State of Board of Health
Agenda
March 31, 2021 – 9:00 a.m.
Perimeter Center, Boardroom 2

Call to Order and Welcome	Faye Prichard, Chair
Introductions	Ms. Prichard
Review of Agenda	Alexandra Jansson, MPP
Approval of December 10, 2021 Minutes	Ms. Prichard
Commissioner's Report	Colin Greene, MD, MPH Acting State Health Commissioner
Break	
Regulatory Action Update	Ms. Jansson
Public Comment Period	
Break	
<u>Regulatory Action Items</u> Regulations for the Licensure of Hospices 12VAC5-391 (Fast Track Amendments)	Rebekah Allen, JD Senior Policy Analyst Office of Licensure and Certification
Regulations for the Licensure of Hospitals in Virginia 12VAC5-410 (Fast Track Amendments)	Ms. Allen
Legislative Update – 2022 General Assembly	Ms. Jansson
Budget Update	Stephanie Gilliam Deputy Director for Budget Office of Financial Management
Appointment of Nominating Committee	Ms. Prichard
Other Business	
Adjourn	

State Board of Health
December 10, 2021 - 9:00am
Hybrid Meeting
Perimeter Center, Boardroom 2, 9960 Mayland Drive, Henrico VA 23233 and via WebEx

Members Present: Faye Prichard, Chair; Jim Edmondson; Wendy Klein, MD, Vice Chair; Benita Miller, DDS; Holly Puritz, MD; Maribel Ramos; Elizabeth Harrison; and Mary Margaret Whipple.

*The following member attended virtually due to personal reasons of public health concerns for physical distancing and transmission levels for COVID-19: Gary Critzer.
*The following member attended virtually due to personal reasons of family emergency: Jim Shuler, DVM.
* The following members attended virtually due to a personal reason of scheduling conflicts: Linda Hines, RN and Stacey Swartz, PharmD.

Members Absent: Melissa Green; Anna Jeng, ScD; and Patricia Kinser, PhD.

VDH Staff Present: Rebekah E. Allen, JD, Senior Policy Analyst, Office of Licensure and Certification; Dr. Danny Avula, Vaccine Coordinator and Director, Richmond and Henrico Health Districts; Kim Beazley, Director, Office of Licensure and Certification; Heather Board, Acting Director, Office of Family Health Services; Robin Buskey, Policy Analyst, Office of Family Health Services; Shameera Carr, Executive Advisor, Public Health and Preparedness; Kristin Collins, Policy Analyst, Office of Epidemiology; Brookie Crawford, Central Region Public Information Officer; Kathryn Crosby, Chief Diversity, Equity, and Inclusion Officer; Dr. Marcia Degen, Office of Environmental Health Services; Tiffany Ford, Deputy Commissioner for Administration; Dr. Laurie Forlano, Deputy Director, Office of Epidemiology; Julie Henderson, Director, Office of Environmental Health Services; Bob Hicks, Deputy Commissioner for Public Health and Preparedness; Joe Hilbert, Deputy Commissioner for Governmental and Regulatory Affairs; Dr. Parham Jaberi, Chief Deputy Commissioner for Community Health Services; Alexandra Jansson, Senior Policy Analyst; Bob Mauskapf, Director, Office of Emergency Preparedness; Dr. M. Norman Oliver, State Health Commissioner; Dr. Lilian Peake, Director, Office of Epidemiology; Carole Pratt, Senior Advisor and Confidential Assistant for Policy; John Ringer, Director of Public Health Planning and Evaluation; Jeff Stover, Chief of Staff; and Sonia Valadez, Executive Advisor for Administration.

Other Staff Present: Alexis Aplasca, Chief Clinical Officer, Department of Behavioral Health and Developmental Services; Emily Hopkins, MS, Director of Laboratory Operations, Division of Consolidated Laboratory Services; Grant Kronenburg, Office of the Attorney General; Robin Kurz, JD, Senior Assistant Attorney General; Vanessa MacLeod, Office of the Attorney General; Krista Samuels, Office of the Attorney General; and Allyson Tysinger, Senior Assistant Attorney General/Section Chief.

Call to Order
Ms. Prichard called the meeting to order at 9:08am.

Introductions
Ms. Prichard welcomed those in attendance to the meeting. Ms. Prichard 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 virtual binder.

Approval of September 2, 2021 Minutes
Dr. Swartz made the motion to approve the minutes from the September 2, 2021 meeting with Ms. Hines seconding the motion. The minutes were approved unanimously by roll call vote.

