: Recommendations of ACIP, MMWR 64
 (15), 2015, CDC.
- Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the
 Advisory Committee on Immunization Practices United States, 2022–23 Influenza Season,
 MMWR 71 (1), 2022, CDC.
- Prevention of Pneumococcal Disease Among Infants and Children Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine:
 Recommendations of ACIP, MMWR 59 (RR-11), 2010, CDC.
- 1822 Updated Recommendations for Prevention of Invasive Pneumococcal Disease Among Adults
 1823 Using the 23-Valent Pneumococcal Polysaccharide Vaccine (PPSV23), MMWR 59 (34), 2010,
 1824 CDC.
- 1825 <u>Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal</u>
 1826 <u>Polysaccharide Vaccine Among Adults Aged >65 Years: Recommendations of ACIP, MMWR 63</u>
 1827 (37), 2014, CDC.
- 1828 <u>Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal</u>
 1829 <u>Polysaccharide Vaccine Among Adults Aged >65 Years: Updated Recommendations of ACIP,</u>
 1830 <u>MMWR 68 (46), 2019, CDC.</u>
- 1831 <u>Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal</u>
 1832 <u>Polysaccharide Vaccine for Adults with Immunocompromising Conditions: Recommendations of</u>
 1833 ACIP, MMWR 61 (40), 2012, CDC.
- 1837 <u>Use of 15-Valent Pneumococcal Conjugate Vaccine and 20-Valent Pneumococcal Conjugate</u>
 1838 <u>Vaccine Among U.S. Adults: Updated Recommendations of ACIP United States, MMWR 71</u>
 1839 <u>(4), 2022, CDC.</u>

Office of Regulatory Management

Economic Review Form

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-410-10 et seq.
VAC Chapter title(s)	Regulations for the Licensure of Hospitals in Virginia
Action title	Amend Regulation After Periodic Review
Date this document prepared	November 28, 2022

Cost Benefit Analysis

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

Table 1a: Costs and Benefits of the Proposed Changes (Primary Option)		
(1) Direct Costs & Benefits	• Hospitals must report specified changes to the Virginia Department of Health (VDH) at least 30 calendar days prior to initiating the change.	
	Direct Costs: VDH is not aware of any quantifiable direct costs at time.	
	Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.	
	 Hospitals have to permit inspectors access to their facilities, records, and persons under their control for the purposes of inspection and have to submit plans of correction for cited deficiencies, and have to implement corrections within 45 business days. 	
	Direct Costs: VDH is not aware of any quantifiable direct costs at time.	
	Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.	
	Hospitals have to meet minimum requirements if they intended to operate a newborn safety device.	
	Direct Costs: VDH is not aware of any quantifiable direct costs at time.	
	Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.	

• Hospitals have to base their patient rights on analogous federal requirements.

Direct Costs: No more than \$1,250 one-time in total and potentially \$0 in total, as all but one licensed hospital already has to meet the analogous federal requirements.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• Hospitals have to meet the minimum requirements for allowing a person with a disability access to a designated support person.

Direct Costs: \$1,250 one-time per hospital to update existing policies and procedures about designated support persons.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• General hospitals have to meet minimum discharge planning standards.

Direct Costs: \$1,250 one-time per general hospital to update existing policies and procedures about discharge planning.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• Hospitals have to meet the minimum requirements for information disclosure about financial assistance and payment plans.

Direct Costs: \$1,250 one-time per hospital to update existing policies and procedures about financial assistance and payment plans.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• Hospitals have to quarterly report sexual assault nurse examiner (SANE) employment information on the first day of each calendar quarter to the Office of Family Health Services.

Direct Costs: \$5,000 annually per general hospital to track and report this information.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• Hospitals have to meet minimum requirements for parent or guardian electronic access to minor patient's medical records.

Direct Costs: VDH is not aware of any quantifiable direct costs at time.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• General hospitals have to report fetal death information as required by law to the Office of Vital Records.

Direct Costs: VDH is not aware of any quantifiable direct costs at time.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• Hospital construction, renovation, or alterations have to 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 time.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• General hospitals providing newborn service can store breast milk for up to 96 hours.

Direct Costs: VDH is not aware of any quantifiable direct costs at time.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• Updates to current clinical standards for infection prevention and control for general hospitals with obstetric and gynecological services

Direct Costs: VDH is not aware of any quantifiable direct costs at time.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

	nursing facilities have to Direct Costs: \$1,250 one existing policies and pro \$5,000 one-time per top procedures about mand registry, and informatio eight hospitals have lon nursing facilities.	long-term care nursing units that are certified to meet minimum statutory requirements e-time per topic per general hospital to update occdures about immunization, and visitation; pic per general hospital to create policies and dated reporting, regarding the sex offender in and notices about the family council. Only ing-term care nursing units that are certified is not aware of any quantifiable direct benefits
(2) Quantitative Factors Direct Costs	Estimated Dollar Amount (a) \$9,896,250	Present Value (c) \$8,846,234
Direct Costs	(a) \$7,870,230	(0) \$6,640,234
Direct Benefits	(b) \$0	(d) \$0
(3) Benefits- Costs Ratio	0.00	(4) Net -\$8,846,234 Benefit
(5) Indirect Costs & Benefits	VDH is not aware of any quantifiable benefits at this time. 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 1.4% increase in construction costs for a 160-bed general hospital, a 2.7% increase in construction costs for a 12-bed general hospital that is certified as a critical access hospital, a 0.7% – 1.3% increase in construction costs for a multi-specialty outpatient surgical hospital. VDH is not aware of any other quantifiable costs at this time.	
(6) Information Sources	The Facility Guidelines Institut Licensure and Certification.	e; Division of Acute Care Services, Office of
(7) Optional		es and constraints that limit a cost benefit availability, limited statutory discretion, and

The regulatory change is designed to conform the regulation to the Code of Virginia, and to promote the health, safety, and welfare of hospital patients by incorporating current clinical and industry practices as well as by requiring reasonable timely information from hospitals, access to information to ensure hospital compliance, remedial action within a reasonable and consistently applied timeframe if noncompliance does occur.

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

(1) Direct Costs & Benefits

Nondiscretionary changes have been omitted from this analysis.

• Hospitals must report specified changes to the Virginia Department of Health (VDH) at least 30 business days prior to initiating the change.

Direct Costs: VDH is not aware of any quantifiable direct costs at time.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• Hospitals have to permit inspectors access to their facilities, records, and persons under their control for the purposes of inspection and have to submit plans of correction for cited deficiencies, and have to implement corrections within 45 business days.

Direct Costs: VDH is not aware of any quantifiable direct costs at time.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• Hospitals have to quarterly report sexual assault nurse examiner (SANE) employment information.

Direct Costs: \$5,000 annually per general hospital to track and report this information.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• General hospitals providing newborn service can store breast milk for up to 48 hours.

	 time. Direct Benefits: VDH is at time. Clinical standards for hospitals with obstetric from pre-1996 	not aware of any quantifiable direct costs at a not aware of any quantifiable direct benefits infection prevention and control for general and gynecological services reference material not aware of any quantifiable direct costs at
	Direct Benefits: VDH is at time.	s not aware of any quantifiable direct benefits
(2) Quantitative		
Factors	Estimated Dollar Amount	Present Value
Direct Costs	(a) \$0	(c) \$0
Direct Benefits	(b) \$0	(d) \$0
(3) Benefits- Costs Ratio	0.00	(4) Net \$0 Benefit
(5) Indirect Costs & & Benefits	VDH is not aware of any quantifiable benefits at this time from the discretionary regulatory changes.	
	VDH is not aware of any quanti regulatory changes.	fiable costs at this time from the discretionary
(6) Information Sources		s, Office of Licensure and Certification
(7) Optional	VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models.	
	Virginia, and to promote the he by incorporating current clinica reasonable timely information f	ned to conform the regulation to the Code of ealth, safety, and welfare of hospital patients I and industry practices as well as by requiring from hospitals, access to information to ensure action within a reasonable and consistently iance does occur.

Table 1c: Costs and Benefits under an Alternative Approach

(1) Direct Costs
& Benefits

Nondiscretionary changes have been omitted from this analysis.

• Hospitals must report specified changes to the Virginia Department of Health (VDH) within an unspecified time frame at the hospital's discretion prior to initiating the change.

Direct Costs: VDH is not aware of any quantifiable direct costs at time.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

 Hospitals have to permit inspectors access to their facilities, records, and persons under their control for the purposes of inspection and have to submit plans of correction for cited deficiencies, and have to implement corrections within an unspecified time frame at the hospital's discretion.

Direct Costs: VDH is not aware of any quantifiable direct costs at time.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• Hospitals have to quarterly report sexual assault nurse examiner (SANE) employment information on a day of their choosing within a quarter to any person at VDH.

Direct Costs: \$5,000 annually per general hospital to track and report this information.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• General hospitals providing newborn service can store breast milk for a length of time to be determined by the hospital.

Direct Costs: VDH is not aware of any quantifiable direct costs at time.

	 at time. Infection prevention and and gynecological service. Direct Costs: VDH is a time. 	d control for general hospitals with obstetric ces do not reference any clinical standards not aware of any quantifiable direct costs at a not aware of any quantifiable direct benefits
(2) Quantitative Factors	Estimated Dollar Amount	Present Value
Direct Costs	(a) \$0	(c) \$0
Direct Benefits	(b) \$0	(d) \$0
(3) Benefits- Costs Ratio	0.00	(4) Net Benefit \$0.00
(5) Indirect Costs & Benefits	discretionary regulatory change	quantifiable benefits at this time from the es. fiable costs at this time from the discretionary
(6) Information Sources	Division of Acute Care Service	s, Office of Licensure and Certification
(7) Optional	VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models. The regulatory change is designed to conform the regulation to the Code of Virginia, and to promote the health, safety, and welfare of hospital patients by incorporating current clinical and industry practices as well as by requiring reasonable timely information from hospitals, access to information to ensure hospital compliance, remedial action within a reasonable and consistently applied timeframe if noncompliance does occur.	

Impact on Local Partners

Table 2: Impact on Local Partners

(1) Direct Costs & Benefits

• Hospitals must report specified changes to the Virginia Department of Health (VDH) at least 30 calendar days prior to initiating the change.

Direct Costs: VDH is not aware of any quantifiable direct costs at time.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

 Hospitals have to permit inspectors access to their facilities, records, and persons under their control for the purposes of inspection and have to submit plans of correction for cited deficiencies, and have to implement corrections within 45 business days.

Direct Costs: VDH is not aware of any quantifiable direct costs at time.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• Hospitals have to meet minimum requirements if they intended to operate a newborn safety device.

Direct Costs: VDH is not aware of any quantifiable direct costs at time.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• Hospitals have to base their patient rights on analogous federal requirements.

Direct Costs: VDH is not aware of any quantifiable direct costs at time.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• Hospitals have to meet the minimum requirements for allowing a person with a disability access to a designated support person.

Direct Costs: \$1,250 one-time per hospital to update existing policies and procedures about designated support persons.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• General hospitals have to meet minimum discharge planning standards.

Direct Costs: \$1,250 one-time per general hospital to update existing policies and procedures about discharge planning.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• Hospitals have to meet the minimum requirements for information disclosure about financial assistance and payment plans.

Direct Costs: \$1,250 one-time per hospital to update existing policies and procedures about financial assistance and payment plans.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• Hospitals have to quarterly report sexual assault nurse examiner (SANE) employment information.

Direct Costs: \$5,000 annually per general hospital to track and report this information.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• Hospitals have to meet minimum requirements for parent or guardian electronic access to minor patient's medical records.

Direct Costs: VDH is not aware of any quantifiable direct costs at time.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• General hospitals have to report fetal death information as required by law to the Office of Vital Records.

Direct Costs: VDH is not aware of any quantifiable direct costs at time.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• Hospital construction, renovation, or alterations have to 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 time.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• General hospitals providing newborn service can store breast milk for up to 96 hours.

Direct Costs: VDH is not aware of any quantifiable direct costs at time.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• Updates to current clinical standards for infection prevention and control for general hospitals with obstetric and gynecological services

Direct Costs: VDH is not aware of any quantifiable direct costs at time.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• General hospitals with long-term care nursing units that are certified nursing facilities have to meet minimum statutory requirements

Direct Costs: \$1,250 one-time per topic per general hospital to update existing policies and procedures about immunization, and visitation; \$5,000 one-time per topic per general hospital to create policies and procedures about mandated reporting, regarding the sex offender registry, and information and notices about the family council. Only eight hospitals have long-term care nursing units that are certified nursing facilities.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

(2) Quantitative	
Factors	Estimated Dollar Amount
Direct Costs	(a) \$112,500
Direct Benefits	(b) \$0
(3) Indirect Costs &	VDH is not aware of any quantifiable benefits at this time.
Benefits	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 1.4% increase in construction costs for a 160-bed general hospital, a 2.7% increase in construction costs for a 12-bed general hospital that is certified as a critical access hospital, a 0.7% – 1.3% increase in construction costs for a multi-specialty outpatient surgical hospital.
	VDH is not aware of any other quantifiable costs at this time.
(4) Information	The Facility Guidelines Institute; Division of Acute Care Services, Office of
Sources	Licensure and Certification.
(5) Assistance	None
(6) Optional	VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models.
	The regulatory change is designed to conform the regulation to the Code of Virginia, and to promote the health, safety, and welfare of hospital patients by incorporating current clinical and industry practices as well as by requiring reasonable timely information from hospitals, access to information to ensure hospital compliance, remedial action within a reasonable and consistently applied timeframe if noncompliance does occur.

Economic Impacts on Families

Table 3: Impact on Families

(1) Direct Costs	Families will not be affected by direct costs or benefits of the regulatory
& Benefits	change as they are not subject to the requirements contained in this regulatory
	chapter and thus will incur no direct cost or benefit

(2) Quantitative	
Factors	Estimated Dollar Amount
Direct Costs	(a) \$0
Direct Benefits	(b) \$0
(3) Indirect Costs & Benefits	VDH is not aware of any quantifiable indirect costs or benefits for families. To the extent that the cost or benefit of regulatory changes may be passed on to families, VDH cannot quantify that cost or benefit at this time.
(4) Information Sources	Division of Acute Care Services, Office of Licensure and Certification.
(5) Optional	VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models.
	The regulatory change is designed to conform the regulation to the Code of Virginia, and to promote the health, safety, and welfare of hospital patients by incorporating current clinical and industry practices as well as by requiring reasonable timely information from hospitals, access to information to ensure hospital compliance, remedial action within a reasonable and consistently applied timeframe if noncompliance does occur.

Impacts on Small Businesses

Table 4: Impact on Small Businesses

Table 4: Impact on Sman businesses		
(1) Direct Costs	VDH is not aware of any general hospital that meets the definition of "small	
& Benefits	business" so regulatory changes that exclusively impact general hospitals	
	have been omitted from this analysis.	
	•	
	Hospitals must report specified changes to the Virginia Department	
	of Health (VDH) at least 30 calendar days prior to initiating the	
	change.	
	Direct Costs: VDH is not aware of any quantifiable direct costs at	
	time.	
	Direct Benefits: VDH is not aware of any quantifiable direct benefits	
	at time.	
	 Hospitals have to permit inspectors access to their facilities, records, 	
	and persons under their control for the purposes of inspection and	

have to submit plans of correction for cited deficiencies, and have to implement corrections within 45 business days.

Direct Costs: VDH is not aware of any quantifiable direct costs at time.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• Hospitals have to meet minimum requirements if they intended to operate a newborn safety device.

Direct Costs: VDH is not aware of any quantifiable direct costs at time.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• Hospitals have to base their patient rights on analogous federal requirements.

Direct Costs: No more than \$1,250 one-time in total and potentially \$0 in total, as all but one licensed hospital already has to meet the analogous federal requirements.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• Hospitals have to meet the minimum requirements for allowing a person with a disability access to a designated support person.

Direct Costs: \$1,250 one-time per hospital to update existing policies and procedures about designated support persons.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• Hospitals have to meet the minimum requirements for information disclosure about financial assistance and payment plans.

Direct Costs: \$1,250 one-time per hospital to update existing policies and procedures about financial assistance and payment plans.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

(2) Quantitative Factors Direct Costs	 Hospitals have to quarterly report sexual assault nurse examiner (SANE) employment information on the first day of each calendar quarter to the Office of Family Health Services. Direct Costs: \$5,000 annually per general hospital to track and report this information. Direct Benefits: VDH is not aware of any quantifiable direct benefits at time. Hospitals have to meet minimum requirements for parent or guardian electronic access to minor patient's medical records. Direct Costs: VDH is not aware of any quantifiable direct costs at time. Direct Benefits: VDH is not aware of any quantifiable direct benefits at time. Hospital construction, renovation, or alterations have to 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 time. Direct Benefits: VDH is not aware of any quantifiable direct benefits at time. Estimated Dollar Amount (a) \$173,750
Direct Benefits	(b) \$0
(3) Indirect Costs & Benefits	VDH is not aware of any quantifiable benefits at this time. 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 1.4% increase in construction costs for a 160-bed general hospital, a 2.7% increase in construction costs for a 12-bed general hospital that is certified as a critical access hospital, a 0.7% – 1.3%

	increase in construction costs for a multi-specialty outpatient surgical hospital. VDH is not aware of any other quantifiable costs at this time.
(4) Alternatives	Of the changes that are discretionary (see Tables 1b and 1c for identification of the discretionary changes), VDH could not identify an alternative that achieved the same purpose without compromising the health, safety, and welfare of patients or without compromising VDH's ability to comply in a cost-efficient manner with statutory/legislative mandates placed on the agency.
(5) Information Sources	The Facility Guidelines Institute; Division of Acute Care Services, Office of Licensure and Certification.
(6) Optional	VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models.
	The regulatory change is designed to conform the regulation to the Code of Virginia, and to promote the health, safety, and welfare of hospital patients by incorporating current clinical and industry practices as well as by requiring reasonable timely information from hospitals, access to information to ensure hospital compliance, remedial action within a reasonable and consistently applied timeframe if noncompliance does occur.

Changes to Number of Regulatory Requirements

Table 5: Total Number of Requirements

	Number of Requirements			
Chapter number	Initial Count	Additions	Subtractions	Net Change
410	3,841	86	24	62



COMMONWEALTH of VIRGINIA

Colin M. Greene, MD, MPH State Health Commissioner Department of Health P O BOX 2448 RICHMOND, VA 23218

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

MEMORANDUM

DATE: November 7, 2022

TO: State Board of Health

FROM: Rebekah E. Allen, JD

Senior Policy Analyst, Office of Licensure and Certification

SUBJECT: Fast Track Action – Regulations for the Licensure of Nursing Facilities – Amend

Regulation to Incorporate Chapter 72 (2021 Acts of Assembly, Special Session I), Chapters 829, 1080, and 1081 (2020 Acts of Assembly), Chapters 10 and 11 (2020 Acts of Assembly), Special Session I), Chapters 177 and 222 (2005 Acts of Assembly) and Chapter 762 (2004 Acts of Assembly), Update Terms to Match

Statutory Language, and Update Licensure Provisions

Enclosed for your review are proposed amendments to Regulations for the Licensure of Nursing Facilities (12VAC5-371-10 *et seq.*).

This fast-track action is being utilized to conform 12VAC5-371-10 *et seq*. to the Code of Virginia and to update out-of-date regulatory provisions. Changes include amendments to address mandates found in:

- Chapter 72 of the 2021 Acts of Assembly, Special Session I (prohibition on discriminating against health insurance enrollee on the basis of the enrollee being a litigant or potential litigant due to a motor vehicle accident);
- Chapters 10 and 11 of the 2020 Acts of Assembly, Special Session I (visitation during public health emergencies);
- Chapter 829 of the 2020 Acts of Assembly (obligations with regards to the Sex Offenders and Crimes Against Minors Registry);
- Chapters 1080 and 1081 of the 2020 Acts of Assembly (prohibition on balance billing);
- Chapter 1278 of the 2020 Acts of Assembly (replacing occurrences of THC-A oil and cannabidiol oil with cannabis oil);
- Chapters 177 and 222 of the 2005 Acts of Assembly (design and construction guidelines for hospitals); and
- Chapter 762 of the 2004 Acts of Assembly (immunization standards for influenza and pneumonia).



November 7, 2022 12VAC5-371 Fast-Track Page 2

The changes include including removing unused terminology, improving terminology consistency, providing definitions for terms to match current clinical and industry practices, moving regulatory provisions to the appropriate part of 12VAC5-371-10 *et seq.*, and revising provisions related to the licensing process and oversight procedures.

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.

Form: TH-04 August 2022



townhall.virginia.gov

Fast-Track Regulation Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-371
VAC Chapter title(s)	Regulations for the Licensure of Nursing Facilities
Action title	Amend Regulation to Incorporate Chapter 72 (2021 Acts of Assembly, Special Session I), Chapters 829, 1080, and 1081 (2020 Acts of Assembly), Chapters 10 and 11 (2020 Acts of Assembly, Special Session I), Chapters 177 and 222 (2005 Acts of Assembly) and Chapter 762 (2004 Acts of Assembly), Update Terms to Match Statutory Language, and Update Licensure Provisions
Date this document prepared	October 26, 2022

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 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.

This fast-track action is being utilized to conform 12VAC5-371-10 *et seq.* to the Code of Virginia and to update out-of-date regulatory provisions. Changes include amendments to address mandates found in:

- Chapter 72 of the 2021 Acts of Assembly, Special Session I (prohibition on discriminating against health insurance enrollee on the basis of the enrollee being a litigant or potential litigant due to a motor vehicle accident);
- Chapters 10 and 11 of the 2020 Acts of Assembly, Special Session I (visitation during public health emergencies);

• Chapter 829 of the 2020 Acts of Assembly (obligations with regards to the Sex Offenders and Crimes Against Minors Registry);

Form: TH-04

- Chapters 1080 and 1081 of the 2020 Acts of Assembly (prohibition on balance billing);
- Chapter 1278 of the 2020 Acts of Assembly (replacing occurrences of THC-A oil and cannabidiol oil with cannabis oil);
- Chapters 177 and 222 of the 2005 Acts of Assembly (design and construction guidelines for nursing facilities); and
- Chapter 762 of the 2004 Acts of Assembly (immunization standards for influenza and pneumonia).

The changes include including removing unused terminology, improving terminology consistency, providing definitions for terms to match current clinical and industry practices, moving regulatory provisions to the appropriate part of 12VAC5-371-10 *et seq.*, and revising provisions related to the licensing process and oversight procedures.

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 Virginia Board of Health.

"FGI Guidelines" means the 2022 edition of *Guidelines for Design and Construction of Residential Health, Care, and Support Facilities*, as amended by the August 2022 Errata, published by The Facilities Guidelines Institute.

"Nursing facility" means any nursing home as defined in § 32.1-123 of the Code of Virginia.

"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.

Chapter 72 (2021 Acts of Assembly, Special Session I) and Chapters 1080 and 1801 (2020 Acts of Assembly) placed prohibitions on balance billing and discrimination against current or potential motor vehicle accident litigants that apply to nursing facilities. Chapters 10 and 11 (2020 Acts of Assembly, Special Session I) required the Board to promulgate regulations about nursing facility visitation during public health emergencies. Chapter 829 (2020 Acts of Assembly) made nondiscretionary changes to nursing facilities'

obligations with regards to the Sex Offenders and Crimes Against Minors Registry. Chapter 1278 (2020 Acts of Assembly) replaced occurrences of "THC-A oil" and "cannabidiol oil" with "cannabis oil." Chapters 177 and 222 (2005 Acts of Assembly) require the Board to promulgate regulations for the licensure of nursing facilities that include minimum standards for the design and construction of nursing facilities consistent with the current edition of design and construction guidelines issued by The Facilities Guidelines Institute (successor to the American Institute of Architects Academy of Architecture for Health). Chapter 762 (2004 Acts of Assembly) requires the Board to promulgate regulations for the licensure of nursing facilities to mandate that nursing facilities "provide or arrange for the administration to its residents of (i) an annual vaccination against influenza and (ii) a pneumococcal vaccination, in accordance with the most recent recommendations of the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention."

Form: TH-04

The rulemaking is expected to be noncontroversial because it is being utilized to conform to the statutory mandates and language and because it is detailing longstanding agency licensing procedures. No new requirements are being developed. Additionally, the agency's subject matter experts believe that proposed changes would not jeopardize the protection of public health, safety, and welfare. Further, the rulemaking does not alter the intent of the regulation or the requirements placed on nursing facilities.

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.

Va. Code § 32.1-12 gives the Board the authority to make, adopt, promulgate, and enforce such regulations as may be necessary to carry out the provisions of Title 32.1 of the Code of Virginia. Va. Code § 32.1-127 requires the Board to adopt regulations that include minimum standards for (i) the construction and maintenance of nursing facilities to ensure the environmental protection and the life safety of its residents, employees, and the public; and (ii) the vaccination of residents, unless medically contraindicated or declined by the resident.

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 regulatory change is that regulations should be clearly written, up to date, conform to the law, and should be the least burdensome means of protecting the health, safety, and welfare of citizens. The regulatory change is essential to protect the health, safety, and welfare of citizens because unclear regulations hamper licensees' ability to comply and out of date regulations may reference standards and practices that are not consistent with current clinical practices. The goals of this regulatory change are to improve consistency across the sections of this regulatory text, bring the regulatory text into alignment with the statutes, and update references to current clinical 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.