Commissioner's Report
Dr. Oliver provided the Commissioner's Report to the Board. They discussed the public health transformation roadmap and updates on the novel coronavirus (COVID-19) situation and response with respect to:

- Disease Burden and Transmission
- Testing
- Containment
- Communications
- Vaccination

There was a brief discussion regarding the transformation roadmap. There was larger discussion about the COVID-19 pandemic and response related to the omicron variant, test supply programs in public libraries, case investigation and contact tracing, and the new case management system. There was also discussion related to communication and vaccination efforts including targeted population outreach and partnerships with providers and community groups.

Regulatory Action Update
Ms. Jansson reviewed the summary of all pending VDH regulatory actions. Since the September 2021 meeting the Commissioner has taken one regulatory action on behalf of the Board while the Board was not in session - taking no action on a petition for rulemaking regarding requiring vaccinations in school settings for students and staff.

Ms. Jansson advised the Board that there are 16 periodic reviews in progress:

- 12 VAC 5-66 Regulations Governing Durable Do Not Resuscitate Orders
- 12 VAC 5-80 Virginia Hearing Impairment Identification and Monitoring System
- 12 VAC 5-195 Virginia Women Infants and Children Program Regulations
- 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 5-460 Regulations Governing Tourist Establishment Swimming Pools and Other Public Pools
- 12 VAC 5-462 Swimming Pool Regulations Governing the Posting of Water Quality Results
- 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

Lunch Presentation: Behavioral Health Update
Dr. Aplasca presented an update on the intersection between health and behavioral health initiatives. There was discussion regarding the capacity of the Department of Behavioral Health and Developmental Services to care for their client population, and the link between housing, health and behavioral health.

Public Comment Period
There were five persons who signed up for public comment. Jennifer Gruber provided comments about violence prevention resources and in favor of religious exemptions for vaccines. Anne Taydus provided comments about vaccine mandates and COVID-19. Doris Knick provided comments about radio frequency radiation and potential health effects; Ms. Knick also provided written comment which is included at the end of the minutes document. Mitchell Opalski provided comments about the amendments to the home care organization regulations. One person was not present at the time of the public comment period.

Proposed Amendments for Home Care Organization Regulations
Ms. Allen presented proposed amendments to the Home Care Organization Regulations. This regulatory action seeks to assess all current regulation content and determine whether it should be amended or retained in its current form. Regulatory language was reviewed and clarified if the content was unclear, inconsistent, or outdated, and was revised to conform to the Form, Style and Procedure Manual for Publication of Virginia Regulations. Language was also revised to more accurately reflect on whom the regulatory requirements were placed.

The various types of policies and procedures required were consolidated into the section entitled "Policies and procedures." Other sections were also consolidated, including home visits and on-site inspections. Sections have been added to more clearly explain the different licensure processes, including creating a new reinstatement licensure process. Language was added to clarify points of ambiguity that have caused confusion and inconsistency for regulants, such as the issue of branch offices and changes to existing licenses.

Dr. Klein made the motion to adopt the proposed amendments and Ms. Whipple seconded the motion. There was a brief discussion around which amendments were thought to be most

disruptive to current practice, the requirement for an audit versus a review by an auditor, and what the purpose of the audit requirement was for these organizations. The amendments were approved unanimously by roll call vote.

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

This amendment removes, edits, and adds definitions as necessary to reflect current public health definitions and needs; removes the requirement to report weekly counts of influenza diagnoses; modifies the timelines for laboratories to submit isolates or specimens for further public health laboratory testing to improve the viability of material available for testing; replaces reporting by use of the Epi-1 form with reporting via an online web portal. The list of isolates or specimens that must be forwarded for further public health testing has been removed from 12VAC5-90-90 in this action because it was added to 12VAC5-90-80 in a separate exempt regulatory action. The section on select agent reporting has been modified to clarify that VDH requires an annual report and an immediate report of a loss, theft, or release.

This action was originally submitted as fast track amendments, but received more than 10 comments objecting to the use of a fast track action. The majority of commenters objected to VDH receiving reports, which include personal information, of their influenza data. This action does not add any influenza reporting requirements. Instead, this amendment will strike "influenza should be reported by number of cases only (and type of influenza, if available)" to clarify that only confirmed influenza cases are required to be reported.

Ms. Whipple made the motion to adopt the proposed amendments and Dr. Miller seconded the motion. There was discussion regarding the reportable disease list and tracking influenza. The proposed amendments were approved unanimously by roll call vote.