Section 10 Definitions

Adds definitions for "ACIP," "business day," "CDC," "CMS," "inspector," and "licensee." Removes definitions for "THC-A oil" and renamed "cannabidiol oil" to "cannabis oil."

Form: TH-04

Section 30 License

Adds language about the non-assignment and non-transferability of a licensee and moves language about nursing facilities' posting licenses for the public from subsection G of 12VAC5-371-110.

Section 55 Plan of correction

Consolidates the plan of correction language found throughout the regulatory chapter to ensure the plan of correction requirements are consistent. Revisions include minimum elements of a plan of correction and the timeline for submission and completion of a plan of correction.

Section 60 On-site inspections

Section is renamed to "Inspection procedure." Amends text to more closely align with the Register of Regulation's style guide, adds language about frequency of inspections, and removes language about plans of correction.

Section 70 Complaint investigation

Amends text to more closely align with the Register of Regulation's style guide, adds language about evaluating the need for an on-site complaint inspection, and removes language about plans of correction.

Section 90 Administrative sections

Section is renamed to "Disciplinary action." Matches statutory provisions about prohibited acts and disciplinary options available.

Section 100 Surrender of license

Section is renamed to "Surrender of license; mid-term change of license." Clarifies what is a mid-term change to a license and clarifies a nursing facility's obligations and the process to obtain a changed license.

Section 110 Management and administration

Removes language about a nursing facility's requirement to inform the OLC of changes impacting its license and to post its license for the public. Updates documents incorporated by reference to the most recent recommendations of the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention.

Section 150 Resident rights

Amends section to match statutory language about registration, reregistration, and verification with the Sex Offender and Crimes Against Minors Registry.

Section 180 Infection control

Amends section to add provisions about visitation during public health emergencies related to COVID-19.

Section 300 Pharmaceutical services

Replaces "THC-A oil" and "cannabidiol oil" with "cannabis oil."

Section 410 Unique design solutions

Updates documents incorporated by reference to the most recent FGI guidelines.

DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-371)

Updated to reflect the changes in the proposed text and to reference the most current edition of each relevant document.

Issues

Form: TH-04

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 removal of language or requirements that were unclear, inconsistent, or outdated and addition of legislative mandates that had previously had not been incorporated into the regulations. The primary advantages to VDH or Commonwealth are clarity on the minimum requirements for nursing facilities and VDH in the administration of the nursing facility licensing program. There are no disadvantages to the public or the Commonwealth. There are no primary disadvantages to the agency or the Commonwealth. There is no other pertinent matters of interest to the regulated community, government officials and the public.

Requirements More Restrictive than Federal

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

VDH is not aware of any applicable federal requirements about:

- discriminating against health insurance enrollees on the basis of the enrollee being a litigant or
 potential litigant due to a motor vehicle accident, which is the subject of the mandate in Chapter 72
 of the 2021 Acts of Assembly, Special Session I;
- Terminology for cannabis oil; and
- licensing of nursing facilities or any processes or procedures related to licensing of nursing facilities.

The regulatory change regarding the prohibition on balance billing derived from Chapters 1080 and 1081 of the 2020 Acts of Assembly do not exceed applicable federal requirements.

42 CFR § 483.80(d)(1) and (2) requires certified nursing facilities to offer influenza and pneumococcal vaccination to residents unless medically contradicted or the resident refuses vaccination. The legislative mandate in Chapter 762 of the 2004 Acts of Assembly is more specific than federal requirements about the clinical guidance informing vaccination, though the mandate does not exceed and is not more restrictive than applicable federal requirements.

The regulatory change regarding the design and construction guidelines for nursing facilities may be more restrictive than federal requirements, specifically 42 CFR § 483.90; however, Chapters 177 and 222 of the 2005 Acts of Assembly mandate 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.

The regulatory changes regarding the Sex Offender and Crimes Against Minors Registry and visitation during public health emergencies related to COVID-19 may be more restrictive than federal requirements in 42 CFR Part 483 Subpart B; however, Chapter 829 of the 2020 Acts of Assembly and Chapters 10 and 11 of the 2020 Acts of Assembly, Special Session I mandates the minimum requirements for nursing facilities 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.

Form: TH-04

Other State Agencies Particularly Affected

The two licensed nursing facilities operated by the Department of Veterans Services will be particularly affected.

Localities Particularly Affected

The licensed nursing facility operated by the County of Bedford will be particularly affected.

Other Entities Particularly Affected

The 286 licensed nursing facilities (including those operated by the County of Bedford and the Department of Veterans Services) and applicants for nursing facility licensure 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: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	There are no projected costs, savings, fees, or revenues resulting from the regulatory change.
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 known projected savings, fees, or revenues resulting from the regulatory change. The Department of Veterans Services would have one-time costs associated with updating policies and procedures related to visitation. For its existing policies and procedures, VDH is estimating it would cost \$1,250 one-time to amend their policies per facility to conform to the regulatory minimums.
For all agencies: Benefits the regulatory change is designed to produce.	The regulatory change is designed to conform the regulation to the Code of Virginia, and to promote the health, safety, and welfare of residents by

incorporating current clinical and industry
practices as well as by requiring reasonable timely
information from nursing facilities, access to
information to ensure nursing facility compliance,
remedial action within a reasonable and a
consistently applied timeframe if noncompliance
does occur.

Impact on Localities

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

Projected costs, savings, fees or revenues resulting from the regulatory change.	There are no known projected savings, fees, or revenues resulting from the regulatory change. The County of Bedford would have one-time costs associated with updating policies and procedures related to visitation. For its existing policies and procedures, VDH is estimating it would cost \$1,250 one-time to amend their policies to conform to the regulatory minimums.
Benefits the regulatory change is designed to produce.	The regulatory change is designed to conform the regulation to the Code of Virginia, and to promote the health, safety, and welfare of residents by incorporating current clinical and industry practices as well as by requiring reasonable timely information from nursing facilities, access to information to ensure nursing facility compliance, remedial action within a reasonable and consistently applied timeframe if noncompliance does occur.

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.	Licensed nursing facilities and applicants for nursing facility licensure.
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 286 licensed nursing facilities (including those operated by the Department of Veterans Services and the County of Bedford) will be required to comply with the regulatory change. Applicants for new nursing facility licensure are infrequent and difficult to estimate. VDH does not have sufficient information to determine which nursing facilities have fewer than 500 full-time employees.

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.

Benefits the regulatory change is designed to produce.

There are no known projected savings, fees, or revenues resulting from the regulatory change.

Form: TH-04

Licensed nursing facilities would have one-time costs associated with updating policies and procedures related to visitation. For its existing policies and procedures, VDH is estimating it would cost \$1,250 one-time to amend their policies per facility to conform to the regulatory minimums.

The regulatory change is designed to conform the regulation to the Code of Virginia, and to promote the health, safety, and welfare of residents by incorporating current clinical and industry practices as well as by requiring reasonable timely information from nursing facilities, access to information to ensure nursing facility compliance, remedial action within a reasonable and consistently applied timeframe if noncompliance does occur.

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 was considered because the General Assembly required the Board to adopt regulations governing the licensure of nursing facilities and amending the regulation is the least burdensome, least intrusive, and less costly method to accomplish the purpose of this action.

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.

The Board is required to regulate the licensure of nursing facilities consistent with the provisions of Article 1 (§ 32.1-123 *et seq.*) of Chapter 5 of Title 32.1 of the Code of Virginia. Initiation of this regulatory action is the least burdensome method to conform the Regulations for the Licensure of Nursing Facilities (12VAC5-371-10 *et seq.*) to the statute.

Public Participation

Form: TH-04

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.

Current chapter- section number	New chapter- section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
371-10	N/A	12VAC5-371-10. Definitions. The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise: * * * "Cannabidiol oil" means the same as the term is defined in subsection A of \$	CHANGE: The Board is proposing the following change: 12VAC5-371-10. Definitions. The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise: * * *

54.1-3408.3 of the Code of "ACIP" means the Advisorv Virginia. Committee on Immunization Practices of the CDC. "THC-A oil" means the same as the term is defined in "Business day" means any day that is subsection A of § 54.1-3408.3 not a Saturday, Sunday, legal holiday, or of the Code of Virginia. day on which the OLC 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. "Cannabidiol oil" "Cannabis oil" means the same as the term is defined in subsection A of § 54.1-3408.3 of the Code of Virginia. "CDC" means the Centers for Disease Control and Prevention. "CMS" means the Centers for Medicare and Medicaid Services. "Inspector" means an individual employed by or contracted by the department and designated by the commissioner to conduct inspections, investigations, or evaluations. "Licensee" means a person that has received and maintains an active license under the provisions of Article 1 (§ 32.1-123 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia and this chapter. "THC-A oil" means the same as the term is defined in subsection A of § 54.1-3408.3 of the Code of Virginia. **INTENT:** The intent of the change is to create, remove, and update definitions for terms that have been cause for confusion. RATIONALE: The rationale for the change is that commonly used terms that may have multiple meanings depending on the speaker should be defined so that audiences have a consistent understanding of the terms' intended meaning.

			LIKELY IMPACT: The likely impact of the change is reduced confusion for nursing facilities, VDH, and the public.
371-30	N/A	12VAC5-371-30. License.	CHANGE: The Board is proposing the following change:
		B. A license to operate a	12VAC5-371-30. License.
		nursing facility is issued to a	* * *
		person or organization. An organization may be a partnership, association, corporation, or public entity. C. Each license and renewal thereof shall be issued for one year. A nursing facility shall operate within the terms of its license, which include the:	B. A license to operate a nursing facility is shall be issued to a person or organization. An organization may be a partnership, association, corporation, or public entity. C. Each license shall expire at midnight December 31 of the year issued and renewal thereof shall be issued for one year. A nursing facility shall operate within the terms of its license, which
		1. Name of the nursing facility;	include the:
		2. Name of the operator;	Name of the nursing facility; Name of the operator;
		3. Physical location of the nursing facility;	Physical location of the nursing facility;
		4. Maximum number of beds allowed; and	4. Maximum number of beds allowed <u>, except as provide in 12VAC5-371-40 G;</u> and
		5. Date the license expires.	5. Date the license expires.
		F. The number of resident beds allowed in a nursing facility shall be determined by the department. Requests to increase beds must be made in writing and must include an approved Certificate of Public	F. The number of resident beds allowed in a nursing facility shall be determined by the department commissioner. Requests to increase beds must be made in writing and must include an approved Certificate of Public Need, except as provided in 12VAC5-371-40 G.
		Need, except as provided in 12VAC5-371-40 G. G. Nursing facility units	G. Nursing facility Long-term care nursing units located in and operated by hospitals shall be licensed under
		located in and operated by hospitals shall be licensed under Regulations for the Licensure of Hospitals in Virginia (12VAC5-410).	Regulations for the Licensure of Hospitals in Virginia (12VAC5-410). Approval for such units shall be included on the annual license issued to each hospital.
		Approval for such units shall be included on the annual	I. The licensee shall at all times:
		license issued to each hospital.	1. Maintain an active and accurate license; and
		* * *	2. Post its current license in a place readily visible and

			accessible to the public at the nursing facility.
			INTENT: The intent of the change is to remove duplicative or confusing provisions, to group general licensing principles together, and to conform the regulation to the statutes.
			RATIONALE: The rationale for the change is that the duplicative material is addressed earlier in 12VAC5-371, that the topics within the regulation should be addressed in singular locations instead of multiple, and that the regulation should be consisted with the Code of Virginia.
			LIKELY IMPACT: The likely impact of the change is reduced confusion for nursing facilities.
N/A	371-55	None	CHANGE: The Board is proposing the following change:
			12VAC5-371-55. Plan of correction.
			A. Upon receipt of a written inspection
			report, the administrator or his designee
			shall prepare a written plan of correction
			addressing each licensing violation cited
			at the time of inspection.
			B. The administrator or his designee
			shall submit to the OLC a written plan of
			correction no more than 15 business days after receipt of the inspection report. The
			plan of correction shall contain for each
			licensing violation cited:
			1. A description of the corrective
			action or actions to be taken and the position title of the employees
			to implement the corrective
			action. If employees share the
			same position title, the
			administrator or his designee shall assign the employees a
			unique identifier to distinguish
			them;
			2. The expected correction date,
			not to exceed 45 business days from the exit date of the
			inspection; and
			3. A description of the measures
			implemented to prevent a

			recurrence of each licensing violation.
			C. The administrator or his designee
			shall ensure that the person responsible for the validity of the plan of correction signs, dates, and indicates their title on
			the plan of correction.
			D. The OLC shall notify the
			administrator or his designee if the OLC determines any item in the plan of correction is unacceptable.
			E. The OLC may conduct an
			inspection to verify any portion of a plan of correction has been implemented.
			F. The administrator or his designee shall ensure the plan of correction is implemented and monitored so that compliance is maintained.
			G. The commissioner may deny
			licensure or renewal of licensure if the
			administrator or his designee fails to
			submit an acceptable plan of correction or fails to implement an acceptable plan of
			correction.
			H. The OLC shall consider the
			submission date of a plan of correction to be the date it is postmarked or the date it
			is received, whichever is earlier.
			INTENT: The intent of the change is to standardize the plan of correction process
			to make it more similar to federal plan of
			correction processes.
			RATIONALE: The rationale for the change is that documentation of remedial action and completion of remedial action should be consistently applied to all nursing facilities.
			LIKELY IMPACT: The likely impact of the change is improved clarity about what should be in a plan of correction, when it is due, and when it should be completed.
371-60	N/A	12VAC5-371-60. On-site	CHANGE: The Board is proposing the
07 1 00		12VAC5-371-60. On-site inspections.	following change:
		A. The licensing	12VAC5-371-60.
		representative shall make unannounced on-site	inspections Inspection procedure.
		inspections of the nursing	A. The licensing representative <u>OLC</u>
		facility. The licensee shall be	shall make <u>periodic</u> unannounced on-site

responsible for correcting any deficiencies found during any on-site inspection. Compliance with all standards will be determined by the OLC.

- B. The licensee shall make available to the licensing representative any necessary records.
- C. The licensee shall also allow the licensing representative to interview the agents, employees, residents, family members, and any person under its custody, control, direction or supervision.
- D. After the on-site inspection, the licensing representative shall discuss the findings of the inspection with the administrator or designee.
- E. As applicable, the administrator shall submit an acceptable plan for correcting any deficiencies found during an on-site inspection.
- F. The administrator will be notified whenever any item in the plan of correction is determined to be unacceptable.
- G. The administrator shall be responsible for assuring the plan of correction is implemented and monitored so that compliance is maintained.

inspections of the nursing facility <u>as</u> <u>necessary but not less often than</u> <u>biennially. The OLC may make on-site inspections of applicants for licensure.</u> The licensee shall be responsible for correcting any deficiencies found during any on-site inspection. Compliance with all standards will <u>shall</u> be determined by the OLC.

- B. The licensee or applicant shall:
 - 1. make Make available to the licensing representative inspector any necessary requested records;
 - 2. Permit an inspector to enter upon and into its property to inspect or investigate as the inspector reasonably deems necessary in order to determine the state of compliance with the provisions of this chapter and all laws administered by the board; and
 - 3. Allow the inspector access to interview the agents, employees, independent contractors, residents, legal representatives, resident's family members, and any person under the licensee's or applicant's control, direction, or supervision.
- C. The licensee shall also allow the licensing representative to interview the agents, employees, residents, family members, and any person under its custody, control, direction or supervision.
- D. C. After the on-site inspection, the licensing representative inspector shall: discuss the findings of the inspection with the administrator or designee.
 - 1. Discuss the findings of the inspection with the administrator or his designee; and
 - 2. Provide a written inspection report to the administrator or his designee.
- E. As applicable, the administrator shall submit an acceptable plan for correcting any deficiencies found during an on-site inspection.

			F. The administrator will be notified whenever any item in the plan of correction is determined to be unacceptable.
			G. The administrator shall be responsible for assuring the plan of correction is implemented and monitored so that compliance is maintained.
			D. If the OLC cites one or more licensing violations in the written inspection report, the administrator or his designee shall submit a plan of correction in accordance with 12VAC5-371-55.
			INTENT: The intent of the change is to more clearly specify what is expected of a hospital and VDH when an inspection occurs.
			RATIONALE: The rationale for the change is nursing facilities are better able to anticipate what may be needed during inspection process if parameters are specified in regulation.
			LIKELY IMPACT: The likely impact of the change is reduced confusion for nursing facilties.
371-70	N/A	12VAC5-371-70. Complaint investigation.	CHANGE: The Board is proposing the following change:
		A. The OLC has the responsibility to investigate any complaints regarding alleged violations of the standards or statutes and complaints of the abuse or neglect of persons in care. The Department of Social Services and the State Ombudsman are notified of complaints received. B. Complaints may be received in written or oral form and may be anonymous. C. When the investigation is complete, the licensee and the complainant, if known, will be notified of the findings of the investigation. D. As applicable, the	12VAC5-371-70. Complaint investigation. A. The OLC has the responsibility to shall investigate any complaints and shall determine if an investigation requires an on-site inspection. In making this determination, the OLC shall consider several factors, to include: regarding alleged violations of the standards or statutes and complaints of the abuse or neglect of persons in care. The Department of Social Services and the State Ombudsman are notified of complaints received. 1. If the complainant has first-hand knowledge of the alleged incident; 2. The nursing facility's regulatory history, including the number and
		D. As applicable, the administrator shall submit an	nistory, including the number and

- acceptable plan for correcting any deficiencies found during a complaint investigation.
- E. The administrator will be notified whenever any item in the plan of correction is determined to be unacceptable.
- F. The administrator shall be responsible for assuring the plan of correction is implemented and monitored so that compliance is maintained.

severity of substantiated prior complaints;

Form: TH-04

- 3. If the OLC has recently inspected the nursing facility and if the alleged incident would have been reviewed during the prior inspection;
- 4. The nature of the complaint, including degree of potential serious harm to residents; and
- 5. If the complaint may be investigated pursuant to Title XVIII or Title XIX of the Social Security Act.
- B. The OLC may request records from the licensee to assist in making a determination pursuant to subsection A of this section. The licensee shall provide the requested records no more than seven calendar days after OLC makes a request pursuant to this subsection.
- B. C. The OLC may receive Complaints complaints may be received in written or oral form and may be receive anonymous complaints.
- C. D. When the investigation is complete, the OLC shall notify the licensee and the complainant, if known, will be notified in writing of the findings of the investigation.
- D. E. As applicable, For any licensing violation cited during a complaint investigation, the administrator or his designee shall submit an acceptable a plan of correction for correcting any deficiencies found during a complaint investigation in accordance with 12VAC5-371-55.
- E. The administrator will be notified whenever any item in the plan of correction is determined to be unacceptable.
- F. The administrator shall be responsible for assuring the plan of correction is implemented and monitored so that compliance is maintained.

INTENT: The intent of the changes is to update the regulatory text to match the style guidelines, and to give VDH

		flexibility in determining whether a complaint warrants an on-site inspection. RATIONALE: The rationale for the change is that the style guidelines ensure more intelligible regulatory text and that VDH should be maximize efficient and effective use of limited agency resources in responding to complaints. LIKELY IMPACT: The likely impact of these proposed changes is improved readability of the section and a more adaptive and efficient complaint process.
371-90 N/A	Administrative sanctions. A. Nothing in this part shall prohibit the department from exercising its responsibility and authority to enforce the regulation, including proceeding directly to imposition of administrative sanctions, when the quality of care or the quality of life has been severely compromised. B. The commissioner may impose such administrative sanctions or take such actions as are appropriate for violation of any of the standards or statutes or for abuse or neglect of persons in care. Such sanctions include: 1. Restricting or prohibiting new admissions to any nursing facility; 2. Petitioning the court to impose a civil penalty or to appoint a receiver, or both; or 3. Revoking or suspending the license of a nursing facility. C. The following reasons may be considered by the department for the imposition of administrative sanctions or	CHANGE: The Board is proposing the following change: 12VAC5-371-90. Administrative sanctions Disciplinary action. A. Nothing in this part shall prohibit the department from exercising its responsibility and authority to enforce the regulation, including proceeding directly to imposition of administrative sanctions, when the quality of care or the quality of life has been severely compromised. B. The commissioner may impose such administrative sanctions or take such actions as are appropriate for violation of any of the standards or statutes or for abuse or neglect of persons in care. Such sanctions include: 1. Restricting or prohibiting new admissions to any nursing facility; 2. Petitioning the court to impose a civil penalty or to appoint a receiver, or both; or 3. Revoking or suspending the license of a nursing facility. C. The following reasons may be considered by the department for the imposition of administrative sanctions or the imposition of civil penalties: 1. Failure to demonstrate or maintain compliance with applicable standards or for violations of the provisions of the Code of Virginia; 2. Permitting, aiding, or abetting the commission of any illegal act in the nursing facility; or

the imposition of civil penalties:

- Failure to demonstrate or maintain compliance with applicable standards or for violations of the provisions of the Code of Virginia;
- 2. Permitting, aiding, or abetting the commission of any illegal act in the nursing facility; or
- 3. Deviating significantly from the program or services for which a license was issued without obtaining prior written approval from the OLC, or failure to correct such deviations within a specified time.
- D. Violations which in the judgment of the OLC jeopardize the health and safety of residents shall be sufficient cause for immediate imposition of this section.
- E. The licensee will receive a notice of the department's intent to impose sanctions. The notice shall describe the reasons for imposing the sanction.
- F. Upon receipt of the notice to impose a sanction, the licensee has the right and the opportunity to appeal according to the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia). The procedures for filing an appeal shall be outlined in the notice.

3. Deviating significantly from the program or services for which a license was issued without obtaining prior written approval from the OLC, or failure to correct such deviations within a specified time.

Form: TH-04

- D. Violations which in the judgment of the OLC jeopardize the health and safety of residents shall be sufficient cause for immediate imposition of this section.
- E. The licensee will receive a notice of the department's intent to impose sanctions. The notice shall describe the reasons for imposing the sanction.
- F. Upon receipt of the notice to impose a sanction, the licensee has the right and the opportunity to appeal according to the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia). The procedures for filing an appeal shall be outlined in the notice.

A. The licensee may not:

- 1. Violate the provisions of this chapter or Articles 1 (§ 32.1-123 et seq.) or 2 (§ 32.1-138 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia;
- 2. Permit, aid, or abet the commission of any illegal act in the nursing facility; or
- 3. Engage in a pattern of violations pursuant to § 38.2-3445.01 of the Code of Virginia.

B. The commissioner may:

- 1. For each violation of subsection A of this section:
 - a. Deny, revoke, or suspend the license to operate the nursing facility in accordance with the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia);
 b. Restrict or prohibit new
 - admissions to the nursing facility in accordance with the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia):

c. Refer the licensee for criminal prosecution pursuant to subsection A of § 32.1-27 of the Code of Virginia;
d. Petition an appropriate court for an injunction, mandamus, or other appropriate remedy against

the licensee pursuant to subsection B of § 32.1-27 of

the Code of Virginia;

- e. Petition an appropriate court for imposition of a civil monetary penalty against the licensee pursuant to subsection C of § 32.1-27 of the Code of Virginia or subsection A of § 32.1-27.1 of the Code of Virginia; or
- f. Petition an appropriate court for appointment of a receiver pursuant to subsection B of § 32.1-27.1 of the Code of Virginia; and
- 2. For each violation of subdivision A 3 of this section, levy a fine upon the licensee in an amount not to exceed \$1,000 per violation, in accordance with the Administrative Process Acts (§ 2.2-4000 et seq. of the Code of Virginia).
- <u>C. Suspension of a license shall in all</u> cases be for an indefinite time.
- D. For each violation of subsection A of this section and with the consent of the person who has violated subsection A of this section, the board may provide, in an order issued by the board, for the payment of civil charges for past violations in specific sums, which may not exceed the limits specified in §§ 32.1-27 or 32.1-27.1 of the Code of Virginia.
- E. Upon receipt of a completed application and a nonrefundable service charge, the commissioner may issue a new license to the licensee that has had its license revoked if the commissioner determines that:

1. The conditions upon which revocation was based have been corrected; and

Form: TH-04

- 2. The applicant is in compliance with this chapter, Articles 1 (§ 32.1-123 et seq.) and 2 (§ 32.1-138 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia, and all other applicable state and federal law and regulations.
- F. Upon receipt of a completed application, the commissioner may partially or completely restore a suspended license to the licensee if the commissioner determines that:
 - 1. The conditions upon which suspension was based have been completely or partially corrected; and
 - 2. The interests of the public will not be jeopardized by resumption of operation.
- G. The commissioner may not require an additional fee for restoring a license pursuant to subsection F of this section.
- H. The licensee shall submit evidence relevant to subdivisions E 1, E 2, F 1, and F 2 of this section that is satisfactory to the commissioner or his designee. The commissioner or his designee may conduct an inspection prior to making a determination.

INTENT: The intent of the change is to describe the grounds upon which the commissioner may take disciplinary action against a nursing facility, the options available to the commissioner for disciplinary action, and how a nursing facility may obtain a license after suspension or revocation.