Fast Track Amendments to Sewage Handling and Disposal Regulations
Dr. Degen presented fast track amendments to the Sewage Handling and Disposal Regulations. These amendments establish minimum design and installation criteria for conveyance pump stations and dispersal areas utilizing treated effluent (TL-2 and TL-3). Historically, the criteria were addressed via agency Guidance Memorandum and Policies (GMP). These types of designs were addressed piecemeal through product specific approvals beginning in 1995 and culminated in a comprehensive policy in 2009, GMP 147, which established procedures for treatment units to receive general approval, hydraulic loading rates for alternative onsite sewage systems, and design and installation criteria for the dispersal areas through a series of blanket variances to 12VAC5-610.

GMP 147 was rescinded following promulgation of the Regulations for Alternative Onsite Sewage Systems (12VAC5-613 AOSS Regulations). However, those regulations are performance regulations and therefore did not include the specific design and installation criteria found in GMP 147. To address this gap, the VDH issued GMP 2016-03, noted that designers

could continue to use design guidance from rescinded GMP 147 which would be in compliance with the AOSS Regulations. Parts of the rescinded GMP are superseded by 12VAC5-613 so there is conflicting and extraneous information that makes it confusing as a definitive reference. In working to resolve the confusion, VDH determined that moving the policy into regulation was necessary to resolve the discrepancies and confusion and also to provide clear design instruction and authority to licensed professionals in Virginia.

Dr. Puritz made the motion to adopt the fast track amendments to the Sewage Handling and Disposal Regulations with Dr. Klein seconding the motion. There was discussion about the representation of public health priorities in the fast track regulations through multiple draftings. The fast track amendments were approved unanimously by roll call vote.

Final Amendments to Regulations Governing Virginia Newborn Screening Services
Ms. Board presented the final amendments to the Regulations Governing Virginia Newborn Screening Services. The proposed regulatory action would amend the existing newborn screening regulation to add spinal muscular atrophy (SMA) and X-linked adrenoleukodystrophy (X-ALD) to the newborn screening panel. Blood spot newborn screening services are provided by the Department of General Services' Division of Consolidated Laboratory Services (DCLS) in partnership with VDH. SMA is a genetic disorder that is estimated to occur in approximately 9.1 out of every 100,000 live births. X-ALD is a genetic disorder that is estimated to occur in approximately 6 out of every 100,000 live births. Treatment for both X-ALD and SMA is available if detected early. Screening is necessary, as these disorders cannot be detected at birth through physical examinations. The additions of SMA and X-ALD to the newborn screening panel have been recommended by the Virginia Genetics Advisory Committee. On the national level, these disorders have been added to the core panel of 35 genetic disorders included in the Recommended Uniform Screening Panel (RUSP) of the U.S. Secretary of Health and Human Services' (HHS) Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC).

Dr. Puritz made the motion to adopt the final amendments and Dr. Klein seconded the motion. There was a brief discussion about the delay in updates after the fee increase went into effect. The final amendments were approved unanimously by roll call vote.

Board of Health Annual Report/Plan for Well-Being Update
Ms. Board presented the update to the Plan for Well-Being which serves as the Board of Health's Annual Report. THe previous Plan for Well-Being ("Plan") lapsed in 2020, and preparations for a new Plan were ongoing, though delayed due to COVID-19. A survey will be conducted in early 2022 targeting publishing a new State Health Assessment to guide the development of the Health Improvement Plan in mid 2022.

Ms. Whipple made the motion to approve the annual report with Dr. Klein seconding the motion. There was discussion around the targeted populations and communications around the needs assessment survey and validation that Virginia residents were the ones responding. The annual report was approved unanimously by roll call vote.

Legislative Update - 2022 Proposals
Mr. Hilbert shared that there were a few proposals under consideration as agency bills, but that final approvals had not been made. Additionally, he shared that many of the details of the upcoming 2022 General Assembly session had not been determined including if the meetings would be in-person, hybrid, or virtual.

Other Business
Several members provided member reports. Dr. Swartz shared that pharmacists and pharmacies play a key role in vaccination efforts. Mr. Edmondson shared historical information regarding the procedures of the regulations of first trimester abortion facilities.

Adjourn
Meeting adjourned at 2:23pm.

Commonwealth of Virginia

Questions, rr <questions@vdh.virginia.gov>

Comments to be added to the VDH meeting for December 10th

1 message

Doris Knick <teachersporch@yahoo.com> Thu, Dec 9, 2021 at 5:05 PM
To: "questions@vdh.virginia.gov" <questions@vdh.virginia.gov>

Hello,

I've signed up to speak for the meeting tomorrow. Just encase I have difficulty connecting and for the public record I'd like my comments to be submitted.

Silent invisible threat VDH has not yet been addressed, nurses in public schools, and doctors must be made aware and educated on the facts that Scientists are discovering that constant exposure to radiofrequency (RF) radiation, even at levels previously thought safe, can have serious and lifelong consequences especially for children. This is why hundreds of medical and public health professionals from around the world have joined together with parents and professional educators to demand that government agencies adopt more stringent standards to protect children from exposure to RF radiation.

Studies show that radiofrequency (RF) radiation from tablets, laptops and Wi-FI routers are NOT SAFE for children

Wireless radiation has been linked to serious health issues. A ten-year study by the National Toxicology Program of the NIH was designed to determine whether non-thermal RF radiation could cause cancer: In 2019, an independent expert panel reviewing the study found “clear evidence” of increased cancer among the **lab animals tested**.

What illnesses in children are most closely linked with exposure to RFR?
The most common illness reported from exposure to RFR is Electromagnetic Hyper-Sensitivity (EHS). EHS is recognized by the WHO, the US Access Board, Department of Labor and others. High incidences among children are well documented.

Other reported medical impacts include:

- Neuropsychiatric (behavioral) effects anxiety, depression, brain fog, nauesea and cognitive impairment,
- Autism
- ADHD
- Childhood leukemia
- Brain tumors
- Sudden cardiac arrest
- Diabetes
- Prenatal effects

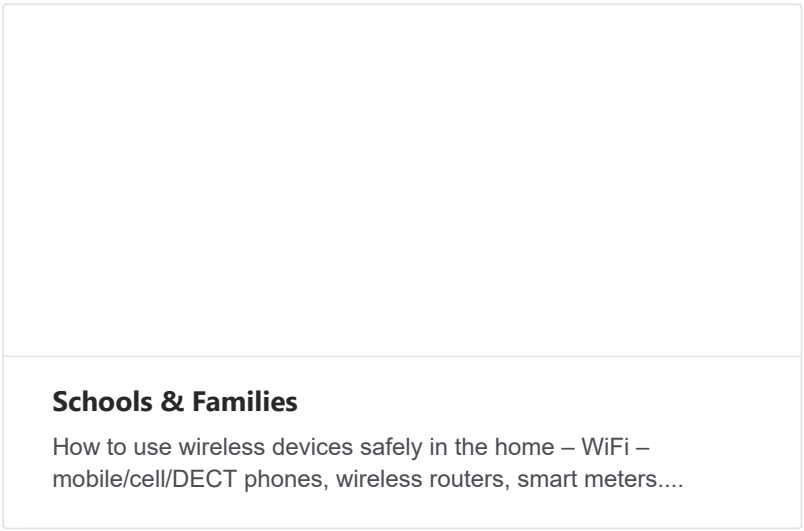
The available data is stronger with some illnesses than others, although sufficient, even if inconclusive, to justify precaution and further inquiry.

The rapid proliferation of wireless devices in classrooms has brought increased concern about the potential health effects of near-constant exposure to RF radiation, particularly for children. These concerns stem from multiple factors:

- All wireless devices emit RF radiation

- Multiple devices used in classrooms increase the amount of radiation exposure
- Cell phone Towers near and on school property
- Wireless devices are NOT tested in current real-life use patterns
- Children are uniquely vulnerable to RF radiation because their still-developing physiology

I am requesting a formal process to begin to protect children from RFR in schools that educates teachers, nurses, and all school staff!
This website could help get the process moving.
Schools & Families - Wireless microwave radiation induction (wirelesseducation.org)



Schools & Families

How to use wireless devices safely in the home – WiFi – mobile/cell/DECT phones, wireless routers, smart meters....

Please advise who I send the research studies and links to be added to this public record to.

Sincerely,

Doris Knick

"Live the changes you wish to see in the world!"

COMMONWEALTH of VIRGINIA

Department of Health

Colin M. Greene, MD, MPH
Acting State Health Commissioner

P O BOX 2448
RICHMOND, VA 23218

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

MEMORANDUM

DATE: March 2, 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 Hospice – Amend Regulation to Conform to Chapter 525 of the 2021 Acts of Assembly, Special Session I

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

Chapter 525 of the 2021 Acts of Assembly, Special Session I amends Code of Virginia § 32.1-127(B), to require the State Board of Health to promulgate regulations that require each hospice establish a protocol to allow patients to receive visits from clergy of any religious denomination or sect consistent with applicable federal or state guidance when there is a declared public health emergency related to a communicable disease of public health threat.