RATIONALE: The rationale for the change is that the regulation should conform to Chapter 72 of the 2021 Acts of Assembly, Special Session I, Chapters 1080 and 1081 of the 2020 Acts of Assembly, and to Va. Code §§ 32.1-27, 32.1-27.1, and 32.1-135.

LIKELY IMPACT: The likely impact of the change is improved clarity for nursing facilities about what acts are not permitted

	T		,
			and what consequences may follow if a prohibited act occurs.
371-100	N/A	12VAC5-371-100. Surrender of a license. A. Upon revocation or suspension of a license, the licensee must surrender its license to a representative of the OLC. B. If a license is revoked, a new license may be issued by the commissioner after satisfactory evidence is submitted that the conditions upon which revocation was based have been corrected and after proper inspection has been made and compliance with this chapter and applicable state and federal law has been obtained. C. Suspension of a license shall in all cases be for an indefinite time. The commissioner may completely or partially restore a suspended license when he determines that the conditions upon which suspension was based have been completely or partially corrected and that the interests of the public will not be jeopardized by resumption of operation. D. Other circumstances under which a license must be surrendered include transfer of ownership and discontinuation of services. The licensee must notify the OLC, in writing, 30 days before discontinuing services.	CHANGE: The Board is proposing the following change: 12VAC5-371-100. Surrender of a license; mid-term change of license. A. Upon revocation or suspension of a license, the licensee must shall surrender its license to a representative of the OLC. B. If a license is revoked, a new license may be issued by the commissioner after satisfactory evidence is submitted that the conditions upon which revocation was based have been corrected and after proper inspection has been made and compliance with this chapter and applicable state and federal law has been obtained. C. Suspension of a license shall in all cases be for an indefinite time. The commissioner may completely or partially restore a suspended license when he determines that the conditions upon which suspension was based have been completely or partially corrected and that the interests of the public will not be jeopardized by resumption of operation. D. Other circumstances under which a license must be surrendered include transfer of ownership and discontinuation of services. The licensee must notify the OLC, in writing, 30 days before discontinuing services. B. A licensee shall notify the director of the OLC in writing by submitting a midterm change application no less than 30 calendar days in advance of implementing any: 1. Change of location of the nursing facility; 2. Change of ownership of the
		surrendered include transfer of ownership and discontinuation of services. The licensee must notify the OLC, in writing, 30 days	term change application no less than 30 calendar days in advance of implementing any: 1. Change of location of the nursing facility;
		C C C C C C C C C C C C C C C C C C C	2. Change of ownership of the nursing facility; 3. Change of operator of the nursing facility; 4. Change of name of the nursing facility; 5. Change of bed capacity,
			except as provided in 12VAC5-

Form: TH-04 371-40 G, which shall be accompanied by an approved Certificate of Public Need if the requested change is for an increase in bed capacity,; 6. Change in management contract or lease agreement to operate the nursing facility; 7. Change of services being provided, including any proposed addition or discontinuation, regardless of whether licensure is required for the service; or 8. Closure of the nursing facility. C. The OLC shall: 1. Consider the submission date of a mid-term change application to be the date it is postmarked or the date it is received, whichever is earlier; and 2. Notify in writing the licensee if the commissioner will issue a changed license. D. The commissioner's issuance of changed license to the licensee shall satisfy the requirements of subdivision C 2 of this section. E Upon receipt of the changed license, the licensee shall surrender its prior license issued by the commissioner to the OLC and destroy any copies of the

license, surrender its prior license issued by the commissioner to the OLC and destroy any copies of the prior license.

1. File for a new license, in accordance with 12VAC5-371-40, no less than 30 calendar days in advance of any operator

2. Upon receipt of the new

F. A license may not be transferred or assigned. The commissioner may not issue a changed license in response to a change of operator of the nursing facility, but shall instead require the nursing facility to obtain a new license. If the nursing facility intends to implement a

change of operator, it shall:

change; and

prior license.

			G. If the nursing facility is closing or will otherwise no longer be operational, it shall: 1. Notify residents, legal representatives, and the OLC no
			fewer than seven calendar days prior to closing or ceasing operations where all clinical records are to be located following closure or cessation of operations; and
			2. Surrender its license to the OLC and destroy all copies of its license no more than five calendar days after the nursing facility closes or ceases operations.
			H. The OLC shall determine if any changes listed in subsection B affect the terms of the license or the continuing eligibility for a license. An inspector may inspect the nursing facility during the process of evaluating a proposed change.
			INTENT: The intent of the change is to create a consistent list of what changes VDH needs to be aware of, when those changes are reportable, and what changes can result in a changed license versus a new license.
			RATIONALE: The rationale for the change is that transfer or assignment of licenses are prohibited by law, that certain license changes may require a new license, a new inspection (in the case of a change of location), or both, and that VDH needs to be aware of nursing facilities' active service lines for disaster preparedness planning and implementation.
			LIKELY IMPACT: The likely impact of the change is reduced confusion for nursing facilities and VDH about when and what changes are reportable, and what changes warrant a new license.
371-110	N/A	12VAC5-371-110. Management and administration.	CHANGE: The Board is proposing the following change:

- D. The nursing facility shall submit, in a timely manner as determined by the OLC, and implement a written plan of action to correct any noncompliance with these regulations identified during an inspection. The plan shall include:
 - 1. Description of the corrective action or actions to be taken;
 - 2. Date of completion for each action; and
 - 3. Signature of the person responsible for the operation.
- E. The nursing facility shall permit representatives from the OLC to conduct inspections to...
- F. A nursing facility shall give written notification 30 calendar days in advance of implementation of changes affecting the accuracy of the license. Changes affecting the accuracy of the license are:
 - 1. Address;
 - 2. Operator;
 - 3. Name of the nursing facility;
 - 4. Any proposed change in management contract or lease agreement to operate the nursing facility;
 - 5. Implementing any proposed addition, deletion, or change in nursing facility services whether or not licensure is required;
 - 6. A change in ownership; or
 - 7. Bed capacity.

12VAC5-371-110. Management and administration.

Form: TH-04

* * *

- D. The nursing facility shall submit, in a timely manner as determined by the OLC, and implement a written plan of action to correct any noncompliance with these regulations identified during an inspection. The plan shall include:
 - 1. Description of the corrective action or actions to be taken;
 - 2. Date of completion for each action; and
 - 3. Signature of the person responsible for the operation.
- E. D. The nursing facility shall permit representatives from the OLC to conduct inspections to...
- F. A nursing facility shall give written notification 30 calendar days in advance of implementation of changes affecting the accuracy of the license. Changes affecting the accuracy of the license are:
 - 1. Address;
 - 2. Operator;
 - 3. Name of the nursing facility;
 - 4. Any proposed change in management contract or lease agreement to operate the nursing facility;
 - 5. Implementing any proposed addition, deletion, or change in nursing facility services whether or not licensure is required;
 - 6. A change in ownership; or
 - 7. Bed capacity.

Notices shall be sent to the attention of the director of the OLC.

- G. The current license from the commissioner shall be posted in a place clearly visible to the general public.
- H. E. The nursing facility shall fully disclose...
- $\frac{1}{1}$. The nursing facility shall identify...
- J. G. Unless the vaccination is medically contraindicated or the resident declines the offer of vaccincation, The the nursing facility shall provide, or arrange

Notices shall be sent to the attention of the director of the OLC.

- G. The current license from the commissioner shall be posted in a place clearly visible to the general public.
- H. The nursing facility shall fully disclose...
- I. The nursing facility shall identify...
- J. The nursing facility shall provide, or arrange for, the administration to its residents of an annual influenza vaccination and a vaccination pneumonia according to the "Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Committee Advisorv Immunization Practices United States. 2020-21 Influenza Season" "Guidelines for Preventing Health-Care-Associated Pneumonia" from the Advisorv Committee on Immunization Practices of the Centers for Disease Control and Prevention, unless the vaccination is medically contraindicated or the resident declines vaccination offer.
- K. Upon request of the nursing facility's family council, the nursing facility shall...

for, the administration to its residents of an annual influenza vaccination and a pneumonia pneumococcal vaccination according in accordance with the following recommendations of ACIP: to the "Prevention and Control of Seasonal with Vaccines: Recommendations of the Advisory Committee on Immunization Practices United States, 2020 21 Influenza Season" and "Guidelines for Preventing Health-Care-Associated Pneumonia" from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, unless the vaccination is medically contraindicated or the resident declines the vaccination offer.

- 1. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices United States, 2022–23 Influenza Season, MMWR 71 (1), 2022, CDC;
- 2. Use of 15-Valent Pneumococcal Conjugate Vaccine and 20-Valent Pneumococcal Conjugate Vaccine Among U.S. Adults: Updated Recommendations of ACIP United States, MMWR 71 (4), 2022, CDC;
- 3. Use of 13-Valent
 Pneumococcal Conjugate
 Vaccine and 23-Valent
 Pneumococcal Polysaccharide
 Vaccine Among Adults Aged >65
 Years: Updated
 Recommendations of ACIP,
 MMWR 68 (46), 2019, CDC;
- 4. Intervals Between PCV13 and PPSV23 Vaccines: Recommendations of ACIP, MMWR 64 (15), 2015, CDC;
- 5.Useof13-ValentPneumococcalConjugateVaccineand23-ValentPneumococcalPolysaccharideVaccineAmongAdultsAgedYears:Recommendationsof

	ACIP, MMWR 63 (37), 2014,
	CDC;
	6. Use of 13-Valent
	Pneumococcal Conjugate
	Vaccine and 23-Valent
	Pneumococcal Polysaccharide
	Vaccine Among Children Aged
	6–18 Years with
	Immunocompromising
	Conditions: Recommendations of
	ACIP, MMWR 62 (25), 2013,
	CDC:
	7. Use of 13-Valent
	Pneumococcal Conjugate
	Vaccine and 23-Valent
	Pneumococcal Polysaccharide Vaccine for Adults with
	Immunocompromising
	Conditions: Recommendations of
	ACIP, MMWR 61 (40), 2012,
	CDC;
	8. Prevention of Pneumococcal
	Disease Among Infants and
	Children — Use of 13-Valent
	Pneumococcal Conjugate
	Vaccine and 23-Valent
	Pneumococcal Polysaccharide
	Vaccine: Recommendations of
	ACIP, MMWR 59 (RR-11), 2010,
	CDC; and
	9. Updated Recommendations
	for Prevention of Invasive
	Pneumococcal Disease Among
	Adults Using the 23-Valent
	Pneumococcal Polysaccharide
	<u>Vaccine (PPSV23), MMWR 59</u>
	(34), 2010, CDC.
	K. H. Upon request of the nursing
	facility's family council, the nursing facility
	shall
	INTENT: The intent of the changes is to
	INTENT: The intent of the changes is to remove duplicative requirements and to
	update references to current
	immunization guidelines.
	RATIONALE: The rationale for the
	changes is that the duplicative material is
	addressed earlier in 12VAC5-371 and
	that the regulation should be consistent
	with Chapter 762 of the 2004 Acts of Assembly.
	Assortibly.

			LIKELY IMPACT: The likely impact of these proposed changes is reduced confusion for nursing facilities.
371-150	N/A	12VAC5-371-150. Resident rights. * * * G. The nursing facility shall register with the Department of State Police to receive notice of the registration or reregistration_of any sex offender within the same or a contiguous zip code area in which the nursing facility is located pursuant to § 9.1-914 of the Code of Virginia. H. Prior to admission, each nursing facility shall determine if a potential resident is a registered sex offender when the potential resident is anticipated to have a length of stay: 1. Greater than three days; or 2. In fact stays longer than three days. * * *	CHANGE: The Board is proposing the following change: 12VAC5-371-150. Resident rights. * * * G. The nursing facility shall register with the Department of State Police to receive notice of the registration, errergistration, or verification of any sex effender person required to register with the Sex Offender and Crimes Against Minors Registry pfursuant to Chapter 9 (§ 9.1-900 et seq.) of Title 9.1 of the Code of Virginia within the same or a contiguous zip code area in which the nursing facility is located pursuant to § 9.1-914 of the Code of Virginia. H. Prior to admission, each nursing facility shall determine ascertain if a potential resident is a registered sex offender required to register with the Sex Offender and Crimes Against Minors Registry pursuant to Chapter 9 (§ 9.1-900 et seq.) of Title 9.1 of the Code of Virginia when if the potential resident is anticipated to have a length of stay: 1. Is anticipated by the nursing facility to have a length of stay: 1. Is anticipated by the nursing facility to have a length of stay: 2. In fact stays longer than three days; or 2. In fact stays longer than three days: * * INTENT: The intent of the change is to describe the minimum requirements a nursing facility must meet in regards to the Sex Offender and Crimes Against Minors Registry. RATIONALE: The rationale for the change is that the regulation should be consistent with Chapter 829 of the 2020 Acts of Assembly. LIKELY IMPACT: The likely impact of the change is reduced confusion for nursing

			T
			facilities about the minimum requirements
			regarding the Sex Offender and Crimes
			Against Minors Registry.
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371-180	N/A	12VAC5-371-180. Infection	CHANGE: The Board is proposing the
		control.	following change:
		* * *	
		E. During a declared	12VAC5-371-180. Infection control.
		public health emergency	* * *
		related to a communicable	E. During a declared public health
		disease of public health	emergency related to a communicable
		threat, the nursing facility shall	disease of public health threat, the
		establish a protocol to allow	nursing facility shall establish a protocol to
		residents to receive visits from	allow residents to receive visits from a
		a rabbi, priest, minister, or	rabbi, priest, minister, or clergy of any
		clergy of any religious	religious denomination or sect consistent
		denomination or sect	with guidance from the Centers for
		consistent with guidance from	Disease Control and Prevention CDC and
		the Centers for Disease	the Centers for Medicare and Medicaid
		Control and Prevention and	Services CMS and subject to compliance
		the Centers for Medicare and	with any executive order, order of public
		Medicaid Services and	health, department guidance, or any other
		subject to compliance with	applicable federal or state guidance
		any executive order, order of	having the effect of limiting visitation.
		public health, department	* * *
		guidance, or any other	F. During a public health emergency
		applicable federal or state	related to COVID-19, a nursing facility
		guidance having the effect of	shall establish a protocol to allow each
		limiting visitation.	resident to receive visits, consistent with
		* * *	guidance from the CDC and as directed
			by CMS and the board, which shall
			include:
			1.Provisions describing:
			a. The conditions, including
			conditions related to the
			presence of COVID-19 in the
			<u>nursing facility and</u>
			community, under which in-
			person visits will be allowed
			and under which in-person
			<u>visits will not be allowed and</u>
			<u>visits will be required to be</u>
			<u>virtual;</u>
			b. The requirements with
			which in-person visitors will
			be required to comply to
			protect the health and safety
			of the residents and staff of
			the nursing facility;
			c. The types of technology,
			including interactive audio or

video technology, and the staff support necessary to ensure visits are provided as required by this subsection; and

Form: TH-04

- d. The steps the nursing facility will take in the event of a technology failure, service interruption, or documented emergency that prevents visits from occurring as required by this subsection;
- 2. A statement of the frequency with which visits, including virtual and in-person, where appropriate, will be allowed, which shall be at least once every 10 calendar days for each resident;
- 3. A provision authorizing a resident or the resident's personal representative to waive or limit visitation, provided that such waiver or limitation is included in the resident's health record; and
- 4. A requirement that the nursing facility publish on its website or communicate to each resident or the resident's authorized representative, in writing or via electronic means, the nursing facility's plan for providing visits to residents as required by this subsection.

INTENT: The intent of the change is to describe the minimum requirements a nursing facility must meet in regards to visitation during certain public health emergencies.

RATIONALE: The rationale for the change is that the regulation should be consistent with Chapters 10 and 11 of the 2020 Acts of Assembly, Special Session I

LIKELY IMPACT: The likely impact of the change is reduced confusion for nursing facilities about the minimum requirements for visitation during a future public health emergency.

371-300	N/A	12VAC5-371-300. Pharmaceutical services.	CHANGE: The Board is proposing the following change:
		E. Excluding cannabidiol oil and THC-A oil, no drug or medication shall be administered to any resident without a valid verbal order or a written, dated and signed order from a physician, dentist, podiatrist, nurse practitioner, or physician assistant, licensed in Virginia. F. Nursing facility employees who are authorized to possess, distribute, or administer medications to residents may store, dispense, or administer cannabidiol oil or THC-A oil to a resident who has: 1. Been issued a valid written certification for the use of cannabidiol oil or THC-A oil in accordance with subsection B of § 54.1-3408.3 of the Code of Virginia; and * * * *	12VAC5-371-300. Pharmaceutical services. * * * E. Excluding cannabidiol oil and THC-A cannabis oil, no drug or medication shall be administered to any resident without a valid verbal order or a written, dated and signed order from a physician, dentist, podiatrist, nurse practitioner, or physician assistant, licensed in Virginia. F. Nursing facility employees who are authorized to possess, distribute, or administer medications to residents may store, dispense, or administer cannabidiol oil or THC-A cannabis oil to a resident who has: 1. Been issued a valid written certification for the use of cannabidiol oil or THC-A cannabis oil in accordance with subsection B of § 54.1-3408.3 of the Code of Virginia; and * * * INTENT: The intent of the change is to match regulatory language to statutory language. RATIONALE: The rationale for the change is that the regulation should be consistent with Chapter 1278 of the 2020 Acts of Assembly. LIKELY IMPACT: The likely impact of the change is reduced confusion for nursing facilities about the correct terminology for
371-410	N/A	12VAC5-371-410.	CHANGE: The Board is proposing the
		Architectural drawings and specifications.	following change:
		A. All construction of new buildings and <u>all</u> additions, renovations, <u>or</u> alterations, <u>or</u> repairs of existing buildings for occupancy as a nursing facility shall conform to state and local codes, zoning	drawings and specifications. A. All construction of new buildings and all additions, renovations, or alterations, or repairs of existing buildings for occupancy as a nursing facility shall conform to state and local codes, zoning

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		ordinances, and the Virginia Uniform Statewide Building Code (13VAC5-63). In addition, nursing facilities shall be designed and constructed consistent with Parts 1 and 2 and section Chapter 3.1 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 Facilities, 2022 Edition (The Facilities Guidelines Institute) pursuant to § 32.1-127.001 of the Code of Virginia. B The architect shall certify that the drawings and specifications were prepared to conform to the Virginia Uniform Statewide Building Code and be consistent with Parts 1 and 2 and section Chapter 3.1 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 Facilities, 2022 Edition (The Facilities Guidelines Institute).	ordinances, and the Virginia Uniform Statewide Building Code (13VAC5-63). In addition, nursing facilities shall be designed and constructed consistent with Parts 1 and 2 and section Chapter 3.1 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 Facilities Guidelines Institute) pursuant to \$32.1 127.001 of the Code of Virginia. BThe architect shall certify that the drawings and specifications were prepared to conform to the Virginia Uniform Statewide Building Code and be consistent with Parts 1 and 2 and section Chapter 3.1 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 Facilities Guidelines Institute). * * * INTENT: The intent of the change is to update the design and construction guidelines to the recently published 2022 edition. RATIONALE: The rationale for the change is that the regulation should be in conformity with the mandates in Chapters 177 and 222 of the 2005 Acts of Assembly. LIKELY IMPACT: The likely impact of the change is reduced confusion about which edition of the FGI guidelines nursing
			facilities should reference.
371- DIBR	N/A	Documents Incorporated by Reference (12VAC5-371)	CHANGE: The Board is proposing the following change:
		Guidelines for Design and Construction of Residential	

Health, Care, and Support Facilities, 2018 Edition, Facility Guidelines Institute http://www.fgiguidelines.org.

Guidelines for Preventing
Health-Care-Associated
Pneumonia, 2003, MMWR 53
(RR-3), Advisory Committee
on Immunization Practices,
Centers for Disease Control
and Prevention.

Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2020–21 Influenza Season, 2020, MMWR 69 (RR-8), Centers for Disease Control and Prevention.

Documents Incorporated by Reference (12VAC5-371)

Errata for Guidelines for Design and Construction of Residential Health, Care, and Support Facilities, The Facilities Guidelines Institute, 2022 Edition, https://fgiguidelines.org/guidelines/errata-addenda/ (eff. 8/2022).

Form: TH-04

Guidelines for Design and Construction of Residential Health, Care, and Support Facilities, The Facilities Guidelines Institute, 2018 2022 Edition, Facility Guidelines Institute http://www.fgiguidelines.org.

Guidelines for Preventing Health-Care-Associated Pneumonia, 2003, MMWR 53 (RR-3), Advisory Committee on Immunization Practices, Centers for Disease Control and Prevention.

Prevention and Control of Seasonal Influenza with Vaccines:
Recommendations of the Advisory Committee on Immunization Practices
United States, 2020–21 Influenza Season, 2020, MMWR 69 (RR-8), Centers for Disease Control and Prevention.

Intervals Between PCV13 and PPSV23 Vaccines: Recommendations of ACIP, MMWR 64 (15), 2015, CDC.

Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2022–23 Influenza Season, MMWR 71 (1), 2022, CDC.

Prevention of Pneumococcal Disease
Among Infants and Children — Use of 13Valent Pneumococcal Conjugate Vaccine
and 23-Valent Pneumococcal
Polysaccharide Vaccine:
Recommendations of ACIP, MMWR 59
(RR-11), 2010, CDC.

Updated Recommendations for Prevention of Invasive Pneumococcal Disease Among Adults Using the 23-Valent Pneumococcal Polysaccharide Vaccine (PPSV23), MMWR 59 (34), 2010, CDC.

Use of 13-Valent Pneumococcal
Conjugate Vaccine and 23-Valent
Pneumococcal Polysaccharide Vaccine
Among Adults Aged >65 Years:
Recommendations of ACIP, MMWR 63
(37), 2014, CDC.

Form: TH-04

Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults Aged >65 Years: Updated Recommendations of ACIP, MMWR 68 (46), 2019, CDC.

Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine for Adults with Immunocompromising Conditions: Recommendations of ACIP, MMWR 61 (40), 2012, CDC.

Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Children Aged 6–18 Years with Immunocompromising Conditions: Recommendations of ACIP, MMWR 62 (25), 2013, CDC.

Use of 15-Valent Pneumococcal
Conjugate Vaccine and 20-Valent
Pneumococcal Conjugate Vaccine
Among U.S. Adults: Updated
Recommendations of ACIP — United
States, MMWR 71 (4), 2022, CDC.

INTENT: The intent of these proposed changes is to ensure documents incorporated by reference are current and accurate.

RATIONALE: The rationale behind these proposed changes is that nursing facilities should be held to current standards and quidelines.

LIKELY IMPACT: The likely impact of these proposed changes is improved resident health and safety at nursing facilities.

Department of Health

Amend Regulation to Incorporate Chapter 72 (2021 Acts of Assembly, Special Session I), Chapters 829, 1080, and 1081 (2020 Acts of Assembly), Chapters 10 and 11 (2020 Acts of Assembly, Special Session I), Chapters 177 and 222 (2005 Acts of Assembly) and Chapter 762 (2004 Acts of Assembly), Update Terms to Match Statutory Language, and Update Licensure Provisions

12VAC5-371-10. Definitions.

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

"Abuse" means the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish, or deprivation by an individual, including caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being. This includes verbal, sexual, physical, or mental abuse.

"ACIP" means the Advisory Committee on Immunization Practices of the CDC.

"Administrator" means the individual licensed by the Virginia Board of Long-Term Care Administrators and who has the necessary authority and responsibility for management of the nursing facility.

"Admission" means the process of acceptance into a nursing facility, including orientation, rules and requirements, and assignment to appropriate staff. Admission does not include readmission to the facility after a temporary absence.

"Advance directive" means (i) a witnessed written document, voluntarily executed by the declarant in accordance with the requirements of § 54.1-2983 of the Code of Virginia, or (ii) a witnessed oral statement, made by the declarant subsequent to the time he is diagnosed as suffering from a terminal condition and in accordance with the provision of § 54.1-2983 of the Code of Virginia.

"Assessment" means the process of evaluating a resident for the purpose of developing a profile on which to base services. Assessment includes information gathering, both initially and on an ongoing basis, designed to assist the multi-disciplinary staff in determining the resident's need for care, and the collection and review of resident-specific data.

"Attending physician" means a physician currently licensed by the Virginia Board of Medicine and identified by the resident, or legal representative, as having the primary responsibility in determining the delivery of the resident's medical care.

"Barrier crime" means any offense set forth in clause (i) of the definition of barrier crime in § 19.2-392.02 of the Code of Virginia.

"Board" means the Board of Health.

"Business day" means any day that is not a Saturday, Sunday, legal holiday, or day on which the OLC 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.

"Cannabidiol oil" "Cannabis oil" means the same as the term is defined in subsection A of § 54.1-3408.3 of the Code of Virginia.

"CDC" means the Centers for Disease Control and Prevention.

"Certified nurse aide" means the title that can only be used by individuals who have met the requirements to be certified, as defined by the Virginia Board of Nursing, and who are listed in the nurse aide registry.

"Chemical restraint" means a psychopharmacologic drug (a drug prescribed to control mood, mental status, or behavior) that is used for discipline or convenience and not required to treat medical symptoms or symptoms from mental illness or mental retardation that prohibit an individual from reaching his highest level of functioning.