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

townhall.virginia.gov

Fast-Track Regulation
Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-391-10 *et seq.*
VAC Chapter title(s)	Regulations for the Licensure of Hospice
Action title	Amend Regulation to Conform to Chapter 525 of the 2021 Acts of Assembly, Special Session I
Date this document prepared	March 2, 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 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1VAC7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code.*

Brief Summary

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

Chapter 525 of the 2021 Acts of Assembly, Special Session I amends Code of Virginia § 32.1-162.5, requiring the State Board of Health to promulgate regulations that "require each hospice facility to establish a protocol to allow patients 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 and the Centers for Medicare and Medicaid Services 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" when there is "a declared public health emergency related to a communicable disease of public health threat."

Acronyms and Definitions

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

"Board" means the State Board of Health.

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 12VAC5-391-10 *et seq.*, Regulations for the Licensure of Hospice, 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 Executive Order 14 (as amended, July 16, 2018), "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

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

The mandate for these regulatory changes is found in Chapter 525 of the 2021 Acts of Assembly, Special Session I. It is anticipated that this rulemaking will be noncontroversial and therefore appropriate for the fast-track process because it is being used to conform 12VAC5-391-10 *et seq.* to the Code of Virginia and no new requirements are being developed beyond what Chapter 525 of the 2021 Acts of Assembly, Special Session I mandates.

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.

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

Purpose

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

This regulation is being amended due to the changes to Code of Virginia § 32.1-162.5. The Board is required by Code of Virginia § 32.1-162.5to promulgate regulations for the licensure of hospices in order to protect the health, safety, and welfare of citizens receiving care in hospices. The goal of the regulatory change is to conform the regulations to the statute. It is intended to solve the problem of the regulation not reflecting the legislative mandate of Chapter 525 of the 2021 Acts of Assembly, Special Session I.

Substance

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

12VAC5-391-370. Spiritual counseling and bereavement services.
Creates a new subsection F requiring hospices to have a protocol to allow patients to receive visits from a rabbi, priest, minister, or clergy of any religious denomination or sect during public health emergencies related to communicable diseases.

Issues

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

This action is being used to conform 12VAC5-391-10 *et seq*. to existing requirements in the Code of Virginia. The advantage to the public, the agency, and the Commonwealth is that 12VAC5-391-10 *et seq*. are in compliance with legislative changes enacted by the General Assembly during the 2021 Special Session I. There are no disadvantages to the public, the agency, or the Commonwealth. There are no other pertinent matters of interest to the regulated community, government officials, and the public.

Requirements More Restrictive than Federal

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

42 CFR § 418.60 requires hospices to have an infection control program that protects visitors from infection and communicable diseases. 42 CFR § 418.64(d)(3)(iii) further requires hospices to "[m]ake all reasonable efforts to facilitate visits by local clergy, pastoral counselors, or other individuals who can support the patient's spiritual needs to the best of its ability." The legislative mandate in Chapter 525 of the 2021 Acts of Assembly, Special Session I is more specific than federal requirements about visitation, though the mandate does not exceed and is not more restrictive than applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

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

Other State Agencies Particularly Affected
There are no other state agencies particularly affected.

Localities Particularly Affected
There are no localities particularly affected.

Other Entities Particularly Affected
There are 147 licensed hospices that will be required to comply with the regulatory change.

Economic Impact

Pursuant to § 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 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	None
For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	None
For all agencies: Benefits the regulatory change is designed to produce.	The regulatory change is designed to conform the regulation to the Code of Virginia.

Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	None
Benefits the regulatory change is designed to produce.	The regulatory change is designed to conform the regulation to the Code of Virginia.

Impact on Other Entities

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	Licensed hospices.
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.	One hundred forty-seven hospices, of which 20 are estimated to 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.	As all licensed hospices are already required to comply with the Code of Virginia, there are no projected costs for compliance with the regulatory change that conforms to the Code of Virginia.
Benefits the regulatory change is designed to produce.	The regulatory change is designed to conform the regulation to the Code of Virginia.

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 hospices and amending the regulation is the least burdensome, least intrusive, and less costly method to accomplish the purpose of this action.

Regulatory Flexibility Analysis

Pursuant to § 2.2-4007.1B 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 hospices consistent with the provisions of Article 7 (§ § 32.1-162.1 *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 Hospices (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.

As required by § 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.

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

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-	New chapter-section	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements

section number	number, if applicable		
391-370	N/A	**12VAC5-391-370. Spiritual counseling and bereavement services.** A. The hospice program shall provide for the delivery of spiritual counseling and bereavement services that reflect the family's needs and desires and are delivered according to the overall plan of care. B. Spiritual counseling may be provided through a working arrangement with individual clergy, clergy associations and other religious programs in the community or by clergy employed by the hospice program. C. The hospice program shall provide bereavement services to the family for a minimum of one year after the patient's death. D. The hospice program shall maintain a list of individuals who provide spiritual and bereavement services. The list shall be made available, upon request to patients, families, hospice program employees and contractors. E. Arrangements for and delivery of spiritual counseling and bereavement services shall be documented in the patient's record. Statutory Authority §§ 32.1-12 and 32.1-162.5 of the Code of Virginia.	**CHANGE:** The Board is proposing the following new requirements: **12VAC5-391-370. Spiritual counseling and bereavement services.** A. The hospice program shall provide for the delivery of spiritual counseling and bereavement services that reflect the family's needs and desires and are delivered according to the overall plan of care. B. Spiritual counseling may be provided through a working arrangement with individual clergy, clergy associations and other religious programs in the community or by clergy employed by the hospice program. C. The hospice program shall provide bereavement services to the family for a minimum of one year after the patient's death. D. The hospice program shall maintain a list of individuals who provide spiritual and bereavement services. The list shall be made available, upon request to patients, families, hospice program employees and contractors. E. Arrangements for and delivery of spiritual counseling and bereavement services shall be documented in the patient's record. F. During a declared public health emergency related to a communicable disease of public health threat, each hospice facility shall establish a protocol to allow patients 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 and the Centers for Medicare and Medicaid Services 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 patient pursuant to this subsection to comply with all reasonable requirements of the hospice adopted to protect the health and safety of the person, patients, and staff of the hospice. Statutory Authority §§ 32.1-12 and 32.1-162.5 of the Code of Virginia. **INTENT:** The intent of the new requirements is to conform 12VAC5-391-10 *et seq*. to the Code of Virginia. **RATIONALE:** The rationale for the new requirements is that Code of Virginia § 32.1-162.5(D) now requires the regulations for the licensure of hospices to include a minimum requirement about establishing protocols that allow patients to receive visits from a rabbi, priest, minister, or clergy of any religious denomination or sect during public health emergencies related to communicable diseases. **LIKELY IMPACT:** The likely impact of the new requirements is reduced confusion for regulants about what their obligations are for visitation during a public health emergency.

Project 6876 - Fast-Track

Department Of Health

Amend Regulation to Conform to Chapter 525 of the 2021 Acts of Assembly, Special Session I

12VAC5-391-370. Spiritual counseling and bereavement services.

A. The hospice program shall provide for the delivery of spiritual counseling and bereavement services that reflect the family's needs and desires and are delivered according to the overall plan of care.

B. Spiritual counseling may be provided through a working arrangement with individual clergy, clergy associations and other religious programs in the community or by clergy employed by the hospice program.

C. The hospice program shall provide bereavement services to the family for a minimum of one year after the patient's death.

D. The hospice program shall maintain a list of individuals who provide spiritual and bereavement services. The list shall be made available, upon request to patients, families, hospice program employees and contractors.

E. Arrangements for and delivery of spiritual counseling and bereavement services shall be documented in the patient's record.

F. During a declared public health emergency related to a communicable disease of public health threat, each hospice facility shall establish a protocol to allow patients to receive visits from a rabbi, priest, minister, or clergy of a religious denomination or sect consistent with guidance from the Centers for Disease Control and Prevention and the Centers for Medicare and Medicaid Services and subject to compliance with an executive order, order of public health, department guidance, or other applicable federal or state guidance having the effect of limiting visitation.

1. The protocol may restrict the frequency and duration of visits and may require visits to be conducted virtually using interactive audio or video technology.

2. The protocol may require the person visiting a patient pursuant to this subsection to comply with all reasonable requirements of the hospice adopted to protect the health and safety of the person, patients, and staff of the hospice.

Statutory Authority

§§ 32.1-12 and 32.1-162.5 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 21, Issue 23, eff. November 1, 2005.

COMMONWEALTH of VIRGINIA

Department of Health

Colin M. Greene, MD, MPH
Acting State Health Commissioner

P O BOX 2448
RICHMOND, VA 23218

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

MEMORANDUM

DATE: March 2, 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 to Conform to Chapters 219, 233, and 525 of the 2021 Acts of Assembly, Special Session I

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

Chapters 219, 233, and 525 of the 2021 Acts of Assembly, Special Session I amend Code of Virginia § 32.1-127 to direct the State Board of Health to promulgate regulations that require:

- each hospital establish and implement policies to ensure the permissible access to and use of an intelligent personal assistant provided by a patient, in accordance with such regulations, while receiving inpatient services;
- each hospital with an emergency department establish a protocol for the treatment and discharge of individuals experiencing a substance use-related emergency; and
- each hospital establish a protocol to allow patients to receive visits from clergy of any religious denomination or sect consistent with applicable federal or state guidance when there is a declared public health emergency related to a communicable disease of public health threat.