"Clinical record" means the documentation of health care services, whether physical or mental, rendered by direct or indirect resident-provider interactions. An account compiled by physicians and other health care professionals of a variety of resident health information, such as assessments and care details, including testing results, medicines, and progress notes.

"CMS" means the Centers for Medicare and Medicaid Services.

"Commissioner" means the State Health Commissioner.

"Complaint" means any allegation received by the Department of Health other than an incident reported by the facility staff. Such allegations include abuse, neglect, exploitation, or violation of state or federal laws or regulations.

"Comprehensive plan of care" means a written action plan, based on assessment data, that identifies a resident's clinical and psychosocial needs, the interventions to meet those needs, treatment goals that are measurable and that documents the resident's progress toward meeting the stated goals.

"Construction" means the building of a new nursing facility or the expansion, remodeling, or alteration of an existing nursing facility and includes the initial and subsequent equipping of the facility.

"Criminal record report" means either the criminal record clearance with respect to convictions for barrier crimes or the criminal history record from the Central Criminal Records Exchange of the Virginia Department of State Police.

"Department" means the Virginia Department of Health.

"Dignity" means staff, in their interactions with residents, carry out activities which assist a resident in maintaining and enhancing the resident's self-esteem and self-worth.

"Discharge" means the process by which the resident's services, delivered by the nursing facility, are terminated.

"Discharge summary" means the final written summary of the services delivered, goals achieved and post-discharge plan or final disposition at the time of discharge from the nursing facility. The discharge summary becomes a part of the clinical record.

"Drug" means (i) articles or substances recognized in the official United States "Drug" Pharmacopoeia National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them; (ii) articles or substances intended for the use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animal; (iii) articles or substances, other than food, intended to affect the structure or any function of the body of man or other animal; and (iv) articles or substances intended for use as a component of any article specified in clause (i), (ii), or (iii). This does not include devices or their components, parts or accessories.

"Electronic monitoring" means an unmanned video recording system with or without audio capability installed in the room of a resident.

"Emergency preparedness plan" means a component of a nursing facility's safety management program designed to manage the consequences of natural disasters or other emergencies that disrupt the nursing facility's ability to provide care.

"Employee" means a person who performs a specific job function for financial remuneration on a full-time or part-time basis.

"Facility-managed" means an electronic monitoring system that is installed, controlled, and maintained by the nursing facility with the knowledge of the resident or legal representative in accordance with the facility's policies.

 "Full-time" means a minimum of 35 hours or more worked per week in the nursing facility.

"Inspector" means an individual employed by or contracted by the department and designated by the commissioner to conduct inspections, investigations, or evaluations.

"Intelligent personal assistant" means a combination of an electronic device and a specialized software application designed to assist users with basic tasks using a combination of natural language processing and artificial intelligence, including such combinations known as digital assistants or virtual assistants.

"Legal representative" means a person legally responsible for representing or standing in the place of the resident for the conduct of his affairs. This may include a guardian, conservator, attorney-in-fact under durable power of attorney, trustee, or other person expressly named by a court of competent jurisdiction or the resident as his agency in a legal document that specifies the scope of the representative's authority to act. A legal representative may only represent or stand in the place of a resident for the function for which he has legal authority to act.

"Licensee" means a person that has received and maintains an active license under the provisions of Article 1 (§ 32.1-123 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia and this chapter.

"Medication" means any substance, whether prescription or over-the-counter drug, that is taken orally or injected, inserted, topically applied, or otherwise administered.

"Neglect" means a failure to provide timely and consistent services, treatment, or care to a resident necessary to obtain or maintain the resident's health, safety, or comfort or a failure to provide timely and consistent goods and services necessary to avoid physical harm, mental anguish, or mental illness.

"Nursing facility" means any nursing home as defined in § 32.1-123 of the Code of Virginia.

"OLC" means the Office of Licensure and Certification of the Virginia Department of Health.

"Person" means any individual, corporation, partnership, association, trust, or other legal entity, whether governmental or private, owning, managing, or operating a nursing facility.

"Physical restraint" means any manual method or physical or mechanical device, material, or equipment attached or adjacent to the resident's body that the individual cannot remove easily which restricts freedom of movement or normal access to one's own body.

"Policy" means a written statement that describes the principles and guides and governs the activities, procedures and operations of the nursing facility.

"Procedures" means a series of activities designed to implement program goals or policy, which may or may not be written, depending upon the specific requirements within this chapter. For inspection purposes, there must be evidence that procedures are actually implemented.

"Progress note" means a written statement, signed and dated by the person delivering the care, consisting of a pertinent, chronological report of the resident's care. A progress note is a component of the clinical record.

"Qualified" means meeting current legal requirements of licensure, registration or certification in Virginia; having appropriate training and experience commensurate with assigned responsibilities; or, if referring to a professional, possessing an appropriate degree or having documented equivalent education, training or experience.

"Quality assurance" means systematic activities performed to determine the extent to which clinical practice meets specified standards and values with regard to such things as appropriateness of service assignment and duration, appropriateness of facilities and resources

utilized, adequacy and clinical soundness of care given. Such activities should also assure changes in practice that do not meet accepted standards. Examples of quality assurance activities include the establishment of facility-wide goals for resident care, the assessment of the procedures used to achieve the goals, and the proposal of solutions to problems in attaining those goals.

"Readmission" means a planned return to the nursing facility following a temporary absence for hospitalization, off-site visit or therapeutic leave, or a return stay or confinement following a formal discharge terminating a previous admission.

"Resident" means the primary service recipient, admitted to the nursing facility, whether that person is referred to as a client, consumer, patient, or other term.

"Resident-managed" means an electronic monitoring system that is installed, controlled, and maintained by the resident with the knowledge of the nursing facility.

"Supervision" means the ongoing process of monitoring the skills, competencies and performance of the individual supervised and providing regular, face-to-face guidance and instruction.

"Sworn disclosure" means a written statement or affirmation disclosing any criminal convictions or any pending criminal charges, whether within or outside the Commonwealth, by an applicant for compensated employment with a nursing facility.

"THC-A oil" means the same as the term is defined in subsection A of § 54.1-3408.3 of the Code of Virginia.

"Volunteer" means a person who, without financial remuneration, provides services to the nursing facility.

161 **Statutory Authority**

162 §§ 32.1-12 and 32.1-127 of the Code of Virginia.

163 Historical Notes

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- Derived from Virginia Register Volume 13, Issue 17, eff. July 1, 1997; amended, Virginia
- Register Volume 23, Issue 10, eff. March 1, 2007; Volume 26, Issue 26, eff. September 30,
- 2010; Volume 35, Issue 5, eff. December 13, 2018; Volume 36, Issue 23, eff. August 6, 2020;
- Volume 37, Issue 17, eff. May 27, 2021; Volume 38, Issue 4, eff. November 11, 2021.

168 **12VAC5-371-30**. License.

- A. This chapter is not applicable to:
 - 1. Those entities listed in § 32.1-124 of the Code of Virginia; and
 - 2. Facilities established or operated for the practice of religious tenets pursuant to § 32.1-128 of the Code of Virginia, except that such facilities shall comply with the statutes and regulations on environmental protection and life safety.
- B. A license to operate a nursing facility is shall be issued to a person or organization. An organization may be a partnership, association, corporation, or public entity.
- C. Each license <u>shall expire at midnight December 31 of the year issued</u> and renewal thereof shall be issued for one year. A nursing facility shall operate within the terms of its license, which include the:
 - 1. Name of the nursing facility;
 - 2. Name of the operator;
 - 3. Physical location of the nursing facility;
 - 4. Maximum number of beds allowed, except as provide in 12VAC5-371-40 G; and
- Date the license expires.

- D. A separate license shall be required for nursing facilities maintained on separate premises, even though they are owned or are operated under the same management.
 - E. Every nursing facility shall be designated by a permanent and unique name.
 - F. The number of resident beds allowed in a nursing facility shall be determined by the department commissioner. Requests to increase beds must be made in writing and must include an approved Certificate of Public Need, except as provided in 12VAC5-371-40 G.
 - G. Nursing facility Long-term care nursing units located in and operated by hospitals shall be licensed under Regulations for the Licensure of Hospitals in Virginia (12VAC5-410). Approval for such units shall be included on the annual license issued to each hospital.
 - H. Any person establishing, conducting, maintaining, or operating a nursing facility without a license shall be guilty of a Class 6 felony.
 - I. The licensee shall at all times:
 - 1. Maintain an active and accurate license; and
 - 2. Post its current license in a place readily visible and accessible to the public at the nursing facility.

Statutory Authority

200 §§ 32.1-12, 32.1-125 and 32.1-127 of the Code of Virginia.

Historical Notes

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- Derived from Virginia Register Volume 13, Issue 17, eff. July 1, 1997; amended, Virginia Register Volume 23, Issue 10, eff. March 1, 2007; Volume 35, Issue 24, eff. August 23, 2019; Volume 37, Issue 17, eff. May 27, 2021.ksystem 2007; Volume 37, Issue 17, eff. May 27, 2021.ksystem 2007; Volume 37, Issue 17, eff. May 27, 2021.ksystem 2007; Volume 37, Issue 18, Issue 19, eff. May 27, 2021.ksystem 2007; Volume 37, Issue 19, eff. May 27, 2021.ksystem 2007; Volume 37, Issue 19, eff. May 27, 2021.ksystem 2007; Volume 37, Issue 19, eff. May 27, 2021.ksystem 2007; Volume 37, Issue 19, eff. May 27, 2021.ksystem 2007; Volume 37, Issue 19, eff. May 27, 2021.ksystem 2007; Volume 37, Issue 19, eff. May 27, 2021.ksystem 2007; Volume 37, Issue 19, eff. May 27, 2021.ksystem 2007; Volume 37, Issue 19, eff. May 27, 2021.
 - 12VAC5-371-55. Plan of correction.
 - A. Upon receipt of a written inspection report, the administrator or his designee shall prepare a written plan of correction addressing each licensing violation cited at the time of inspection.
 - B. The administrator or his designee shall submit to the OLC a written plan of correction no more than 15 business days after receipt of the inspection report. The plan of correction shall contain for each licensing violation cited:
 - 1. A description of the corrective action or actions to be taken and the position title of the employees to implement the corrective action. If employees share the same position title, the administrator or his designee shall assign the employees a unique identifier to distinguish them;
 - 2. The expected correction date, not to exceed 45 business days from the exit date of the inspection; and
 - <u>3. A description of the measures implemented to prevent a recurrence of each licensing violation.</u>
 - C. The administrator or his designee shall ensure that the person responsible for the validity of the plan of correction signs, dates, and indicates their title on the plan of correction.
 - <u>D. The OLC shall notify the administrator or his designee if the OLC determines any item in the plan of correction is unacceptable.</u>
- E. The OLC may conduct an inspection to verify any portion of a plan of correction has been implemented.
 - F. The administrator or his designee shall ensure the plan of correction is implemented and monitored so that compliance is maintained.
 - G. The commissioner may deny licensure or renewal of licensure if the administrator or his designee fails to submit an acceptable plan of correction or fails to implement an acceptable plan of correction.

H. The OLC shall consider the submission date of a plan of correction to be the date it is postmarked or the date it is received, whichever is earlier.

232 **Statutory Authority**

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

12VAC5-371-60. On-site inspections Inspection procedure.

A. The licensing representative <u>OLC</u> shall make <u>periodic</u> unannounced on-site inspections of the nursing facility <u>as necessary but not less often than biennially</u>. <u>The OLC may make on-site inspections of applicants for licensure</u>. <u>The licensee shall be responsible for correcting any deficiencies found during any on-site inspection</u>. Compliance with all standards <u>will shall</u> be determined by the OLC.

- B. The licensee or applicant shall:
 - <u>1.</u> make <u>Make</u> available to the licensing representative <u>inspector</u> any necessary requested records;
 - 2. Permit an inspector to enter upon and into its property to inspect or investigate as the inspector reasonably deems necessary in order to determine the state of compliance with the provisions of this chapter and all laws administered by the board; and
 - 3. Allow the inspector access to interview the agents, employees, independent contractors, residents, legal representatives, resident's family members, and any person under the licensee's or applicant's control, direction, or supervision.
- C. The licensee shall also allow the licensing representative to interview the agents, employees, residents, family members, and any person under its custody, control, direction or supervision.
- D. C. After the on-site inspection, the licensing representative inspector shall: discuss the findings of the inspection with the administrator or designee.
 - 1. Discuss the findings of the inspection with the administrator or his designee; and
 - 2. Provide a written inspection report to the administrator or his designee.
- E. As applicable, the administrator shall submit an acceptable plan for correcting any deficiencies found during an on-site inspection.
- F. The administrator will be notified whenever any item in the plan of correction is determined to be unacceptable.
- G. The administrator shall be responsible for assuring the plan of correction is implemented and monitored so that compliance is maintained.
- D. If the OLC cites one or more licensing violations in the written inspection report, the administrator or his designee shall submit a plan of correction in accordance with 12VAC5-371-55.

Statutory Authority

266 §§ 32.1-12 <u>, 32.1-25</u>, and 32.1-127 of the Code of Virginia.

267 Historical Notes

- Derived from Virginia Register Volume 13, Issue 17, eff. July 1, 1997; amended, Virginia Register Volume 23, Issue 10, eff. March 1, 2007; Volume 37, Issue 17, eff. May 27, 2021.
- 270 12VAC5-371-70. Complaint investigation.
- A. The OLC has the responsibility to shall investigate any complaints and shall determine if
 an investigation requires an on-site inspection. In making this determination, the OLC shall
 consider several factors, to include: regarding alleged violations of the standards or statutes and
 complaints of the abuse or neglect of persons in care. The Department of Social Services and
 the State Ombudsman are notified of complaints received.

- 276 <u>1. If the complainant has first-hand knowledge of the alleged incident;</u>
- 277 <u>2. The nursing facility's regulatory history, including the number and severity of substantiated prior complaints;</u>
 - 3. If the OLC has recently inspected the nursing facility and if the alleged incident would have been reviewed during the prior inspection;
 - 4. The nature of the complaint, including degree of potential serious harm to residents; and
 - <u>5. If the complaint may be investigated pursuant to Title XVIII or Title XIX of the Social Security Act.</u>
 - B. The OLC may request records from the licensee to assist in making a determination pursuant to subsection A of this section. The licensee shall provide the requested records no more than seven calendar days after OLC makes a request pursuant to this subsection.
 - B. C. The OLC may receive Complaints complaints may be received in written or oral form and may be receive anonymous complaints.
 - C. D. When the investigation is complete, the OLC shall notify the licensee and the complainant, if known, will be notified in writing of the findings of the investigation.
 - D. E. As applicable, For any licensing violation cited during a complaint investigation, the administrator or his designee shall submit an acceptable a plan of correction for correcting any deficiencies found during a complaint investigation in accordance with 12VAC5-371-55.
 - E. The administrator will be notified whenever any item in the plan of correction is determined to be unacceptable.
 - F. The administrator shall be responsible for assuring the plan of correction is implemented and monitored so that compliance is maintained.

Statutory Authority

300 §§ 32.1-12 and 32.1-127 of the Code of Virginia.

301 Historical Notes

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- Derived from Virginia Register Volume 13, Issue 17, eff. July 1, 1997; amended, Virginia Register Volume 23, Issue 10, eff. March 1, 2007; Volume 37, Issue 17, eff. eff. May 27,
- 304 2021.</span.</s.

12VAC5-371-90. Administrative sanctions Disciplinary action.

- A. Nothing in this part shall prohibit the department from exercising its responsibility and authority to enforce the regulation, including proceeding directly to imposition of administrative sanctions, when the quality of care or the quality of life has been severely compromised.
- B. The commissioner may impose such administrative sanctions or take such actions as are appropriate for violation of any of the standards or statutes or for abuse or neglect of persons in care. Such sanctions include:
 - 1. Restricting or prohibiting new admissions to any nursing facility;
 - 2. Petitioning the court to impose a civil penalty or to appoint a receiver, or both; or
 - 3. Revoking or suspending the license of a nursing facility.
- 315 C. The following reasons may be considered by the department for the imposition of 316 administrative sanctions or the imposition of civil penalties:
 - 1. Failure to demonstrate or maintain compliance with applicable standards or for violations of the provisions of the Code of Virginia;
- 2. Permitting, aiding, or abetting the commission of any illegal act in the nursing facility;
 or

- 321 3. Deviating significantly from the program or services for which a license was issued
 322 without obtaining prior written approval from the OLC, or failure to correct such
 323 deviations within a specified time.
 324 D. Violations which in the judgment of the OLC jeopardize the health and safety of residents
 325 shall be sufficient cause for immediate imposition of this section.
 - E. The licensee will receive a notice of the department's intent to impose sanctions. The notice shall describe the reasons for imposing the sanction.
 - F. Upon receipt of the notice to impose a sanction, the licensee has the right and the opportunity to appeal according to the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia). The procedures for filing an appeal shall be outlined in the notice.

A. The licensee may not:

- 1. Violate the provisions of this chapter or Articles 1 (§ 32.1-123 et seq.) or 2 (§ 32.1-138 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia;
- 2. Permit, aid, or abet the commission of any illegal act in the nursing facility; or
- 3. Engage in a pattern of violations pursuant to § 38.2-3445.01 of the Code of Virginia.

B. The commissioner may:

- 1. For each violation of subsection A of this section:
 - a. Deny, revoke, or suspend the license to operate the nursing facility in accordance with the Administrative Process Act (§ 2.2-4000 et seg. of the Code of Virginia);
 - b. Restrict or prohibit new admissions to the nursing facility in accordance with the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia);
 - c. Refer the licensee for criminal prosecution pursuant to subsection A of § 32.1-27 of the Code of Virginia;
 - d. Petition an appropriate court for an injunction, mandamus, or other appropriate remedy against the licensee pursuant to subsection B of § 32.1-27 of the Code of Virginia;
 - e. Petition an appropriate court for imposition of a civil monetary penalty against the licensee pursuant to subsection C of § 32.1-27 of the Code of Virginia or subsection A of § 32.1-27.1 of the Code of Virginia; or
 - f. Petition an appropriate court for appointment of a receiver pursuant to subsection B of § 32.1-27.1 of the Code of Virginia; and
- 2. For each violation of subdivision A 3 of this section, levy a fine upon the licensee in an amount not to exceed \$1,000 per violation, in accordance with the Administrative Process Acts (§ 2.2-4000 et seq. of the Code of Virginia).
- C. Suspension of a license shall in all cases be for an indefinite time.
- D. For each violation of subsection A of this section and with the consent of the person who has violated subsection A of this section, the board may provide, in an order issued by the board, for the payment of civil charges for past violations in specific sums, which may not exceed the limits specified in §§ 32.1-27 or 32.1-27.1 of the Code of Virginia.
- E. Upon receipt of a completed application and a nonrefundable service charge, the commissioner may issue a new license to the licensee that has had its license revoked if the commissioner determines that:
 - 1. The conditions upon which revocation was based have been corrected; and
 - 2. The applicant is in compliance with this chapter, Articles 1 (§ 32.1-123 et seq.) and 2 (§ 32.1-138 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia, and all other applicable state and federal law and regulations.

- F. Upon receipt of a completed application, the commissioner may partially or completely restore a suspended license to the licensee if the commissioner determines that:
 - 1. The conditions upon which suspension was based have been completely or partially corrected; and
 - 2. The interests of the public will not be jeopardized by resumption of operation.
- 372 <u>G. The commissioner may not require an additional fee for restoring a license pursuant to</u> subsection F of this section.
- H. The licensee shall submit evidence relevant to subdivisions E 1, E 2, F 1, and F 2 of this section that is satisfactory to the commissioner or his designee. The commissioner or his designee may conduct an inspection prior to making a determination.
- **Statutory Authority**
- 378 §§ 32.1-12, 32.1-27, 32.1-27.1, and 32.1-127 of the Code of Virginia.
- 379 **Historical Notes**

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- Derived from Virginia Register Volume 13, Issue 17, eff. July 1, 1997; amended, Virginia Register Volume 23, Issue 10, eff. March 1, 2007.
 - 12VAC5-371-100. Surrender of a license; mid-term change of license.
 - A. Upon revocation or suspension of a license, the licensee must shall surrender its license to a representative of the OLC.
 - B. If a license is revoked, a new license may be issued by the commissioner after satisfactory evidence is submitted that the conditions upon which revocation was based have been corrected and after proper inspection has been made and compliance with this chapter and applicable state and federal law has been obtained.
 - C. Suspension of a license shall in all cases be for an indefinite time. The commissioner may completely or partially restore a suspended license when he determines that the conditions upon which suspension was based have been completely or partially corrected and that the interests of the public will not be jeopardized by resumption of operation.
 - D. Other circumstances under which a license must be surrendered include transfer of ewnership and discontinuation of services. The licensee must notify the OLC, in writing, 30 days before discontinuing services.
 - B. A licensee shall notify the director of the OLC in writing by submitting a mid-term change application no less than 30 calendar days in advance of implementing any:
 - 1. Change of location of the nursing facility;
 - 2. Chapge of ownership of the nursing facility;
 - 3. Change of operator of the nursing facility;
 - 4. Change of name of the nursing facility;
 - <u>5. Change of bed capacity, except as provided in 12VAC5-371-40 G, which shall be accompanied by an approved Certificate of Public Need if the requested change is for an increase in bed capacity;</u>
 - Change in management contract or lease agreement to operate the nursing facility;
 - 7. Change of services being provided, including any proposed addition or discontinuation, regardless of whether licensure is required for the service; or
 - 8. Closure of the nursing facility.
 - C. The OLC shall:
 - 1. Consider the submission date of a mid-term change application to be the date it is postmarked or the date it is received, whichever is earlier; and

- 412 <u>2. Notify in writing the licensee if the commissioner will issue a changed license.</u>
- D. The commissioner's issuance of changed license to the licensee shall satisfy the requirements of subdivision C 2 of this section.
 - <u>E Upon receipt of the changed license</u>, the licensee shall surrender its prior license issued by the commissioner to the OLC and destroy any copies of the prior license.
 - F. A license may not be transferred or assigned. The commissioner may not issue a changed license in response to a change of operator of the nursing facility, but shall instead require the nursing facility to obtain a new license. If the nursing facility intends to implement a change of operator, it shall:
 - 1. File for a new license, in accordance with 12VAC5-371-40, no less than 30 calendar days in advance of any operator change; and
 - 2. Upon receipt of the new license, surrender its prior license issued by the commissioner to the OLC and destroy any copies of the prior license.
 - G. If the nursing facility is closing or will otherwise no longer be operational, it shall:
 - 1. Notify residents, legal representatives, and the OLC no fewer than seven calendar days prior to closing or ceasing operations where all clinical records are to be located following closure or cessation of operations; and
 - 2. Surrender its license to the OLC and destroy all copies of its license no more than five calendar days after the nursing facility closes or ceases operations.
- H. The OLC shall determine if any changes listed in subsection B affect the terms of the license or the continuing eligibility for a license. An inspector may inspect the nursing facility during the process of evaluating a proposed change.
- 434 **Statutory Authority**
- 435 §§ 32.1-12, 32.1-125, and 32.1-127 of the Code of Virginia.
- 436 Historical Notes

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- Derived from Virginia Register Volume 13, Issue 17, eff. July 1, 1997; amended, Virginia Register Volume 23, Issue 10, eff. March 1, 2007.
- 439 **12VAC5-371-110. Management and administration.**
 - A. No person shall own, establish, conduct, maintain, manage, or operate any nursing facility, as defined in § 32.1-123 of the Code of Virginia, without having obtained a license.
 - B. The nursing facility must comply with:
 - 1. These regulations (12VAC5-371);
 - 2. Other applicable federal, state, or local laws and regulations; and
 - 3. Its own policies and procedures.
 - C. The nursing facility shall submit, or make available, reports and information necessary to establish compliance with these regulations and applicable statutes.
 - D. The nursing facility shall submit, in a timely manner as determined by the OLC, and implement a written plan of action to correct any noncompliance with these regulations identified during an inspection. The plan shall include:
 - 1. Description of the corrective action or actions to be taken;
 - 2. Date of completion for each action; and
 - 3. Signature of the person responsible for the operation.
- 454 E. D. The nursing facility shall permit representatives from the OLC to conduct inspections to:
 - 1. Verify application information;

- 2. Determine compliance with this chapter;
 - 3. Review necessary records; and
 - 4. Investigate complaints.
 - F. A nursing facility shall give written notification 30 calendar days in advance of implementation of changes affecting the accuracy of the license. Changes affecting the accuracy of the license are:
 - 1. Address;

- 2. Operator;
- 3. Name of the nursing facility;
- 4. Any proposed change in management contract or lease agreement to operate the nursing facility;
- 5. Implementing any proposed addition, deletion, or change in nursing facility services whether or not licensure is required;
- 6. A change in ownership; or
- 7. Bed capacity.

Notices shall be sent to the attention of the director of the OLC.