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

townhall.virginia.gov

Fast-Track Regulation
Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-410-10 *et seq.*
VAC Chapter title(s)	Regulations for the Licensure of Hospitals in Virginia
Action title	Amend Regulation to Conform to Chapters 219, 233, and 525 of the 2021 Acts of Assembly, Special Session I
Date this document prepared	March 2, 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 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1VAC7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code.*

Brief Summary

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

Chapter 219 of the 2021 Acts of Assembly, Special Session I amends Code of Virginia § 32.1-127(B), requiring the State Board of Health to promulgate regulations that "require each hospital…to establish and implement policies to ensure the permissible access to and use of an intelligent personal assistant provided by a patient, in accordance with such regulations, while receiving inpatient services."

Chapter 233 of the 2021 Acts of Assembly, Special Session I amends Code of Virginia § 32.1-127(B)(27), requiring the Board to amend regulations that "require each hospital with an emergency department to establish a protocol for the treatment and discharge of individuals experiencing a substance use-related emergency."

Chapter 525 of the 2021 Acts of Assembly, Special Session I amends Code of Virginia § 32.1-127(B), requiring the Board to promulgate regulations that "require each hospital…to establish a protocol to allow patients 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 and the Centers for Medicare and Medicaid Services 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" when there is "a declared public health emergency related to a communicable disease of public health threat."

Acronyms and Definitions

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

"Board" means the State Board of Health.

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 Executive Order 14 (as amended, July 16, 2018), "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

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

The mandate for these regulatory changes is found in Chapters 219, 233, and 525 of the 2021 Acts of Assembly, Special Session I. It is anticipated that this rulemaking will be noncontroversial and therefore appropriate for the fast-track process because it is being used to conform 12VAC5-410-10 *et seq.* to the Code of Virginia and no new requirements are being developed beyond what Chapters 219, 233, and 525 of the 2021 Acts of Assembly, Special Session I mandate.

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.

Code of Virginia § 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. Code of Virginia § 32.1-127 requires the Board to adopt regulations that include minimum standards for (i) the

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

Purpose

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

This regulation is being amended due to the changes to Code of Virginia § 32.1-127. The Board is required by Code of Virginia § 32.1-127 to promulgate regulations for the licensure of hospitals in order to protect the health, safety, and welfare of citizens receiving care in hospitals. The goal of the regulatory change is to conform the regulations to the statute. It is intended to solve the problem of the regulation not reflecting the legislative mandates of Chapters 219, 233, and 525 of the 2021 Acts of Assembly, Special Session I.

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.

12VAC5-410-10. Definitions.
Added a definition for "intelligent personal assistant."

12VAC5-410-230. Patient care management.
Creates a new subdivision in subsection F requiring general hospitals to have a protocol to allow patients to receive visits from a rabbi, priest, minister, or clergy of any religious denomination or sect during public health emergencies related to communicable diseases. Creates a new subsection L requiring general hospitals to establish policies governing the access and use of intelligent personal assistants.

12VAC5-410-280. Emergency service.
Amends subsection J

12VAC5-410-1170. Policy and procedures manual.
Creates a new subdivision in subsection F requiring outpatient surgical hospitals to have a protocol to allow patients to receive visits from a rabbi, priest, minister, or clergy of any religious denomination or sect during public health emergencies related to communicable diseases

Issues

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

This action is being used to conform 12VAC5-410-10 *et seq.* to existing requirements in the Code of Virginia. The advantage to the public, the agency, and the Commonwealth is that 12VAC5-410-10 *et seq.* are in compliance with legislative changes enacted by the General Assembly during the 2021 Special Session I. There are no disadvantages to the public, the agency, or the Commonwealth. There are no other pertinent matters of interest to the regulated community, government officials, and the public.

Requirements More Restrictive than Federal

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

There are no applicable federal requirements about intelligent personal assistants, which is the subject of the mandate in Chapter 219 of the 2021 Acts of Assembly, Special Session I.

42 CFR 482.55 requires general hospitals to meet the emergency needs of patients. The legislative mandate in Chapter 233 of the 2021 Acts of Assembly, Special Session I is more specific than federal requirements about emergency needs of patients experiencing a substance use emergency, though the mandate does not exceed and is not more restrictive than applicable federal requirements.