- G. The current license from the commissioner shall be posted in a place clearly visible to the general public.
- H. E. The nursing facility shall fully disclose its admission policies, including any preferences given, to applicants for admission.
- 4. <u>F.</u> The nursing facility shall identify its operating elements and programs, the internal relationship among these elements and programs, and the management or leadership structure.
- J. G. Unless the vaccination is medically contraindicated or the resident declines the offer of vaccincation. The the nursing facility shall provide, or arrange for, the administration to its residents of an annual influenza vaccination and a pneumonia pneumococcal vaccination according in accordance with the following recommendations of ACIP: to the "Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices United States, 2020–21 Influenza Season" and "Guidelines for Preventing Health-Care-Associated Pneumonia" from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, unless the vaccination is medically contraindicated or the resident declines the vaccination offer.
 - <u>1. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices United States, 2022–23 Influenza Season, MMWR 71 (1), 2022, CDC;</u>
 - 2. Use of 15-Valent Pneumococcal Conjugate Vaccine and 20-Valent Pneumococcal Conjugate Vaccine Among U.S. Adults: Updated Recommendations of ACIP United States, MMWR 71 (4), 2022, CDC;
 - 3. Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults Aged >65 Years: Updated Recommendations of ACIP, MMWR 68 (46), 2019, CDC;
- 4. Intervals Between PCV13 and PPSV23 Vaccines: Recommendations of ACIP, MMWR 64 (15), 2015, CDC;
- 5. Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults Aged >65 Years: Recommendations of ACIP, MMWR 63 (37), 2014, CDC;

- 6. Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal
 Polysaccharide Vaccine Among Children Aged 6–18 Years with Immunocompromising
 Conditions: Recommendations of ACIP, MMWR 62 (25), 2013, CDC;
 - 7. Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine for Adults with Immunocompromising Conditions: Recommendations of ACIP, MMWR 61 (40), 2012, CDC;
 - <u>8. Prevention of Pneumococcal Disease Among Infants and Children Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine: Recommendations of ACIP, MMWR 59 (RR-11), 2010, CDC; and State of the Control o</u>
 - 9. Updated Recommendations for Prevention of Invasive Pneumococcal Disease Among Adults Using the 23-Valent Pneumococcal Polysaccharide Vaccine (PPSV23), MMWR 59 (34), 2010, CDC.
 - K. <u>H.</u> Upon request of the nursing facility's family council, the nursing facility shall send notices and information about the family council mutually developed by the family council and the administration of the nursing facility, and provided to the nursing facility for such purpose, to the legal representative or a contact person of the resident's choice up to six times a year. Such notices may be included together with a monthly billing statement or other regular communication. Notices and information shall also be posted in a designated location within the nursing facility.

Statutory Authority

522 §§ 32.1-12 and 32.1-127 of the Code of Virginia.

523 Historical Notes

- Derived from Virginia Register Volume 13, Issue 17, eff. July 1, 1997; amended, Virginia
- Register Volume 20, Issue 26, eff. September 27, 2004; Volume 23, Issue 10, eff. March 1,
- 526 2007; Volume 27, Issue 24, eff. September 1, 2011; Volume 37, Issue 17, eff. May 27,
- 527 2021.

12VAC5-371-150. Resident rights.

- A. The nursing facility shall develop and implement policies and procedures that ensure resident's rights as defined in §§ 32.1-138 and 32.1-138.1 of the Code of Virginia.
 - B. The procedures shall:
 - 1. Not restrict any right a resident has under law;
 - 2. Provide staff training to implement resident's rights; and
 - 3. Include grievance procedures.
- C. The name and telephone number of the complaint coordinator of the OLC, the Adult Protective Services toll-free telephone number, and the toll-free telephone number for the State Ombudsman shall be conspicuously posted in a public place.
- D. Copies of resident rights shall be given to residents upon admittance to the nursing facility and made available to residents currently in residence, to legal representatives, next of kin, or sponsoring agency or agencies, and to the public.
- E. The nursing facility shall have a plan to review resident rights with each resident annually, or with the legal representative at least annually, and have a plan to advise each staff member at least annually.
- F. The nursing facility shall certify, in writing, that it is in compliance with the provisions of §§ 32.1-138 and 32.1-138.1 of the Code of Virginia, relative to resident rights, as a condition of license issuance or renewal.

- G. The nursing facility shall register with the Department of State Police to receive notice of the registration, or reregistration, or verification of any sex offender person required to register with the Sex Offender and Crimes Against Minors Registry pursuant to Chapter 9 (§ 9.1-900 et seq.) of Title 9.1 of the Code of Virginia within the same or a contiguous zip code area in which the nursing facility is located pursuant to § 9.1-914 of the Code of Virginia.
- H. Prior to admission, each nursing facility shall determine ascertain if a potential resident is a registered sex offender required to register with the Sex Offender and Crimes Against Minors Registry pursuant to Chapter 9 (§9.1-900 et seq.) of Title 9.1 of the Code of Virginia when if the potential resident is anticipated to have a length of stay:
 - 1. <u>Is anticipated by the nursing facility to have a length of stay</u> Greater greater than three days; or
 - 2. In fact stays longer than three days.
- I. The nursing facility shall not restrict the rights of a resident's family and legal representative to meet in the nursing facility with the families and legal representatives of other residents .

Statutory Authority

\$\ \\$\ 32.1-12 and 32.1-127 of the Code of Virginia.

564 **Historical Notes**

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- Derived from Virginia Register Volume 13, Issue 17, eff. July 1, 1997; amended, Virginia
- Register Volume 17, Issue 1, eff. October 27, 2000; Volume 23, Issue 10, eff. March 1, 2007;
- Volume 24, Issue 11, eff. March 5, 2008; Volume 34, Issue 11, eff. February 21, 2018; Volume 37, Issue 17, eff. May 27, 2021.

12VAC5-371-180. Infection control.

- A. The nursing facility shall establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment and to prevent the development and transmission of disease and infection.
 - B. The infection control program shall encompass the entire physical plant and all services.
- C. The infection control program addressing the surveillance, prevention and control of infections in the nursing facility shall include:
 - 1. Procedures to isolate the infecting organism;
 - 2. Access to handwashing equipment for staff;
 - 3. Training of staff in proper handwashing techniques, according to accepted professional standards, to prevent cross contamination;
 - 4. Implementation of universal precautions by direct resident care staff;
 - 5. Prohibiting employees with communicable diseases or infections from direct contact with residents or their food, if direct contact will transmit disease;
 - 6. Monitoring staff performance of infection control practices;
 - 7. Handling, storing, processing and transporting linens, supplies and equipment in a manner that prevents the spread of infection;
 - 8. Handling, storing, processing and transporting regulated medical waste in accordance with applicable regulations;
 - 9. Maintaining an effective pest control program; and
 - 10. Staff education regarding infection risk-reduction behavior.
- D. The nursing facility shall report promptly to its local health department diseases designated as "reportable" according to 12VAC5-90-80 when such cases are admitted to or are

diagnosed in the nursing facility and shall report any outbreak of infectious disease as required by 12VAC5-90. An outbreak is defined as an increase in incidence of any infectious disease above the usual incidence at the nursing facility.

E. During a declared public health emergency related to a communicable disease of public health threat, the nursing facility shall establish a protocol to allow residents to receive visits from a rabbi, priest, minister, or clergy of any religious denomination or sect consistent with guidance from the Centers for Disease Control and Prevention CDC and the Centers for Medicare and Medicaid Services CMS and subject to compliance with any executive order, order of public health, department guidance, or any other applicable federal or state guidance having the effect of limiting visitation.

- 1. Such protocol may restrict the frequency and duration of visits and may require visits to be conducted virtually using interactive audio or video technology.
- 2. Any such protocol may require the person visiting a resident pursuant to this subsection to comply with all reasonable requirements of the nursing facility adopted to protect the health and safety of the person, residents, and staff of the nursing facility.
- F. During a public health emergency related to COVID-19, a nursing facility shall establish a protocol to allow each resident to receive visits, consistent with guidance from the CDC and as directed by CMS and the board, which shall include:

1.Provisions describing:

- a. The conditions, including conditions related to the presence of COVID-19 in the nursing facility and community, under which in-person visits will be allowed and under which in-person visits will not be allowed and visits will be required to be virtual;
- b. The requirements with which in-person visitors will be required to comply to protect the health and safety of the residents and staff of the nursing facility;
- c. The types of technology, including interactive audio or video technology, and the staff support necessary to ensure visits are provided as required by this subsection; and
- d. The steps the nursing facility will take in the event of a technology failure, service interruption, or documented emergency that prevents visits from occurring as required by this subsection;
- 2. A statement of the frequency with which visits, including virtual and in-person, where appropriate, will be allowed, which shall be at least once every 10 calendar days for each resident;
- 3. A provision authorizing a resident or the resident's personal representative to waive or limit visitation, provided that such waiver or limitation is included in the resident's health record; and
- 4. A requirement that the nursing facility publish on its website or communicate to each resident or the resident's authorized representative, in writing or via electronic means, the nursing facility's plan for providing visits to residents as required by this subsection.

Statutory Authority

633 §§ 32.1-12 and 32.1-127 of the Code of Virginia.

Historical Notes

- Derived from Virginia Register Volume 13, Issue 17, eff. July 1, 1997; amended, Virginia
- Register Volume 22, Issue 7, eff. January 11, 2006; Volume 37, Issue 17, eff. May 27, 2021;
- 637 Volume 38, Issue 4, eff. November 11, 2021.

12VAC5-371-300. Pharmaceutical services.

- A. Provision shall be made for the procurement, storage, dispensing, and accounting of drugs and other pharmacy products in compliance with 18VAC110-20. This may be by arrangement with an off-site pharmacy, but must include provisions for 24-hour emergency service.
- B. Each nursing facility shall develop and implement policies and procedures for the handling of drugs and biologicals, including procurement, storage, administration, self-administration, and disposal of drugs.
- C. Each nursing facility shall have a written agreement with a qualified pharmacist to provide consultation on all aspects of the provision of pharmacy services in the nursing facility.
- D. The consultant pharmacist shall make regularly scheduled visits, at least monthly, to the nursing facility for a sufficient number of hours to carry out the function of the agreement.
- E. Excluding cannabidiol oil and THC-A cannabis oil, no drug or medication shall be administered to any resident without a valid verbal order or a written, dated and signed order from a physician, dentist, podiatrist, nurse practitioner, or physician assistant, licensed in Virginia.
- F. Nursing facility employees who are authorized to possess, distribute, or administer medications to residents may store, dispense, or administer cannabidiol oil or THC-A cannabis oil to a resident who has:
 - 1. Been issued a valid written certification for the use of cannabidiol oil or THC-A cannabis oil in accordance with subsection B of § 54.1-3408.3 of the Code of Virginia; and
 - 2. Registered with the Board of Pharmacy.
- G. Verbal orders for drugs or medications shall only be given to a licensed nurse, pharmacist, or physician.
- H. Drugs and medications not limited as to time or number of doses when ordered shall be automatically stopped, according to the written policies of the nursing facility, and the attending physician shall be notified.
- I. Each resident's medication regimen shall be reviewed by a pharmacist licensed by the Virginia Board of Pharmacy. Any irregularities identified by the pharmacist shall be reported to the physician and the director of nursing, and their response documented.
- J. Medication orders shall be reviewed at least every 60 days by the attending physician, nurse practitioner, or physician's assistant.
- K. Prescription and nonprescription drugs and medications may be brought into the nursing facility by a resident's family, friend, or other person provided:
 - 1. The individual delivering the drugs and medications assures timely delivery, in accordance with the nursing facility's written policies, so that the resident's prescribed treatment plan is not disrupted;
 - 2. Each drug or medication is in an individual container; and
 - 3. Delivery is not allowed directly to an individual resident.
 - In addition, prescription medications shall be obtained and labeled as required by law.
- **Statutory Authority**
- 680 §§ 32.1-12 and 32.1-127 of the Code of Virginia.
- 681 Historical Notes

Derived from Virginia Register Volume 13, Issue 17, eff. July 1, 1997; amended, Virginia 682 Register Volume 22, Issue 7, eff. January 11, 2006; Volume 36, Issue 23, eff. August 6, 2020; 683 684 Volume 37, Issue 17, eff. May 27, 2021.<a href="https://span.com/s

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

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

In addition, nursing facilities shall be designed and constructed consistent with Parts 1 and 2 and section Chapter 3.1 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 Facilities Guidelines Institute) pursuant to § 32.1-127.001 of the Code of Virginia.

- B. Architectural drawings and specifications for all new construction or for additions, alterations or renovations to any existing building, shall be dated, stamped with professional seal, and signed by the architect. The architect shall certify that the drawings and specifications were prepared to conform to the Virginia Uniform Statewide Building Code and be consistent with Parts 1 and 2 and section Chapter 3.1 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 Facilities Guidelines Institute).
 - C. Additional approval may include a Certificate of Public Need.
- 705 D. Upon completion of the construction, the nursing facility shall maintain a complete set of legible "as built" drawings showing all construction, fixed equipment, and mechanical and 706 707 electrical systems, as installed or built.

708 **Statutory Authority**

709 §§ 32.1-12, 32.1-127, and 32.1-127.001 of the Code of Virginia.

710 **Historical Notes**

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- Derived from Virginia Register Volume 13, Issue 17, eff. July 1, 1997; amended, Virginia 711
- Register Volume 22, Issue 7, eff. January 11, 2006; Volume 23, Issue 10, eff. March 1, 2007; 712
- Volume 26, Issue 22, eff. August 4, 2010; Volume 37, Issue 14, eff. March 31, 2021. 713
- Documents Incorporated by Reference (12VAC5-371) 714
- 715 Errata for Guidelines for Design and Construction of Residential Health, Care, and Support **Facilities** The Guidelines Institute. 2022 716 Edition. https://fgiguidelines.org/guidelines/errata-addenda/ (eff. 8/2022). 717
- Guidelines for Design and Construction of Residential Health, Care, and Support Facilities, 718 The Facilities Guidelines Institute, 2018 2022 Edition, Facility Guidelines Institute 719 http://www.fgiguidelines.org. 720
- Guidelines for Preventing Health-Care-Associated Pneumonia, 2003, MMWR 53 (RR-3), 721 Advisory Committee on Immunization Practices, Centers for Disease Control and Prevention. 722
- Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the 723 Advisory Committee on Immunization Practices — United States, 2020-21 Influenza Season. 724
- 725 2020, MMWR 69 (RR-8), Centers for Disease Control and Prevention.

- 726 <u>Intervals Between PCV13 and PPSV23 Vaccines: Recommendations of ACIP, MMWR 64</u> 727 (15), 2015, CDC.
- Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the
 Advisory Committee on Immunization Practices United States, 2022–23 Influenza Season,
 MMWR 71 (1), 2022, CDC.
- 731 Prevention of Pneumococcal Disease Among Infants and Children Use of 13-Valent
 732 Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine:
 733 Recommendations of ACIP, MMWR 59 (RR-11), 2010, CDC.
- 734 <u>Updated Recommendations for Prevention of Invasive Pneumococcal Disease Among</u> 735 <u>Adults Using the 23-Valent Pneumococcal Polysaccharide Vaccine (PPSV23), MMWR 59 (34),</u> 736 <u>2010, CDC.</u>
- 737 <u>Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal</u> 738 <u>Polysaccharide Vaccine Among Adults Aged >65 Years: Recommendations of ACIP, MMWR 63</u> 739 (37), 2014, CDC.
- 740 <u>Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal</u> 741 <u>Polysaccharide Vaccine Among Adults Aged >65 Years: Updated Recommendations of ACIP,</u> 742 <u>MMWR 68 (46), 2019, CDC.</u>
- 743 <u>Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal</u> 744 <u>Polysaccharide Vaccine for Adults with Immunocompromising Conditions: Recommendations of</u> 745 ACIP, MMWR 61 (40), 2012, CDC.
- 746 <u>Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal</u> 747 <u>Polysaccharide Vaccine Among Children Aged 6–18 Years with Immunocompromising</u> 748 Conditions: Recommendations of ACIP, MMWR 62 (25), 2013, CDC.
- 749 <u>Use of 15-Valent Pneumococcal Conjugate Vaccine and 20-Valent Pneumococcal</u> 750 <u>Conjugate Vaccine Among U.S. Adults: Updated Recommendations of ACIP — United States,</u> 751 <u>MMWR 71 (4), 2022, CDC.</u>

Office of Regulatory Management

Economic Review Form

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-371-10 et seq.
VAC Chapter title(s)	Regulations for the Licensure of Nursing Facilities
Action title	Amend Regulation to Incorporate Chapter 72 (2021 Acts of Assembly, Special Session I), Chapters 829, 1080, and 1081 (2020 Acts of Assembly), Chapters 10 and 11 (2020 Acts of Assembly, Special Session I), Chapters 177 and 222 (2005 Acts of Assembly) and Chapter 762 (2004 Acts of Assembly), Update Terms to Match Statutory Language, and Update Licensure Provisions
Date this document prepared	November 29, 2022

Cost Benefit Analysis

Fable 1a: Costs and Benefits of the Proposed Changes (Primary Option)		
(1) Direct Costs	Nursing facilities must report specified changes to the Virginia Description of Health (VDII) at least 20 and 10 days are a second at least 20 and 10 day	
& Benefits	Department of Health (VDH) at least 30 calendar days prior to initiating the change.	
	Direct Costs: VDH is not aware of any quantifiable direct costs at time.	
	Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.	
	• Nursing facilities have to permit inspectors access to their facilities, records, and persons under their control for the purposes of inspection and have to submit plans of correction for cited deficiencies, and have to implement corrections within 45 business days.	
	Direct Costs: VDH is not aware of any quantifiable direct costs at time.	
	Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.	
	• Nursing facility construction, renovation, or alterations have to 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 time.	

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• Nursing facilities must have a policy addressing registration, reregistration, and verification with the Sex Offender and Crimes Against Minors Registry that meets statutory minimums.

Direct Costs: \$1,250 one-time per topic per nursing facility to update existing policies and procedures about the Sex Offender and Crimes Against Minors Registry.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• Nursing facilities must utilize current clinical recommendations for influenza and pneumococcal vaccination.

Direct Costs: VDH is not aware of any quantifiable direct costs at time.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

 Nursing facilities must have a policy addressing visitation during public health emergencies related to COVID-19 that meets statutory minimums.

Direct Costs: \$1,250 one-time per topic per nursing facility to update existing policies and procedures about visitation.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

(2) Quantitative		
Factors	Estimated Dollar Amount	Present Value
Direct Costs	(a) \$715,000	(c) \$715,000
Direct Benefits	(b) \$0	(d) \$0
(3) Benefits-	0.00	(4) Net -\$715,000
Costs Ratio		Benefit
		·

(5) Indirect	VDH is not aware of any quantifiable benefits at this time.	
Costs &		
Benefits	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 0.2% increase in construction costs for a	
	180-bed nursing facility that is multiple stories of non-combustible	
	construction and a 0.4% increase in construction costs for a 180-bed nursing	
	facility that is a single story of combustible construction.	
	, ,	
	VDH is not aware of any other quantifiable costs at this time.	
(6) Information	The Facility Guidelines Institute; Division of Acute Care Services, Office of	
Sources	Licensure and Certification.	
(7) Ontional	VDII has numarous shallowers and constraints that limit a cost honefit	
(7) Optional	VDH has numerous challenges and constraints that limit a cost benefit	
	analysis, including limited data availability, limited statutory discretion, and	
	insufficient analytical models.	
	The manufacture of a manufacture of the control of	
	The regulatory change is designed to conform the regulation to the Code of	
	Virginia, and to promote the health, safety, and welfare of nursing facility	
	residents by incorporating current clinical and industry practices as well as	
	by requiring reasonable timely information from nursing facilities, access to	
	information to ensure nursing facility compliance, remedial action within a	
	reasonable and consistently applied timeframe if noncompliance does occur.	

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

(1) Direct Costs	Nondiscretionary changes have been omitted from this analysis.	
& Benefits		
	 Nursing facilities must report specified changes to the Virginia Department of Health (VDH) at least 30 calendar days prior to initiating the change, excluding nursing facility closures. 	
	Direct Costs: VDH is not aware of any quantifiable direct costs at time.	
	Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.	
	 Nursing facilities have to permit inspectors access to their facilities, records, and persons under their control for the purposes of inspection and have to submit plans of correction for cited deficiencies, and have to implement corrections within an unspecified time. 	

	Direct Costs: VDH is not aware of any quantifiable direct costs at time. Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.	
(2) Quantitative		
Factors	Estimated Dollar Amount	Present Value
Direct Costs	(a) \$0	(c) \$0
Direct Benefits	(b) \$0	(d) \$0
(3) Benefits-	0.00	(4) Net \$0
Costs Ratio		Benefit
(5) Indirect Costs & Benefits	J 1	
(6) Information Sources	Division of Acute Care Services, Office of Licensure and Certification	
(7) Optional	VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models.	
	Virginia, and to promote the h residents by incorporating curr by requiring reasonable timely information to ensure nursing t	ned to conform the regulation to the Code of ealth, safety, and welfare of nursing facility ent clinical and industry practices as well as information from nursing facilities, access to facility compliance, remedial action within a blied timeframe if noncompliance does occur.

Table 1c: Costs and Benefits under an Alternative Approach

(1) Direct Costs	Nondiscretionary changes have been omitted from this analysis.
& Benefits	
	• Nursing facilities must report specified changes to the Virginia Department of Health (VDH) within an unspecified time frame at the nursing facility's discretion prior to initiating the change.

	 time. Direct Benefits: VDH is at time. Nursing facilities have to records, and persons under and have to submit plans to implement correction. Direct Costs: VDH is retime. 	not aware of any quantifiable direct costs at a not aware of any quantifiable direct benefits to permit inspectors access to their facilities, der their control for the purposes of inspection s of correction for cited deficiencies, and have s within 45 calendar days. not aware of any quantifiable direct costs at a not aware of any quantifiable direct benefits
(2) Quantitative		
Factors	Estimated Dollar Amount	Present Value
Direct Costs	(a) \$0	(c) \$0
Direct Benefits	(b) \$0	(d) \$0
(3) Benefits- Costs Ratio	0.00	(4) Net Benefit \$0.00
(5) Indirect Costs & Benefits	VDH is not aware of any quantifiable benefits at this time from the discretionary regulatory changes. VDH is not aware of any quantifiable costs at this time from the discretionary regulatory changes.	
(6) Information Sources	Division of Acute Care Service	s, Office of Licensure and Certification
(7) Optional	VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models. The regulatory change is designed to conform the regulation to the Code of Virginia, and to promote the health, safety, and welfare of nursing facility residents by incorporating current clinical and industry practices as well as by requiring reasonable timely information from nursing facilities, access to	

information to ensure nursing facility compliance, remedial action within a reasonable and consistently applied timeframe if noncompliance does occur.

Impact on Local Partners

Table 2: Impact on Local Partners

(1) Direct Co	sts
& Benefits	

• Nursing facilities must report specified changes to the Virginia Department of Health (VDH) at least 30 calendar days prior to initiating the change.

Direct Costs: VDH is not aware of any quantifiable direct costs at time.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• Nursing facilities have to permit inspectors access to their facilities, records, and persons under their control for the purposes of inspection and have to submit plans of correction for cited deficiencies, and have to implement corrections within 45 business days.

Direct Costs: VDH is not aware of any quantifiable direct costs at time.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• Nursing facility construction, renovation, or alterations have to 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 time.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• Nursing facilities must have a policy addressing registration, reregistration, and verification with the Sex Offender and Crimes Against Minors Registry that meets statutory minimums.

Direct Costs: \$1,250 one-time per topic per nursing facility to update existing policies and procedures about the Sex Offender and Crimes Against Minors Registry.

	Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.
	Nursing facilities must utilize current clinical recommendations for influenza and pneumococcal vaccination.
	Direct Costs: VDH is not aware of any quantifiable direct costs at time.
	Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.
	 Nursing facilities must have a policy addressing visitation during public health emergencies related to COVID-19 that meets statutory minimums.
	Direct Costs: \$1,250 one-time per topic per nursing facility to update existing policies and procedures about visitation.
	Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) \$2,500
Direct Benefits	(b) \$0
	VDH is not aware of any quantifiable benefits at this time.
Costs & Benefits	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 0.2% increase in construction costs for a 180-bed nursing facility that is multiple stories of non-combustible construction and a 0.4% increase in construction costs for a 180-bed nursing facility that is a single story of combustible construction.
	VDH is not aware of any other quantifiable costs at this time.
(4) Information Sources	The Facility Guidelines Institute; Division of Acute Care Services, Office of Licensure and Certification.

(5) Assistance	None
(6) Optional	VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models. The regulatory change is designed to conform the regulation to the Code of Virginia, and to promote the health, safety, and welfare of nursing facility residents by incorporating current clinical and industry practices as well as by requiring reasonable timely information from nursing facilities, access to information to ensure nursing facility compliance, remedial action within a reasonable and consistently applied timeframe if noncompliance does occur.

Economic Impacts on Families

Table 3: Impact on Families

(1) Direct Costs	Families will not be affected by direct costs or benefits of the regulatory	
& Benefits	change as they are not subject to the requirements contained in this regulatory	
	chapter and thus will incur no direct cost or benefit.	
(2) Quantitative		
Factors	Estimated Dollar Amount	
Direct Costs	(a) \$0	
Direct Benefits	(b) \$0	
(3) Indirect	VDH is not aware of any quantifiable indirect costs or benefits for families.	
Costs &		
Benefits	to families, VDH cannot quantify that cost or benefit at this time.	
(4) Information	Division of Acute Care Services, Office of Licensure and Certification.	
Sources		
(5) Optional	VDH has numerous challenges and constraints that limit a cost benefit	
	analysis, including limited data availability, limited statutory discretion, and	
	insufficient analytical models.	
	The regulatory change is designed to conform the regulation to the Code of	
	Virginia, and to promote the health, safety, and welfare of nursing facility	
	residents by incorporating current clinical and industry practices as well as	
	by requiring reasonable timely information from nursing facilities, access to	

information to ensure nursing facility compliance, remedial action within a reasonable and consistently applied timeframe if noncompliance does occur.

Impacts on Small Businesses

Table 4: Impact on Small Businesses

(1) Direct Cost	S
& Benefits	

• Nursing facilities must report specified changes to the Virginia Department of Health (VDH) at least 30 calendar days prior to initiating the change.

Direct Costs: VDH is not aware of any quantifiable direct costs at time.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• Nursing facilities have to permit inspectors access to their facilities, records, and persons under their control for the purposes of inspection and have to submit plans of correction for cited deficiencies, and have to implement corrections within 45 business days.

Direct Costs: VDH is not aware of any quantifiable direct costs at time.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• Nursing facility construction, renovation, or alterations have to 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 time.

Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.

• Nursing facilities must have a policy addressing registration, reregistration, and verification with the Sex Offender and Crimes Against Minors Registry that meets statutory minimums.

Direct Costs: \$1,250 one-time per topic per nursing facility to update existing policies and procedures about the Sex Offender and Crimes Against Minors Registry.

	Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.
	• Nursing facilities must utilize current clinical recommendations for influenza and pneumococcal vaccination.
	Direct Costs: VDH is not aware of any quantifiable direct costs at time.
	Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.
	 Nursing facilities must have a policy addressing visitation during public health emergencies related to COVID-19 that meets statutory minimums.
	Direct Costs: \$1,250 one-time per topic per nursing facility to update existing policies and procedures about visitation.
	Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) \$2,500 per nursing facility (see Response to #6 in this Table)
Direct Benefits	(b) \$0
(3) Indirect	VDH is not aware of any quantifiable benefits at this time.
Costs & Benefits	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 0.2% increase in construction costs for a 180-bed nursing facility that is multiple stories of non-combustible construction and a 0.4% increase in construction costs for a 180-bed nursing facility that is a single story of combustible construction.
	VDH is not aware of any other quantifiable costs at this time.
(4) Alternatives	Of the changes that are discretionary (see Tables 1b and 1c for identification of the discretionary changes), VDH could not identify an alternative that achieved the same purpose without compromising the health, safety, and

	welfare of patients or without compromising VDH's ability to comply in a cost-efficient manner with statutory/legislative mandates placed on the agency.
(5) Information Sources	The Facility Guidelines Institute; Division of Acute Care Services, Office of Licensure and Certification.
(6) Optional	VDH does not have any data to indicate whether a currently licensed nursing facility meets the definition of "small business" so there may be no direct costs or direct benefits for small businesses.
	VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models.
	The regulatory change is designed to conform the regulation to the Code of Virginia, and to promote the health, safety, and welfare of nursing facility residents by incorporating current clinical and industry practices as well as by requiring reasonable timely information from nursing facilities, access to information to ensure nursing facility compliance, remedial action within a reasonable and consistently applied timeframe if noncompliance does occur.

Changes to Number of Regulatory Requirements

Table 5: Total Number of Requirements

	Number of Requirements				
Chapter number	Initial Count	int Additions Subtractions		Net Change	
371	1,357	31	15	16	

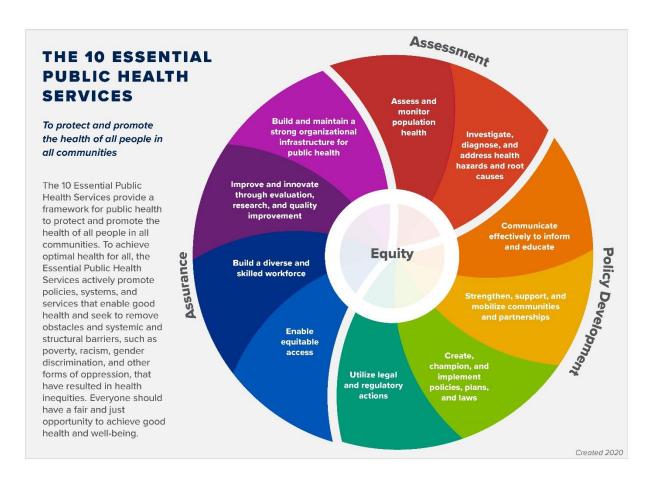
ANNUAL REPORT OF THE BOARD OF HEALTH



INTRODUCTION

Pursuant to Virginia Code §32.1-14 the Virginia Department of Health (VDH) is submitting the following State Board of Health annual report summarizing health care issues affecting citizens of Virginia and the corresponding collaborative efforts to address health disparities.

Throughout 2022, the VDH continued leading the way for COVID-19 response while simultaneously providing services, programs, and interventions across the Commonwealth. VDH remains committed to ensure that every Virginian has a fair and equitable opportunity to achieve optimal health, and for Virginia to become the healthiest state in the nation. The COVID-19 pandemic underscored the importance of using data and partnering with communities to improve community health outcomes. Ensuring all Virginians have the opportunity for optimal health requires actions designed to understand and address the root causes of health disparities. VDH is focused on a team-of-teams approach to improve the health of all Virginians.



HIGHLIGHTED ACCOMPLISHMENTS

Response to Global Emerging Disease

During 2022, VDH continued to track COVID-19 and investigate outbreaks in higher risk settings. In May 2022, Monkeypox was identified in countries where it had not been detected in the past and began to spread globally. The Office of Epidemiology quickly developed and disseminated guidance for its clinical partners and the general public and established data systems and procedures to track and control the disease. Local health departments investigated cases, identified contacts of cases, and provided Monkeypox vaccine to targeted groups in order to prevent further transmission. In September 2022, the World Health Organization declared an outbreak of Ebola in Uganda, and VDH worked with Centers for Disease Control and Prevention (CDC) and other states to quickly re-establish its public health response to prevent transmission of Ebola in the United States. Beginning in early October, all travelers from Uganda were funneled through five US airports, including Dulles International. The Office of Epidemiology, the Office of Emergency Preparedness, and local health districts are worked closely with clinical partners to ensure preparedness; and VDH's regional epidemiology surge teams (established during the COVID-19 pandemic) conducted outreach to travelers from Uganda to provide public health guidance and monitoring.

Collaboration and Focus on Data to Foster Community Health Improvement

VDH launched several centers and programs that are focused on developing the capabilities of all programs and offices to drive measurable outcomes utilizing the Public Health 3.0 Framework.

- The Center for Community Health Improvement (CCHI) coordinates with and provides guidance and technical support to the VDH Central Office and local health districts to meet national public health accreditation requirements for (1) engaging with the public health system and the community in identifying and addressing health problems through collaborative processes; (2) conducting and disseminating assessments focused on population health status and public health issues facing the community; and (3) conducting comprehensive planning processes that result in population health improvement plans. The CCHI facilitates the collaborative State Health Assessment at least every five years.
- The Office of Family Health Services' Community Health Epidemiology Program (CHEP) provides strategic direction for community-engaged research and informatics activities supporting population health and equity, including metrics and dashboards, vulnerable population data systems, interoperability standards, and Community Health Assessment (CHA) and Community Health Improvement Plan (CHIP) monitoring. Since its inception in late August 2022, CHEP has worked to build relationships and work collaboratively with CCHI and local health districts to improve community health via evidence-based methods and appropriate data analyses regarding the distribution and determinants of population health.
- The Office of Information Management's Center of Public Health Informatics (CPHI) supports programs through the provision of expertise in the development, translation, visualization, and dissemination of public health data and informatics knowledge. CPHI improves population health outcomes by developing innovative ways to improve use and understanding of data to better inform and promote the health of all Virginians. The Community Health Informatics Team within the CPHI provides informatics, data and assessment support for the Community Health Assessments and Improvement Plans (CHAs/CHIPs); supports CCHI and Population Health with CARES portal data system's needs; standardizes key performance indicators; establishes data management best practices; and collects and maintains reliable, comparable and valid data that provides information on conditions of public health importance and on the health status of the population.

In 2022, VDH facilitated Virginia's State Health Assessment. The State Health Assessment (SHA) Data Highlights Report (Appendix A) provides an overview of health indicators and whether they have improved, remained stable, or worsened. These data show where community health efforts are working and where renewed attention is needed. The findings of the SHA will be analyzed, prioritized, and made actionable through the State Health Improvement Plan (SHIP) in 2023.

Virginia Community Health Improvement Data Portal

Partnering for a Healthy Virginia (PHV) was founded by VDH and the Virginia Hospital and Healthcare Association (VHHA) to impact population health efforts and activities. The goal of PHV is to ensure that every Virginian has a fair and equitable opportunity to achieve optimal health, making Virginia the healthiest state in the nation. Partnering for a Healthy Virginia is Virginia's state-level population health improvement collaborative and continues to grow and expand partnerships, including stakeholders from local health districts, hospitals, community health coalitions, businesses, and foundations. In 2022, PHV continued its work towards population health improvement including the launch of the Virginia Community Health Improvement Portal.

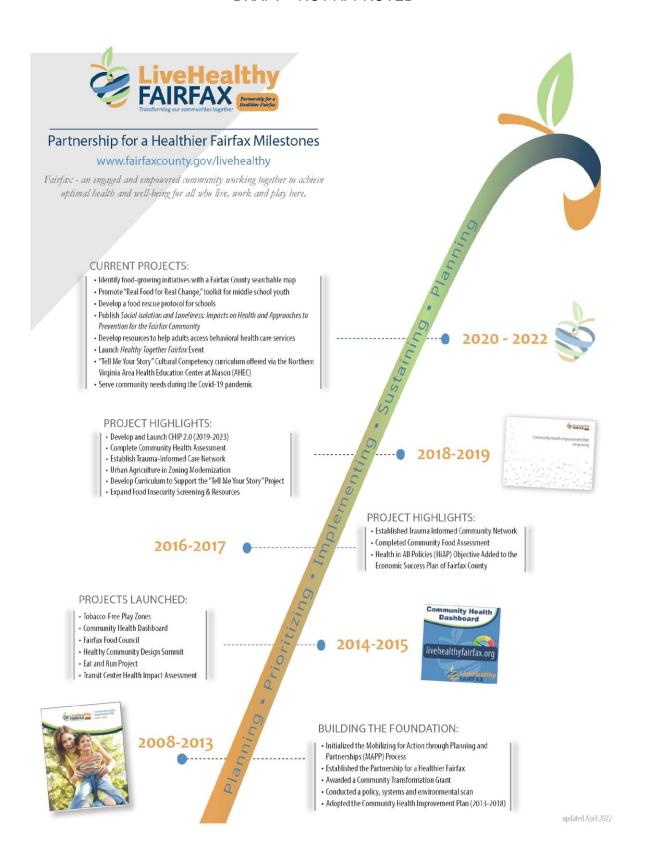
Community Health Assessment and Improvement Planning

For the first time in 2022 the Rappahannock Area Health District and Mary Washington Healthcare partnered to complete a joint CHA for the City of Fredericksburg and Caroline, King George, Spotsylvania, and Stafford Counties, as well as parts of Westmoreland, Orange, and Prince William Counties. Over 70 organizations and nearly 2,000 community members provided feedback during this collaborative assessment process. Using data from the assessment, mental health, affordable housing, and access to healthcare were identified as the top three priority issues to be addressed through a community health improvement plan (CHIP), which can be viewed in its entirety at www.vdh.virginia.gov/rappahannock/fy23-fy25_cha-chip. The plan outlines ways in which community organizations will come together to enhance collaboration around these issues, improve access to care, ensure equitable housing options, and develop a strategy to increase the healthcare workforce pathway.

The Rappahannock-Rapidan Health District is collaborating with five counties, two hospitals, two community foundations, and one community-based organization to complete a joint CHA. They pooled financial resources to contract with a facilitator to meet the varying needs of localities, hospitals, health departments, and community partners. Each organization selected key priority targets for improvement for the community health improvement process, and they will continue to collaborate implementing these strategies over the next CHIP cycle.

The Crater Health District has partnered with a private foundation that serves five of the eight health district localities to complete a community health needs assessment (CHNA) for its local health system. As a part of this partnership, Crater Health District has trained three staff to lead focus groups for the CHNA and is supporting the distribution of the community survey. The foundation will share all data collected and analyzed with the health district, which means this partnership will greatly expedite the CHA for Crater Health District.

The Fairfax Health District provides backbone support for the work of the Partnership for a Healthier Fairfax and the Fairfax Food Council, multi-sector community coalitions working to implement the goals, objectives and key actions of the Live Healthy Fairfax CHIP. Partnership for a Healthier Fairfax is engaged in implementation activities for year 4 of the CHIP and work is underway to complete a 2022 Community Health Assessment. The CHIP and local community health indicators are found on www.livehealthyfairfax.org. Current projects include promoting the "Real Food for Real Change" toolkit for middle school students, developing resources to help adults' access behavioral care services, and developing a food rescue protocol for schools.



Office of Vital Records Improved Customer Service

The VDH Office of Vital Records (OVR) is the official repository of vital events (birth, death, spontaneous fetal death, marriage, divorce, and induced termination of pregnancy) occurring in the Commonwealth of Virginia. It is the responsibility of the various reporting sources (i.e. hospitals, clinics, courts, funeral homes) to file these vital events with OVR. With the exception of marriage and divorce records, these vital events are filed electronically via the Virginia Vital Event and Screening Tracking System (VVESTS). VVESTS is a web application used for the registration, collection, preservation, amendment and certification of vital records. In addition to collecting Virginia's vital events, OVR has reciprocity arrangements among the other states and US territories to receive vital records data pertaining to Virginia residents. Likewise, OVR exchanges data on vital events occurring in Virginia to non-residents with the proper states. In Virginia's vital records data, a distinction is made in the tables and analyses as to those events occurring in Virginia and to those occurring to residents of Virginia.

In April 2022 the fully online vital records application service was launched. This new service allows customers from around the world to request a copy of a vital record from a computer, phone or tablet. This new system decreases processing times and improves access to vital records for customers. In June 2022 the National Association for Public Health Statistics and Information Systems (NAPHSIS) awarded the OVR's Field Services Team the '2022 Team Excellence Award' for improving mortality and natality data quality in the state. OVR significantly improved customer satisfaction during the pandemic, with their rating on Google improving from 2.0 stars (out of 5.0) before the pandemic to 4.2 stars as of October 2022.

VDH's Office of Information Management's Vital Event Statistics Program analyzes Virginia vital event data, develops statistical reports, charts, tables and graphs and publishes the annual Virginia Health Statistics report online at: https://apps.vdh.virginia.gov/HealthStats/stats.htm.

School-Aged Dental Health Program

VDH's Division of Child and Family Health in the Office of Family Health Services has collaborated with the Virginia Health Catalyst and the Virginia Department of Education to create a School-Aged Dental Health Program. This program provides education, training, and resources to school nurses to increase the number of Virginia children receiving oral health services. This program focuses on preventative care by growing the number of school-based oral health programs. The school nurse training programs are designed to break down barriers to dental care by providing technical assistance. The first cohort (2021-2022 school year) consisted of twelve school nurses. The schools selected were in the underserved communities of Campbell County, Wythe County, Giles County, Pulaski County, Petersburg, Hopewell, Hampton Roads, Orange County and Eastern Shore.

Additionally, as of September 2022, Alexandria Health District's Neighborhood Health Team began to see patients enrolled at Mount Vernon Community School and William Ramsay Elementary School in Alexandria to provide dental care to 400 students during the 2022-2023 school year.

Pregnancy Loss Services Project

In 2022, VDH partnered with five organizations: Birth in Color RVA, Full Circle Grief Center, Kennedy's Angel Gowns, Sisters in Loss, and VCU, to create the Pregnancy Loss Services Project. VDH launched the project to support individuals and families who have experienced pregnancy loss. VDH's Pregnancy Loss Services Project aims to build community organizations' capacity by providing support and education services to individuals and groups (including families) who have experienced pregnancy loss. This program is supported by Title V funds and came about as a result of the Title V Maternal Child Health Needs Assessment. The program services include grief groups, community events, material support, education materials, and training for doulas.

State-Certified Doulas

Doulas positively impact maternal and infant health outcomes and the need for access to doula services was underscored during the Maternal Health Listening Sessions. The Board of Health finalized regulations guiding the State Doula Certification program in January 2022. VDH developed a process to allow doulas to apply for state certification. Interested doulas submit applications to the Virginia Certification Board. Doulas receiving state certification have the option of being listed in a public-facing database. Consumers can use the database to find a doula that meets their needs. State-certified doulas are eligible for Medicaid reimbursement and work with DMAS to become Medicaid providers. As of August 23, 2022, 37 doulas have received state certification. Of the 37, 22 have completed Medicaid enrollment, 21 have completed contracting with at least one MCO, and five are pending Medicaid enrollment.

The Rare Disease Council and Additional Newborn Screening Tests

This Virginia Newborn Screening and Birth Defects Surveillance Program includes the Newborn Bloodspot Screening (NBS) Program, Early Hearing Detection and Intervention (EHDI) program, the Critical Congenital Heart Disease (CCHD) Program, and the Birth Defects Surveillance (BDS) Program. The BDS program provided expertise and staff support to the new Virginia Rare Disease Council. The Rare Disease Council is a Governor appointed council with diverse representation to learn about the challenges of those affected by or living with family members of rare diseases and reports to the Governor and the General Assembly.

The NBS program implemented screening for two new disorders, Spinal Muscular Atrophy (SMA) and X-Linked Adrenoleukodystrophy (X-ALD), on March 16, 2022.

Maternal and Child Health Key Collaborations

VDH collaborated with Healthy Beginnings' learning cohort *Advancing Anti-Racism in Preterm Birth Prevention*, CityMatCH's Alignment for Action Learning Collaborative, and *Listening to the Living*, efforts aimed at bringing together firsthand knowledge of and access to Black maternal experiences and inspiring collective action to support better birth outcomes for Black women.

Stroke Care Partnerships

VDH and Virginia Hospital and Healthcare Association (VHHA) have identified key partners to improve the continuation of stroke care including EMS regional councils, Unite Us, Sheltering Arms Institute, Kwikpoint, Medical Society of Virginia, and the Virginia Pharmacists Association.

The Virginia Stroke Registry, developed by the VDH, and the ESO Data Exchange, a trauma registry, allow participating hospitals and EMS agencies in Virginia to access and use their own data to improve protocols and achieve better outcomes. Analysis of stroke outcomes across Virginia hospitals, as well as peer-reviewed research on stroke protocols, drove the development of a statewide Stroke Smart initiative in 2021. Stroke Smart aims to reduce pre-hospital delays of stroke by educating the public to recognize and activate 9-1-1 early. Clinical and community partners were critical for the implementation of new public health research-based protocols, training delivery, and successful dissemination of educational materials.

Substance Use Response

Harm reduction is a public health strategy to reduce negative health outcomes for persons who engage in behaviors that put them and others at risk for disease or injury. VDH has long-term experience implementing a public health approach to reduce the impact of drug-related injuries, including active monitoring and surveillance, primary prevention strategies, rescue initiatives, and comprehensive harm reduction (CHR) efforts. VDH works through its local health departments and partners with community based organizations to provide a set of public health strategies intended to reduce the negative impact of drug use, including infections, overdose, and death, among people who are unable or not ready to stop using drugs. Comprehensive Harm Reduction sites provide referral and linkage to other services such as substance use disorder treatment. Peer counselors play an important role in this program, working with participants over time to improve health outcomes. VDH is working to expand its network of harm reduction partners to more settings in order to reach those at greatest risk of encountering fentanyl and experiencing an overdose. Currently, there are eight authorized CHR sites in Virginia. Comprehensive Harm Reduction sites provide health education on the potential impact of fentanyl and how to identify it using test strips. These sites distribute both fentanyl test strips to identify when fentanyl is present and naloxone to reverse its impact in the event of an overdose. VDH Central Pharmacy Services supports sites with Fentanyl Test Strips (FTS) for distribution to community members and program participants, and designs protocol and processes for Local Health Districts in the distribution of these supplies. Through partnership with Virginia Broadcast Solutions, VDH continues to stand up public facing communication campaigns through a variety of media channels to message the overdose risks associated with drug use and link individuals to treatment.

The Mount Rogers Health District Population Health Team was a key partner in planning a fentanyl awareness day, held at Virginia High School in Bristol in the spring of 2022. In response to student overdoses, dozens of partners provided a day of programming for high school students, including an internationally known speaker, stories of local lived experience, and a resource fair focused on substance use prevention, mental health resources, and dispensing naloxone to students and staff. The event was so successful and well received by the students that other similar events are in the works locally.

Stay WellNo Va

Since the summer of 2020, the Northern Virginia health districts of the City of Alexandria, and the counties of Arlington, Fairfax, Loudoun, and Prince William, have been collaborating on a public health information campaign, StayWellNoVa. The initiative began to boost childhood and flu immunizations, and then changed focus to promote COVID-19 vaccinations. Close collaboration with community partners to inform cultural competency, as well as engagement of trusted messengers and influencers, have served as the 'special sauce' to ensure that all promotions truly resonate with the intended audiences and deliver results. The initiative continues today with a new focus on monkeypox vaccination. This regional communications approach has innovated the way the local health districts target and connect with key public health audiences in Virginia's most populous and diverse health districts.



Virginia Partners in Prayer and Prevention

Virginia Partners in Prayer and Prevention (Virginia P3) is a community health initiative that has developed meaningful partnerships across faith-based coalitions throughout the Commonwealth since its inception in 2016. These partnerships have increased collaboration between VDH and faith-based organizations and their members. Additionally, by working with these organizations on health and prevention, trust has been established and strengthened in VDH and public health among populations that have historical mistrust in the medical and public health systems, especially Black and African American communities. This year, Virginia P3 continued to develop partnerships with other organizations to deliver training, facilitate discussions, and disseminate resources across its faith-based coalitions. These partners include Department of Homeland Security for a faith-based safety active shooter training, Virginia Breast Cancer Foundation, American Association of Retired Persons, American Heart Association for Heart Health Matters, Walgreens for community collaborations, VDH Arthritis Coalition for Walk with Ease and the Chronic Disease Self-Management Program, and Alzheimer's Association for Purple Power Virginia.

Telehealth-in-a-Box

VDH partnered with the Salem Veterans Affairs Health Care System to establish a new point of access at the Martinsville Health Department for telehealth services provided by the U.S. Veterans Health Administration. Services will be provided at the Martinsville Health Department, utilizing the "telehealth-in-a-box" model that the Salem Veterans Affairs Health Care System has utilized at several sites in their region. These are examples of the several partnerships with clinical providers and medical technology vendors, which allow VDH to better serve the public health needs of Virginia.

The Academic Advisory Council

The Academic Advisory Council is composed of the Chairs of all Council on Education for Public Health-accredited Master of Public Health programs in Virginia, and VDH staff. The Council represents the public health programs at

Old Dominion University, Virginia Commonwealth University, Eastern Virginia Medical School, University of Virginia, Virginia Polytechnic Institute and State University, George Mason University, and Liberty University. During quarterly meetings the Council determines public health issues that can be better understood and addressed through collaboration with MPH program support. Community health initiatives and public health education are also incorporated into partnerships with several Historically Black Colleges and Universities in Virginia. These educational partnerships are invaluable resources to public health initiatives that serve student communities as well as the communities that these institutions are already working with directly.

Community Health Workers

Many health districts utilized the opportunity granted by COVID-19 funds to hire community health workers (CHWs). Rappahannock-Rapidan Health District has placed CHWs in each of their free clinics. The CHWs are working together, alongside the free clinic and the health district, to screen patients for social determinants of health and connect patients with resources. Mount Rogers Health District has partnered with the Institute for Public Health Innovation to hire a team of six CHWs. The CHWs were deployed in May and have been assisting with COVID-19 recovery and response efforts, in addition to training hundreds of people on how to use naloxone. Central Shenandoah Health District hired nine CHWs, who have supported 475 families since June 2021 (see graphic on page 9).

Central Shenandoah Health District

2021-2022 Community Health Improvement Efforts

The Population Health Program at the Central Shenandoah Health District launched Spring 2019. Since then, our team has grown into a robust community health improvement program focused on health equity and data driven interventions. Below are some program and district highlights from the past year.

Connection 2 Care CHW Program



- Onboarded and trained 9 Community Health Workers (CHW)
- 475 families supported since June 2021 through Unite Virginia
- Continue to distribute rapid COVID-19 test kits to food pantries, domestic violence shelters, clothing closets, and other social safety net providers

Community Engagement & Outreach



- 112 community events attended by Population Health Staff since September 2021
- Actively participate in 8 local Community Coalitions
- Established Weekly Wellness Newsletter with approximately 26,300 subscribers

Substance Abuse Prevention Program



- Conducted 52 REVIVE! Training events since March 2022
- 298 Individuals received REVIVE! Lay Rescue training since March 2022 of individual Narcan met
- 305 boxes of Narcan distributed since March 2022 approximate of
- Established Quarterly Substance Use Prevention newsletter to highlight community efforts across the district

COVID-19 Response



- CSHD hosted approximately 247 community-based COVID-19 vaccine clinics since July 2021
- Approximately 138,000 total COVID-19 vaccines dispensed by CSHD
- Approximately 29,360 COVID-19 tests performed by CSHD staff in community testing settings

Funding Community Health Improvement Initiatives



- Provided 8 Community Based Organizations (CBOs) with funding to address health disparities in the district
- CBOs include: Augusta Health Hospital, Rockbridge Area Health Center, Health Communities Health Centers, Highland County Medical Center, Valley Program for Aging Services, Community Foundation, Strength in Peers, and Rockbridge Area Transit Services



HIGHLIGHTS FROM STATE HEALTH ASSESSMENT

DEMOGRAPHICS

According to the U.S. Census Bureau 2021 population estimates, there are 8,642,274 residents in Virginia. Figure 1 displays the racial and ethnic make-up of Virginia residents. In 2021, the median household income in Virginia was \$76,398, higher than the US median income of \$67,340. As shown in Figure 2, the median annual household income was highest for Asian residents (\$121,000) and lowest for Black or African American residents (\$55,000).

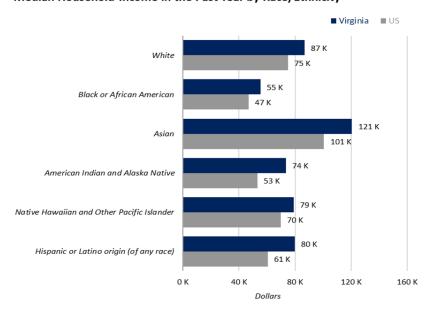
Figure 1

Race and Hispanic Origin	
White alone, percent	68.8%
Black or African American alone, percent	20.0%
American Indian and Alaska Native alone, percent	0.6%
Asian alone, percent	7.2%
Native Hawaiian and Other Pacific Islander alone, percent	0.1%
Two or More Races, percent	3.4%
Hispanic or Latino, percent	10.2%

Data Source: U.S Census Bureau

Figure 2

Median Household Income in the Past Year by Race/Ethnicity



 $Source: U.S.\ Census\ Bureau,\ 2021\ American\ Community\ Survey\ 1-Year\ Estimates\\ Note:\ Median\ Household\ Income\ (In\ 2021\ Inflation-Adjusted\ Dollars)$

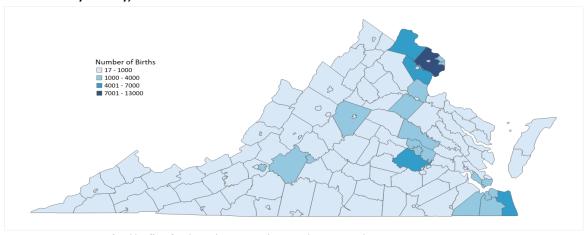
VDHDEPARTMENT

BIRTHS

Figure 3

In 2021, there were a total of 95,620 live births in Virginia Figure 3 shows the distribution of births by locality.

Total Births by Locality, 2021



Source: Virginia Department of Health, Office of Vital Records, Virginia Vital Events and Screening Tracking System. Note: Residence refers to the Virginia city or county where the mother resided for a birth, where the patient resided for an induced termination of pregnancy or a natural fetal death, or where the deceased reside.

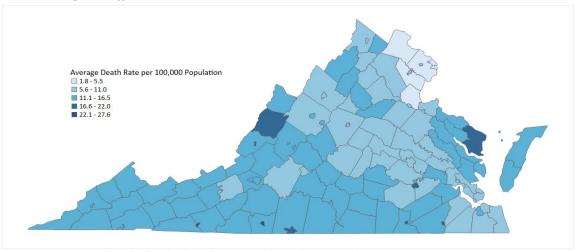
VDHVIRGINIA DEPARTMENT OF HEALTH

DEATHS

From 2018 to 2020 the overall death rate in Virginia was highest in Bath, Northumberland and Lancaster counties (Figure 4). 75.9% of deaths occurred in white residents (Figure 5). In 2021, the top three leading causes of deaths were heart disease, cancer, and COVID-19. Among adults 20-44 years old, the leading cause of death in Virginians was accidental poisoning and exposure to noxious substances (Figure 5).

Figure 4

Death Rate by Locality, 2018-2020

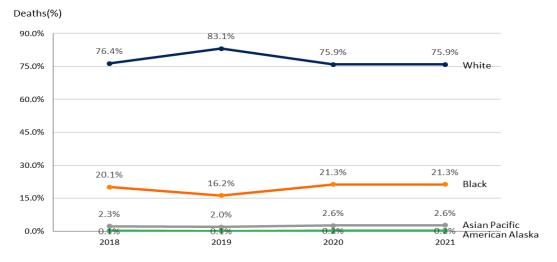


Source: Virginia Department of Health, Office of Vital Records, Virginia Vital Events and Screening Tracking System. Note: Residence refers to the Virginia city or county where the mother resided for a birth, where the patient resided for an induced termination of pregnancy or a natural fetal death, or where the deceased reside.

VDHVIRGINIA DEPARTMENT OF HEALTH

Figure 5

Total Deaths by Race, 2018-2021 (Residence)



Source: Virginia Department of Health, Office of Vital Records, Virginia Vital Events and Screening Tracking System.

Note: Residence refers to the Virginia city or county where the mother resided for a birth, where the patient resided for an induced termination of pregnancy or a natural fetal death, or where the deceased reside.



Figure 6

15 Leading Causes of Deaths by Age Group, 2021						
	0-4	5-19	20-44	45-69	>70	
Accidental Poisoning and Exposure to Noxious Substances	0.1%	1.5%	56.8%	39.9%	1.7%	
Acute Myocardial Infarction	0.0%	0.0%	2.2%	34.3%	63.5%	
All Other and Unspecified Malignant Neoplasms	0.4%	0.8%	3.6%	32.7%	62.5%	
All Other Diseases	0.2%	0.3%	3.7%	21.0%	74.8%	
All Other Forms of Heart Disease	0.2%	0.3%	4.6%	28.2%	66.7%	
All Other Forms of Ischemic Heart Disease	0.0%	0.0%	0.6%	22.0%	77.4%	
Alzheimers Disease	0.0%	0.0%	0.0%	3.7%	96.3%	
Cerebrovascular Diseases	0.2%	0.1%	2.0%	19.0%	78.7%	
COVID-19	0.1%	0.1%	4.3%	34.4%	61.1%	
Diabetes Mellitus	0.0%	0.1%	4.1%	39.9%	55.9%	
Heart Failure	0.1%	0.0%	1.0%	16.3%	82.6%	
Other Chronic Lower Respiratory Diseases	0.0%	0.0%	0.2%	24.9%	74.9%	
Other Diseases of Respiratory System	1.1%	0.2%	1.8%	27.8%	69.2%	
Renal Failure	0.0%	0.0%	1.7%	27.1%	71.1%	
Trachea, Bronchus, and Lung	0.0%	0.0%	0.7%	39.7%	59.6%	

Source: Virginia Department of Health, Office of Vital Records, Virginia Vital Events and Screening Tracking System.

Note: Residence refers to the Virginia city or county where the mother resided for a birth, where the patient resided for an induced termination of pregnancy or a natural fetal death, or where the deceased reside.



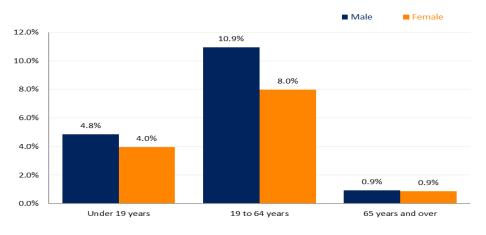
HEALTH INSURANCE

Since January 1, 2019, more adults living in Virginia have access to quality, low-cost health comprehensive health insurance through Virginia Medicaid. Covered adults include individuals ages 19-64 with income at or below 138% of the federal poverty level. In 2021, 10.9% of female adults 19 to 64 years old were uninsured, compared to 8% of males (Figure 7). As Figure 8 shows, 28.1% of Hispanic/Latino Virginians 19 to 64 years old were uninsured in

2021, compared to 6.7% of White Virginians and 9.1% of African American Virginians. Figure 9 shows that 28.4% of uninsured Virginians 26 to 64 years old had less than a high school education.

Figure 7

Percent Uninsured by Sex and Age, Virginia

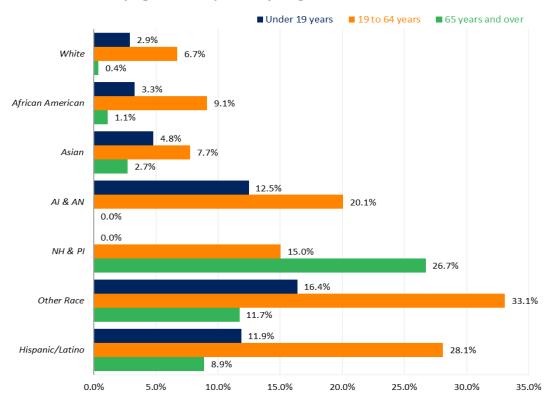


Source: U.S. Census Bureau, 2021 American Community Survey 1-Year Estimates

VDHDHARIMANT

Figure 8

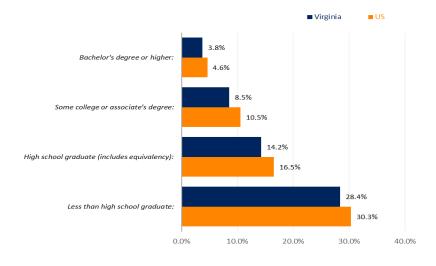
Percent Uninsured by Age and Race/Ethnicity, Virginia



Source: U.S. Census Bureau, 2021 American Community Survey 1-Year Estimates

VDH DEPARTMENT

Figure 9 Percent Uninsured by Educational Attainment, Age 26-64 Years

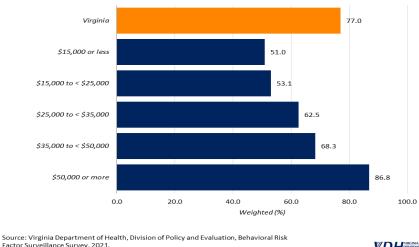


Source: U.S. Census Bureau, 2021 American Community Survey 1-Year Estimates

VDHOFFARMAN

Figure 10

Dental Insurance Coverage Among Adults 18+ by Income, 2021



Factor Surveillance Survey, 2021.

Note: Weighted counts and weighted percents are weighted to population characteristics.

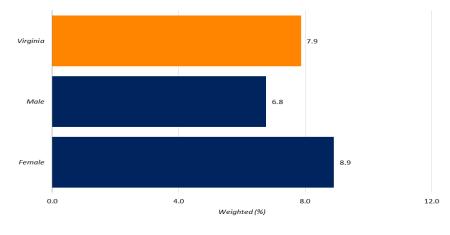
WDH VIRGINIA DEPARTMENT OF HEALTH

HEALTH CARE AFFORDABILITY

Even when Virginia residents have health insurance coverage, people with limited funds or lack of transportation options still may not be able to get the care they need. Delays in seeking medical care for injuries, illness or chronic conditions can have significant impact on the individual, the economy, and the healthcare system. These delays are mostly attributed to cost. According to the Kaiser Family Foundation, dental services are the most common type of care that people report delaying or skipping.

Lower income families spend a greater share of their income on health care costs than those families with higher incomes. In 2021, 7.9% of adults reported that they could not afford to see a doctor (Figure 11). The group with the highest percentage of adults who could not afford to see a doctor were in households earning \$15,000 to less than \$25,000 (Figure 12). The racial/ethnic group with the highest percentage of adults who could not afford to see a doctor were those that identified as Hispanic (Figure 13). By education level, Virginians with less than a high school education were the largest group that could not afford to see a doctor in 2021 (Figure 14). Figure 11

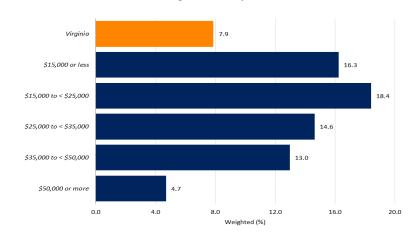
Could Not Afford To See Doctor Among Adults 18+ by Sex, 2021



Source: Virginia Department of Health, Division of Policy and Evaluation, Behavioral Risk Factor Surveillance Survey, 2021. Note: Weighted counts and weighted percents are weighted to population characteristics.

VDHVIRGINIA DEPARTMENT OF HEALTH

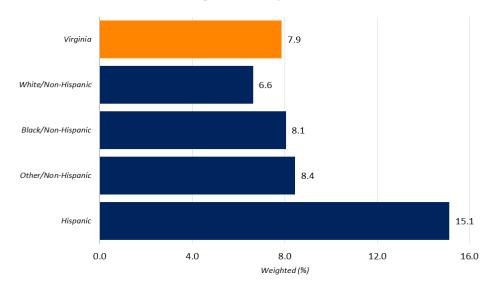
Figure 12 Could Not Afford To See Doctor Among Adults 18+ by Income, 2021



Source: Virginia Department of Health, Division of Policy and Evaluation, Behavioral Risk Factor Surveillance Survey, 2021.
Note: Weighted counts and weighted percents are weighted to population characteristics.



Figure 13 Could Not Afford To See Doctor Among Adults 18+ by Race, 2021

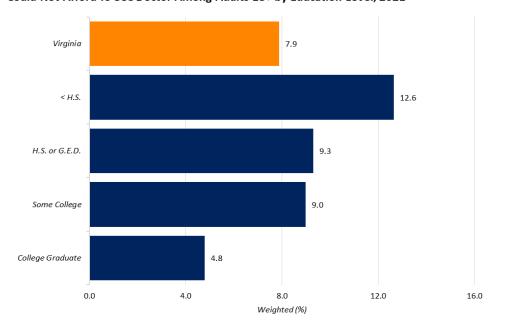


Source: Virginia Department of Health, Division of Policy and Evaluation, Behavioral Risk Factor Surveillance Survey, 2021.

Note: Weighted counts and weighted percents are weighted to population characteristics.

VDHVIRGINIA DEPARTMENT OF HEALTH

Figure 14 Could Not Afford To See Doctor Among Adults 18+ by Education Level, 2021



 $Source: Virginia\ Department\ of\ Health,\ Division\ of\ Policy\ and\ Evaluation,\ Behavioral\ Risk\ Factor\ Surveillance\ Survey,\ 2021.$

Note: Weighted counts and weighted percents are weighted to population characteristics.



HEALTH OPPORTUNITY

Virginians who live in communities with higher income are able to access resources that contribute to their health more easily than Virginians who live in communities with lower income. The Social Vulnerability Index (Figure 14) measures the relative vulnerability of each US Census tract (subdivisions of counties). The tracts are ranked across 15 social factors (unemployment, minority status, disability, etc.) that are further grouped into four themes. Each tract is rated on each of the four themes as well as overall. Virginia's variance in its SVI scores illustrates the wide array of needs and experiences of Virginians across our state.

A locality's rurality also impacts the distribution of hospitals, clinics, and other healthcare services. Figure 15 from the <u>Virginia Rural Health Plan</u> shows the distribution of primary care shortage areas and illustrates the overlap between rurality and in gaps in healthcare access and health equity.

The Health Opportunity Index (Figure 18) is a multivariate tool that is used to identify and understand the effect of social determinants of health on health outcomes. The index uses 29 indicators to measure neighborhood health for residents. Some of these indicators include school poverty, access to healthy food, access to green space, home ownership rate, as well as other related indicators. Each indicator has an individual weight that correlates to the indicators ability to impact health. The indicators are all measured on different scales.

Figure 14

SOCIAL VULNERABILITY INDEX

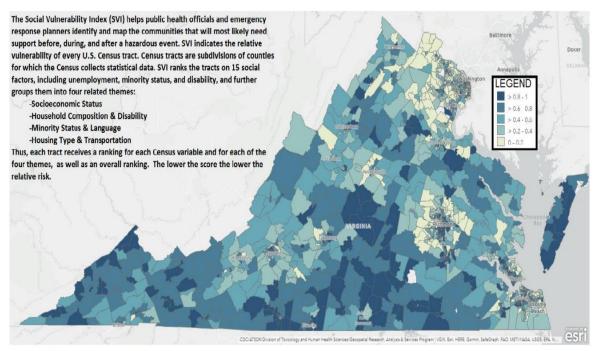
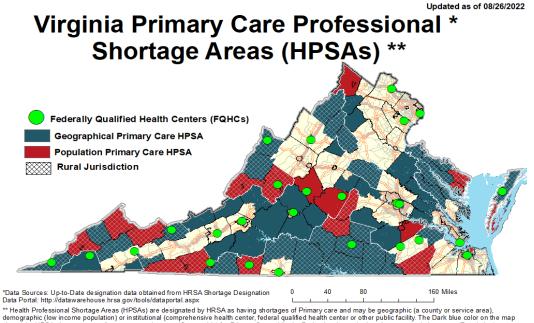


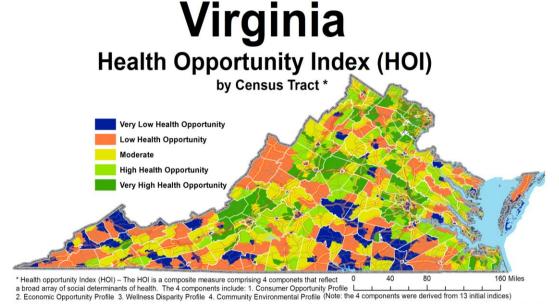
Figure 2.0
Data Source: CDC/ATSDR Social Vulnerability Index

Figure 15



shows the HRSA shortage area of county or service area (Geographic) for Primary Care while the Red color shows the Low-income population areas (Population)

Figure 16



The HOI was developed to assist the public, businesses, policy makers, communities, healthcare organizations and public health professionals in identifying key social and economic factors (also known as social determinants of health) that affect the health outcomes of the residents of Virginia communities. The set of factors chosen to be included within the HOI was designed to capture the processes by which "opportunities to be healthy" emerge; upon determination of the community HOI score it can suggest where specific interventions may aid in developing a healthy community. Not only does the HOI assist in identifying such areas, it can facilitate a positive attitude toward change within the local community

INFANT MORTALITY

In 2020, 543 infants died before their first birthday in Virginia, making the overall infant mortality rate 5.7 per 1,000 live births, improved from 5.9 in 2019. Since 2011, the overall infant mortality numbers have remained relatively constant, with a slight downward trend apparent in recent years. However, infant mortality rate varies by race and ethnicity. As Figure 17 shows, the infant mortality rate among the non-Hispanic white population was 4.8, while the rate among non-Hispanic Black infants was 10.7, which has remained stable in recent years. This disparity in infant mortality rates shows that Black infants were 2.2 times more likely to die than their White counterparts. Infant mortality also differed by locality. The top ten localities by highest counts had infant mortality rates ranging from 4.0 to 12.7 deaths per 1,000 live births (Figure 18). Due to the small numbers, localities could not be further broken down by race/ethnicity.

Figure 17

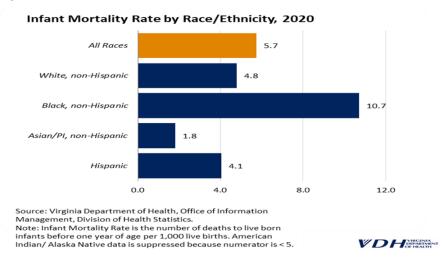
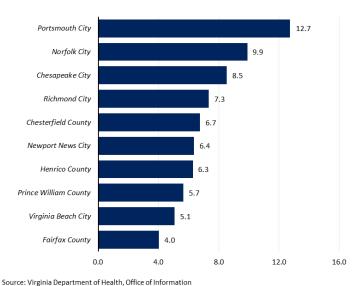


Figure 18

Infant Mortality Rate by Top Ten Localities, 2020



Management, Division of Health Statistics.

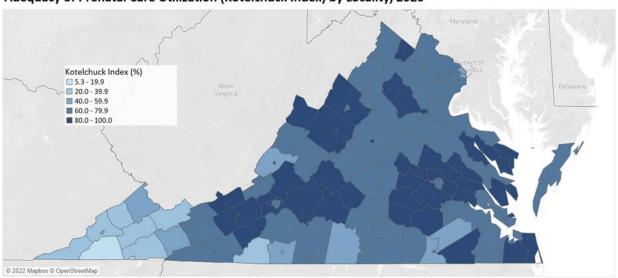
Note: Infant Mortality Rate is the number of deaths to live born infants before one year of age per 1,000 live births.

PRENATAL CARE

Adequacy of Prenatal Care is measured by the Kotelchuck Index. The index accounts for when prenatal care began (initiation) and the number of prenatal visits from when prenatal care began until delivery (received services), as documented on the birth record. Adequacy of initiation is classified as months 1-2, months 3-4, months 5-6, and months 7-9 of pregnancy. Adequacy of received services is classified by comparing the number of prenatal visits to the expected number of visits for the period between when care began and the delivery date, based on the ACOG prenatal care standards, and adjusted for gestational age when care began and at delivery. A ratio of observed to expected visits is calculated, with at least adequate care to have received 80% or more of expected visits. Overall, in 2020, nearly three-quarters (73.1%) of pregnant women received at least adequate prenatal care in Virginia, as measured by the Kotelchuck Index. However, this percentage varies by locality, from less than 25.0% (counties in the Southwest region) to 91.1% (Figure 19). Note that the Kotelchuck Index does not measure the quality of prenatal care services received.

Figure 19

Adequacy of Prenatal Care Utilization (Kotelchuck Index) by Locality, 2020



Source: Virginia Department of Health, Office of Information Management, Division of Health Statistics; Compiled from birth and death certificate files by the Division of Population Health Data, Office of Family Health Services.

Note: The Kotelchuck Index does not measure the quality of prenatal care services received.



MATERNAL MORTALITY

Maternal mortality, as defined by the World Health Organization, is deaths related to or aggravated by pregnancy (not due to accidental/incidental causes) and occurring within 42 days of the end of a pregnancy. Maternal mortality has been trending upwards in Virginia. For 2016-2020, the five-year maternal mortality rate was 21.6 per 100,000 live births, higher than the US rate (19.3 per 100,000 live births). The maternal mortality rate is more than two times higher among non-Hispanic Black birthing mothers when compared with their non-Hispanic White counterparts (49.1 vs 23.7 per 100,000, respectively) (Figure 20). For 2016-2020, maternal deaths were highest in the most populous counties in Virginia, with rates ranging from 11.7 to 39.4 (Figure 21), well above the national rate for 2016-2020. (Note that in smaller counties, numbers are too small to make meaningful interpretations.)

Figure 20

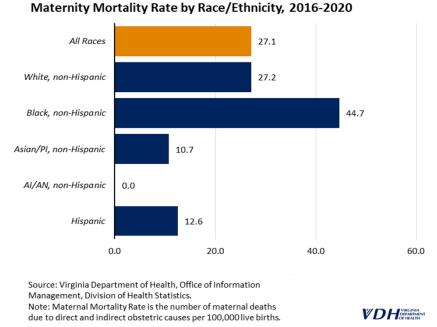
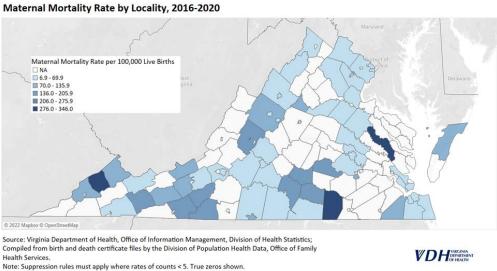


Figure 21

Maternal Mortality Rate by Locality, 2016-2020



CHILD MORTALITY

In 2020, there were 139 deaths among children ages 1 through 9, with a rate of 12.3 per 100,000 children aged 1-9, which is below the national rate. The child mortality rate varied by race/ethnicity, with higher rates among non-Hispanic Black children (Figure 22) and by county, ranging from 36.9 to 7.2 (Figure 23).

Figure 22

Child Mortality Rate by Race/Ethnicity, 2020

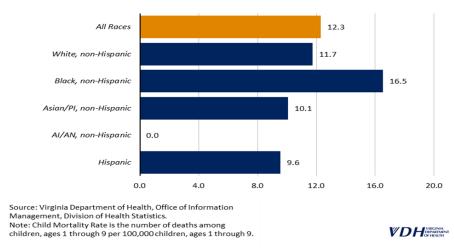
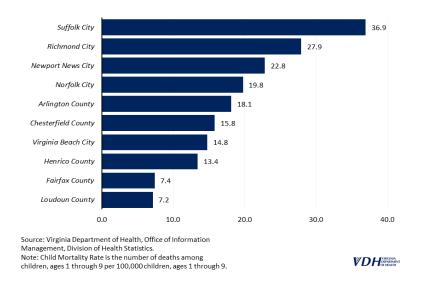


Figure 23

Child Mortality Rate by Top Ten Localities, 2020



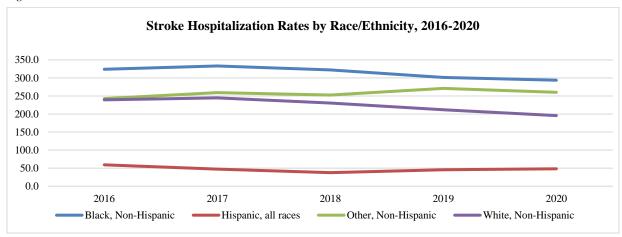
STROKE

Six in ten Americans live with at least one chronic disease, like asthma, heart disease, cancer, stroke, or diabetes. These and other chronic diseases are a leading causes of death and disability in Virginia, and they are also a leading driver of health care costs. Chronic conditions are typically defined as lasting one year or more. These conditions may limit the activities of daily living and may require ongoing medical attention.

Virginia is a member of the Stroke Belt, a region of southeastern states with high stroke incidence (stroke is the fourth leading cause of death in Virginia) and prevalence of cardiometabolic conditions including hypertension, diabetes, hypercholesterolemia, and obesity. Age is still the strongest predictive factor for stroke hospitalization and stroke death. Stroke and stroke death disproportionately impact Black or African American communities, where the stroke death rate is 50.8 compared to 38.3 for Virginia overall. The same disparities appear in stroke hospitalization rates in Virginia as shows in Figure 24. Disparities are also evident by geographic location. The localities with three

highest age-adjusted stroke mortality rates per 100,000 population for 2016-2020 were Franklin City at 96.3, Martinsville City at 94.4, and Galax City at 82.6. Figure 25 shows stroke hospitalization rates by locality.

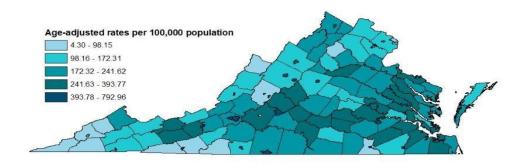
Figure 24



Data Source: Virginia Health Information, 2020

Figure 25

Stroke Hospitalization Rates by Locality, 2020

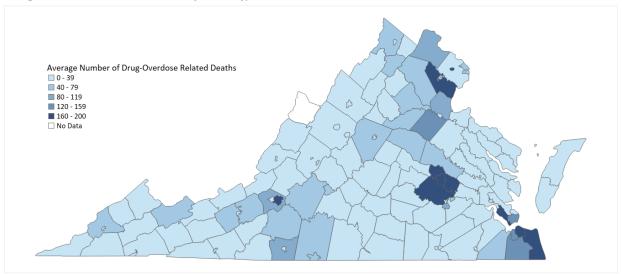


SUBSTANCE USE DISORDER

On average, almost six Virginians died by drug overdose every day during 2019-2021. Drug overdose deaths increased 70% from 2019 to 2021, and more than eight out of ten drug overdose deaths involved an opioid. Figure 26 shows drug overdose-related deaths by locality for 2019-2021.

Figure 26

Drug Overdose-Related Deaths by Locality, 2019-2021



Source: Virginia Department of Health, Office of Vital Records, Virginia Vital Events and Screening Tracking System; Analyzed by the OFHS Division of Population Health Data.

Note: Data are death certificate data maintained by VDH; data include Virginia residents only. Counts by locality are based on the locality of residence at time of death, whether or not the death occurred within the state.

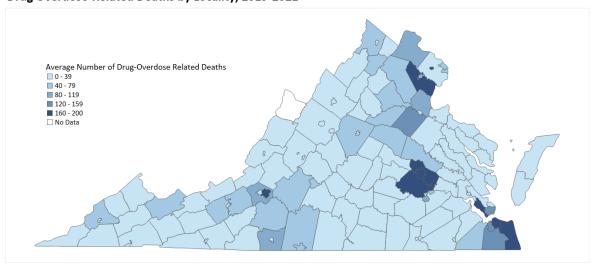


INJURY DEATHS

On average, three Virginians died by a firearm every day during 2019-2021. Virginia saw a 21% increase in firearm-related deaths from 2019 to 2021. Most firearm-related deaths in 2019-2021 were suicide deaths (60%), followed by homicide deaths (37%). Firearm-related homicide deaths increased 47% from 2019 to 2021 (342 in 2019 to 502 in 2021). Figure 27 shows firearm-related deaths by locality in Virginia for 2019-2021.

Figure 27

Drug Overdose-Related Deaths by Locality, 2019-2021



Source: Virginia Department of Health, Office of Vital Records, Virginia Vital Events and Screening Tracking System; Analyzed by the OFHS Division of Population Health Data.

Note: Data are death certificate data maintained by VDH; data include Virginia residents only. Counts by locality are based on the locality of residence at time of death, whether or not the death occurred within the state.

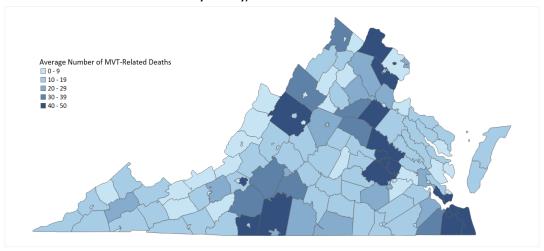


MOTOR VEHICLE DEATHS

On average, more than two Virginians died due to a motor vehicle traffic-related crash every day during 2019-2021. Motor vehicle-related deaths increased 14% from 2019 to 2021. Figure 27 shows motor vehicle traffic-related deaths by locality in Virginia for 2019-2021.

Figure 28

Motor Vehicle Traffic-Related Deaths by Locality, 2019-2021



Source: Virginia Department of Health, Office of Vital Records, Virginia Vital Events and Screening Tracking System; Analyzed by the OFHS Division of Population Health Data.

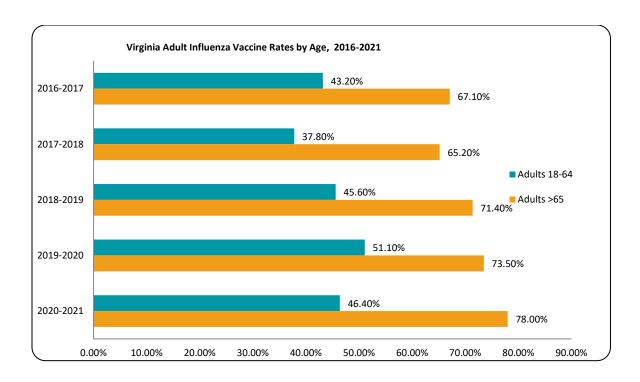
Note: Data are death certificate data maintained by VDH; data include Virginia residents only. Counts by locality are based on the locality of residence at time of death, whether or not the death occurred within the state.



FLU IMMUNIZATION

In 2021 the proportion of adults > 65 years in Virginia who received their annual influenza vaccine reached 78%, an increase of 10.9% between 2016 and 2021, and exceeded the Healthy People 2030 goal of 70%.

Figure 29



APPENDIX: State Health Assessment 2022 Data Highlights Report

Indicators with Improving Trends

- 1. **Beach Water Quality Monitoring** The number of days for which beaches are under advisory in Virginia decreased from **67** days in 2017 to **61** days in 2021. The number of advisories decreased annually from **68** in 2018 to **32** in 2021. The number of beaches under advisory has been fairly stable with little variations over the years from 18 in 2017 to 16 in 2021.
- 2. **Elevated Blood Lead Levels in Children** The percentage of children < 6 years with elevated blood lead levels decreased from **2.9%** in 2016 to **1.9%** in 2019. (The number of children < 6 years tested for blood lead levels increased from **53,474** to **62,293** in 2021 from the previous year). The number of children < 16 years with elevated blood lead levels decreased from **3.0%** in 2017 to **2.0%** in 2021. (The number of children < 16 years tested for blood lead levels increased from **57,013** to **64,919** in 2021 from the previous year).
- 3. **Percent Population Served with Lead Levels Below Action Limit (0.015mb/L) (NTNC School and Non-School)** The percentage of the population served by non-transient non-community water systems that serve a school (NTNC School) and had lead levels below the action limit increased from **89.20%** in 2020 to **96.25%** in 2021. The percentage of the population served by non-transient non-community that do not serve a school (NTNC Non-school) increased from **84.75%** in 2020 to **97.80%** in 2021.
- 4. **Water Systems with Optimized Fluoride levels** The number of systems with optimized fluoride levels decreased yearly from **71** in 2016 to **63** in 2019; however, the number increased substantially in 2020 to **73**.
- 5. **Stroke Hospitalization Rate** The rate of stroke hospitalization decreased from **244.4** per 100,000 in 2016 to **208.1** per 100,000 in 2020. The rate of stroke hospitalization decreased yearly prior to 2020.
- 6. **Ischemic Heart Disease Hospitalization Rate** The incidence of hospitalizations due to ischemic heart disease decreased from **1,456.2** per 100,000 people in 2016 to **1,221.4** in 2020.

- 7. **Asthma Hospitalization Rate** The asthma hospitalization rate in 2020 was **447.95** per 1000,000 people, lower than it was in 2016 at **662.62**.
- 8. **Alzheimer's and Dementia-related Disorders (ADRD) Hospitalization** The rate of ADRD hospitalization decreased from **555.76** in 2016 per 100,000 people to **466.27** in 2020.
- 9. **Arthritis Hospitalization Rate** The rate of arthritis hospitalizations decreased each year between 2016 and 2020, from **1059.78** per 100,000 people to **621.94** in 2020.
- 10. **Tuberculosis** The rate of tuberculosis infection in Virginia has decreased within 5 years from **2.4** per 100,000 population in 2017 to **1.9** per 100,000 population in 2021. However, Virginia has not met the Healthy People 2030 goal of 1.4 per 100,000 population.
- 11. **High School Students Who Reported Being in a Physical Fight** The percentage of high school students who reported being in a physical fight decreased between 2013 and 2019 from **23.5%** to **19.5%**.
- 12. **Non-Fatal Assault Hospitalizations** The number of hospitalizations from nonfatal assaults declined from **1,058** to **816** between 2016 and 2020.
- 13. Nonfatal Hospitalizations from Traumatic Brain Injury among Youths in Virginia Aged 10-24 Years
 The number of hospitalizations due to traumatic brain injury among Virginia youths decreased from 2016
 at 742 to 591 in 2020.
- 14. **Nonfatal Hospitalizations from Non-Drug Poisoning** The number of hospitalizations from non-drug poisoning decreased yearly between 2016 and 2020 from **683** to **435**.
- 15. **Deaths From Non-Drug Poisoning** The number of non-drug poisoning deaths declined from **107** in 2016 to **78** in 2020.
- 16. **Influenza Vaccination Rate in Adults >65 Years Old** The proportion of adults > 65 years in Virginia who received their annual influenza vaccine increased between 2016 and 2021 from **67.1%** to **78.0%**. Virginia met the Healthy People 2030 goal of 70%.
- 17. **HPV Vaccination Among Adolescent Males** Among adolescent males, the HPV vaccination rate increased yearly from 2015 to 2019 from **32.0%** to **62.6%**. However, this is below the Healthy People 2030 goal of 80%.
- 18. Combined 7-Series Vaccination among Children Aged 24 Months and Aged 35 Months The percentage of children aged 24 months who received the combined 7-series vaccine increased to 73.3% in 2018 from 68.8% in 2017. The proportion of children aged 35 months increased between 2015 and 2018 from 75.2% to 84.0%
- 19. **Percentage of High School Students Who Reported Current Alcohol Use** The percentage of high school students who reported current alcohol use declined from **30.5%** in 2011 to **25.4%** in 2019.
- 20. Percentage of High School Students Who Rode With A Driver Who Had Been Drinking The percentage of high school students who rode with a driver who had been drinking declined for both male and females. For males, this percentage reduced from 19.6% to 11.9% between 2011 and 2019. For females, the percentage declined from 20.2% to 14.1%.
- 21. **Adults Who Reported Binge Drinking In The Past Month** The percentage of adults who reported binge drinking in the past month declined yearly from **16.0%** to **14.8%** between 2017 and 2020. Virginia met the Healthy People 2030 goal of 25.4% or below.
- 22. **Drug Overdose Deaths from Heroin** The number of deaths from heroin overdose declined annually from **540** deaths in 2017 to **414** deaths in 2020.
- 23. **Drug Overdose Deaths from Benzodiazepines** The number of deaths from benzodiazepine overdose decreased yearly from 210 in 2016 to 174 deaths in 2020.
- 24. **Uninsured Children under the Age of 19** The rate of uninsured children under the age of 19 decreased from **7%** in 2010 to **4.50%** in 2020.

- 25. **Avoidable Hospitalizations** The percentage of avoidable hospitalizations in Virginia decreased from **14.20%** in 2016 to **12.60%** in 2019.
- 26. **Proportion of Adults that Delayed Medical Care due to Cost** The percentage of adults that delayed medical care due to cost decreased yearly from **12.10%** in 2015 to **10.40%** in 2020.
- 27. **Lung and Bronchus Cancer** The lung and bronchus cancer incidence declined yearly from 62.3 in 2012 to 53 in 2019. The rate of deaths from lung and bronchus cancer declined yearly from **48.5** per 100,000 population in 2010 to **33.8** in 2019. This is below the Healthy People 2030 goal of 25.1 per 100,000 population.
- 28. Colorectal Cancer The incidence of colorectal cancer in Virginia decreased from 37.8 in 2015 to 34.7 in 2019. The rate of deaths due to colorectal cancer decreased from 15.2 deaths per 100,000 population in 2010 to 12.8 in 2019. However, Virginia has not met the Healthy People 2030 goal of 8.9 per 100,000 population.
- 29. **Teen Pregnancy** The rate of teen pregnancy in Virginia declined steadily from **40.2** per 1,000 females in 2010 to **17.3** per 1,000 females in 2020. The rates decreased for all races and ethnicities.
- 30. **Maternal Opioid Use Disorder** The rate of maternal opioid use disorder declined yearly from **5.6** to **4.7** per 1,000 delivery hospitalizations between 2016 and 2020. The rates decreased for all races.
- 31. Children (ages 0 -17 years) with Special Health Care Needs The percentage of children with special care needs decreased from 21% in 2016 to 18% in 2019-2020.
- 32. **HIV Incidence and Linkage to Care** The HIV incidence in Virginia declined from **925** in 2016 to **631** in 2020. The percentage of people with HIV diagnosis that were not linked in 90 days declined between 2016 and 2020 from **19.26%** to **13.47%**. The percentage of HIV Viral suppression increased from **74%** in 2016 to **80%** in 2020.

Indicators with Little or No Change in Trend

- 1. Percent Population Served by Community Water Systems with Lead Levels Below Action Limit (0.015mb/L) © Although on the increase, there have been subtle changes in the percentage of the population served with lead levels below action limit by community water systems © in Virginia over the years from 98.55% in 2017 to 98.15% in 2021.
- **2. Hypertension Hospitalization Rate** The rate of hospitalizations due to hypertension decreased from 3,968.2 per 100,000 population in 2017 to 3,814.9 in 2018. In 2019, it increased to 3,900.2 and then decreased to 3,410.8 in 2020. The decrease in 2020 may be affected by issues with access to care during the pandemic.
- 3. Chronic Kidney Disease (CKD) Hospitalization Rate The rate of CKD hospitalization remained fairly stable in a 5-year period between 2016 and 2020 with rates ranging from 2,267.56 per 100,000 people to 2,277.28.
- **4. Nonfatal Hospitalizations From Traumatic Brain Injury (TBI)** Nonfatal traumatic brain injury related hospitalizations remained relatively stable within 5 years from **4,742** to **4,752** hospitalizations between 2016 and 2020.
- 5. Households With No Vehicle Available The proportion of households with no available vehicles remained fairly constant with mild variations within 11 years from 6.3% in 2010 to 6.1% in 2020.
- **6. Proportion of Adults With a Usual Primary Care Provider** The proportion of adults with a usual primary care provider was relatively stable at around **69.5%** from 2013 to 2019.
- 7. **Female Breast Cancer** The female cancer incidence increased slightly from **126.1** in 2010 to **132.3** in 2019. The rate of deaths from breast cancer decreased from **22.2** per 100,000 population in 2010 to **19.2** per 100,000 population in 2019; however, it has not met the Healthy People 2030 goal of 15.3 per 100,000 females.

- **8. Prostate Cancer** The incidence rate of prostate cancer has fluctuated over the past 10 years; it increased from **99** in 2018 to **107.6** in 2019. The rate of prostate cancer deaths had mild variations over 10 years from 2010 to 2019, from **22.2** deaths per 100,000 population to **19.9**. However, Virginia has not met the Healthy People 2030 goal of 16.9 per 100,000 population.
- 9. **Hepatitis C Infection** The incidence rate of Hepatitis C infection decreased yearly between 2016 and 2018 from **75.2** to **52.4** cases per 100,000 population. It increased in 2019 to **65.2** and decreased in 2020 (**42.2**) and 2021(**41.1**).
- **10. Infant Mortality** The overall infant mortality rate in Virginia remained fairly constant in 11 years from **5.26** per 1,000 live births in 2010 to **5.73** per 1,000 live births in 2020. This is true for all races and ethnicities except for American Indian/Alaska Natives whose infant mortality rate varied from **6.37** per 1,000 live births in 2016 decreasing to **0.00** in 2018 and then increased yearly between 2019 and 2020 from **6.25** to **12.12** per 1,000 live births in 2020. However, the AI/AN population in Virginia is very small, which leads to instability in the rates when comparing them annually to other races.
- **11. Child (1 to 9 years) Mortality Rate** The child mortality rate had little variation between 2009 and 2020, from **15.7** per 100,000 population to **15.0**.

Indicators with Worsening Trends/Issues of Concern from the Virginia State Health Assessment 2022

- 1. **Adults Reporting Poor Physical Health** The percentage of adults reporting 14 or more days of poor physical health in the past 30 days increased from **11%** in 2016 to **11.7%** in 2019
- 2. **Adult Consumption of Fruits and Vegetables** The percentage of adults who consumed fruits and vegetables 5+ more times a day decreased from **17.8%** in 2013 to **16.1%** in 2019. The percentage of adults who did not eat fruits and vegetables at least once a day increased from **37.4%** in 2013 to **38.3%** in 2019
- 3. Adults Who are Aerobically Active For 150 Minutes Each Week and No Leisure Time Physical Activity in the Past Month The percentage of adults who are aerobically active for 150 minutes each week has decreased from 51.9% in 2013 to 50% in 2019. This is below the Healthy People 2030 goal of 59.2%. The percentage of people with no leisure activity has worsened in four years increasing from 23.3% in 2016 to 25.3% in 2019. This has not met the Healthy People 2030 target of 21.2%.
- 4. **Adults who are Overweight or Obese** The percentage of adults who are overweight or obese had a little increase from **65.4%** in 2016 to **66.4%** in 2019. However, Virginia is far from meeting the Healthy People 2030 goal of 36.0%
- 5. **Diabetes Hospitalization Rate** The rate of hospitalization due to diabetes increased yearly from **1588.8** in 2016 to **1852.49** in 2019. The rate decreases in 2020 to 1,648.15 in 2020; however, this may be due to decreased access to care during the COVID 19 pandemic.
- 6. **Hotline Calls Related to Sexual Violence** Hotline calls to the state sexual and domestic violence increased between 2017 and 2021, from **9,077** to **11,086** calls.
- 7. **Nonfatal Hospitalizations and Deaths from Firearms** The rate of nonfatal hospitalizations from firearms worsened, increasing from **728** in 2016 to **756** in 2020. The number of deaths from firearms increased from **1,027** in 2016 to **1,164** in 2020.
- 8. **Homicide Deaths** The number of deaths from homicides worsened, increasing from **434** deaths in 2016 to **516** deaths in 2020.
- 9. **Middle School Students Who Reported Being in a Physical Fight** The proportion of middle school students who reported being in a physical fight increased from **44.4%** in 2013 to **45.8%** in 2019.
- 10. **Deaths from Unintentional Falls** Deaths from unintentional falls increased yearly from **811** in 2016 to **981** in 2020.
- 11. **Deaths from Traumatic Brain Injury** The number of deaths from traumatic brain injury increased between 2016 and 2020 from **1,644** to **1,876**. The number of traumatic brain injury deaths among youths in Virginia worsened, increasing from **258** to **317** between 2016 and 2020.

- 12. **Influenza Vaccine Rates in Adults 18-64 years and in Minority Groups** The percentage of adults who received influenza vaccine declined from **51.1%** from 2019-2020 to **46.40%** in 2020-2021. While the percentage of the white population who received influenza vaccine increased between 2016 and 2021 from 51.3% to 60.9%, it decreased among the Black population from **52.5%** in 2019 to **45.6%** in 2021 and decreased among the Hispanic population from **51.4%** in 2016 to **45.2%** in 2021. For other/multiple races, the influenza vaccine rates declined from **61.3%** to **56.6%** between 2019 and 2021.
- 13. **HPV Vaccine Among Adolescent Females** The proportion of females who received the HPV vaccine declined from **60.1%** in 2018 to **56.6%** in 2019. This is below the Healthy People 2030 goal of 80%.
- 14. Percentage of Middle School Students Who Rode With A Driver Who Had Been Drinking The percentage of middle school students who rode with a driver who had been drinking worsened for both boys and girls. For boys, it increased from 13.7% in 2017 to 15.3% in 2019, and for girls, it increased from 16.5% in 2017 to 18.0% in 2019.
- 15. **Alcohol Attributable Deaths** Alcohol attributable deaths in Virginia increased every year between 2016 and 2020, from **2,926** to **3,667** deaths.
- 16. **High School Students Who Reported Marijuana Use in the Past 30 Days** The percentage of high school students who reported marijuana use in the past 30 days increased yearly between 2015 and 2019 from **16.2%** to **17.3%**.
- 17. **Nonfatal Cannabis Hospitalizations** Hospitalizations from cannabis increased every year from **17,796** in 2016 to **20,303** in 2019. There was a decrease to **19,837** in 2020, which may be related to the pandemic.
- 18. **Drug Overdose Deaths** While the number of nonfatal drug overdose hospitalizations decreased yearly from 2016 (except in 2019) to 2020 from **8,069** to **7,526**, the number of deaths from drug overdose increased yearly between 2016 and 2020 from **1,324** to **1,749** deaths. This is true for all opioids, which increased from 1,078 deaths in 2016 to 1,478 deaths in 2020); synthetic opioids (except methadone), which increased from 624 in 2016 to 1,303 deaths in 2020; cocaine, which increased from 335 in 2016 to 435 in 2020; and psychostimulants, which increased from 66 in 2016 to 326 in 2020.
- 19. **Cost Burdened Households** The percentage of cost burdened households in Virginia increased from **28.5%** in 2017 to **29.0%** in 2020.
- 20. **Homeless Students in Virginia** The number of homeless students in Virginia increased from **7,663** in 2011 to **10,268** students in 2020.
- 21. **Average Commute To Work Driving Alone** The average commute to work driving alone increased yearly 2010 to 2020 from **25.9** minutes to **28.6** minutes.
- 22. **Early Syphilis Infection** The rate of early syphilis increased in Virginia from **13.5** in 2017 to **16.4** per 100,000 population in 2021.
- 23. **Congenital Syphilis Infection** The number of congenital syphilis increased from **0-2** cases per year in 2009-2012 to **17** cases in 2021.
- 24. **Gonorrhea Infection** The rate of gonorrhea infections per 100,000 population increased yearly from **144.08** in 2017 to **174.12** in 2020. However, this rate decreased to **167.1** in 2021
- 25. **Prenatal Care** The number of women who received inadequate care increased for all races. It increased from **7.7%** in 2012 to **21.6%** in 2020 for Hispanics, **2.8%** in 2012 to **14.5%** in 2020 for Blacks, and **4.0%** in 2012 to **9.3%** in 2020 for White.
- 26. **Proportion of Adults Who Have Seen a Dentist in the Past Year** Although the proportion of adults who have seen a dentist in the past year has varied widely in 11 years, it decreased from **76.2%** in 2019 to **70.0%** in 2020.
- 27. **Life Expectancy and Years of Potential Life Lost** The overall life expectancy in Virginia decreased from **79.7** years in 2019 to **78.3** years in 2020. The years of potential life lost increased between 2016 and 2020, from **6,584.3** per 100,000 population to **7,549.4**.

- 28. Chronic Obstructive Pulmonary Disease (COPD) Hospitalization Rate The rate of COPD hospitalization increased yearly from **1,188.3** per 100,000 people in 2016 to **1,357.5** in 2019. It decreased in 2020 to 1,202.9, likely due to factors associated with the COVID-19 pandemic.
- 29. **Deaths From Drowning** The number of deaths from drowning in Virginia increased yearly from **78** in 2017 to **93** in 2019. There was a decline in 2020 to **88**, but this may have been affected by the pandemic.
- 30. **Reports of Forcible Sex Offenses** Although the number of forcible sex offenses reported to the police decreased in 2020, this number had an increasing trend between 2016 and 2019 from **5,529** to **5,854**. The decrease in 2020 may be due to the effect of the pandemic
- 31. **Maternal Opioid Related Diagnosis** The rate of maternal opioid related diagnosis increased yearly from **7.7** in 2016 to **9.0** in 2019. However, this rate decreased to **7.7** per 1000 delivery hospitalizations in 2020. The decline in 2020 may be due to the effects of the pandemic.
- 32. **Rate of Neonatal Abstinence Syndrome** The overall rate of neonatal abstinence syndrome decreased between 2016 and 2018 from **6.5** to **7.0** per 1,000 birth hospitalizations and then increased to **7.2** in 2019. However, in 2020, there was a marked decrease to **5.8** per 1,000 birth hospitalizations. This decline in 2020 may be due to the effects of the pandemic.