42 CFR § 482.13(h) requires general hospitals to have written policies and procedures regarding the visitation rights of patients, including addressing any clinical restrictions or limitations on such rights. The legislative mandate in Chapter 525 of the 2021 Acts of Assembly, Special Session I is more specific than federal requirements about the clinical restrictions or limitations those policies and procedures must address, though the mandate does not exceed and is not more restrictive than applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

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

Other State Agencies Particularly Affected
Virginia Commonwealth University Health Systems Authority will be required to comply with the regulatory change.

Localities Particularly Affected
Lee County Hospital Authority and Chesapeake Hospital Authority will be required to comply with the regulatory change.

Other Entities Particularly Affected
The 106 licensed general hospitals (including those operated by Lee County Hospital Authority and Chesapeake Hospital Authority) and 63 outpatient surgical hospitals will be required to comply with the regulatory change.

Economic Impact

Pursuant to § 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 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	None
For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	None
For all agencies: Benefits the regulatory change is designed to produce.	The regulatory change is designed to conform the regulation to the Code of Virginia.

Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	None
Benefits the regulatory change is designed to produce.	The regulatory change is designed to conform the regulation to the Code of Virginia.

Impact on Other Entities

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	Licensed general hospitals and licensed outpatient surgical hospitals.
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.	106 general hospitals and 63 outpatient surgical hospitals. Three of the outpatient surgical hospitals are estimated to meet the definition of "small business"
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to:	As all licensed hospitals are already required to comply with the Code of Virginia, there are no projected costs for compliance with the regulatory change that conforms to the Code of Virginia.

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.	The regulatory change is designed to conform the regulation to the Code of Virginia.

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.

Regulatory Flexibility Analysis

Pursuant to § 2.2-4007.1B 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.

As required by § 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.

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

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
410-10	N/A	There is no existing definition of “intelligent personal assistant.”	**CHANGE:** The Board is proposing to add the following definition: "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. **INTENT:** The intent of the new definition is to conform 12VAC5-410-10 *et seq*. to the Code of Virginia. **RATIONALE:** The rationale for the new requirements is that Code of Virginia §

			32.1-127(B)(29) includes a definition for intelligent personal assistant. **LIKELY IMPACT:** The likely impact of the new requirements is reduced confusion for regulants about what an intelligent personal assistant is.
410-230	N/A	**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 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	**CHANGE:** The Board is proposing the following new requirements: **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 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.

		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	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. 1. During a declared public health emergency related to a communicable disease of public health threat, each hospital shall establish a protocol to allow patients 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 and the Centers for Medicare and Medicaid Services 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. a. Such protocol may restrict the frequency and duration of visits and may require visits to be conducted virtually using interactive audio or video technology. b. Any such protocol may require the person visiting a patient pursuant to subdivision F 1 of this section to comply with all reasonable requirements of the hospital adopted to protect the health and safety of the person, patients, and staff of the hospital. 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,

		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; 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 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	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; 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 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 §

		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. Each hospital shall establish a protocol requiring that, before a health care provider arranges for air	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. 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. 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.

		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. 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	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. L. Each hospital shall establish and implement policies to ensure the permissible access to and use of an intelligent personal assistant provided by a patient while receiving inpatient services. Such policies shall ensure protection of health information in accordance with the requirements of the federal Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. § 1320d et seq., as amended. Statutory Authority §§ 32.1-12 and 32.1-127 of the Code of Virginia. **INTENT:** The intent of the new requirements is to conform 12VAC5-410-10 *et seq*. to the Code of Virginia. **RATIONALE:** The rationale for the new requirements is that Code of Virginia § 32.1-127(B)(29) and (30) now require the regulations for the licensure of hospitals to include minimum requirements about (i) access and use of intelligent personal assistants and (ii) protocols that allow patients to receive visits from a rabbi, priest, minister, or clergy of any religious denomination or sect during public health emergencies related to communicable diseases. **LIKELY IMPACT:** The likely impact of the new requirements is reduced confusion for regulants about what their obligations are regarding intelligent personal assistants and visitation during a public health emergency.

		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.	
410-280	N/A	**12VAC5-410-280. Emergency service.** A. Hospitals with an emergency department/service shall have 24-hour staff coverage and shall have at least one physician on call at all times. Hospitals without emergency service shall have written policies governing the handling of emergencies. B. No less than one registered nurse shall be assigned to the emergency service on each shift. Such assignment need not be exclusive of other duties, but must have priority over all other assignments. C. Those hospitals that provide ambulance services shall comply with Article 2.1 (§ 32.1-111.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia and 12VAC5-31. D. The hospital shall provide equipment, drugs, supplies, and ancillary services commensurate with the scope of anticipated needs, including radiology and laboratory services and facilities for handling and administering of blood and blood products. Emergency drugs and equipment shall remain accessible in the emergency department at all times. E. Current roster of medical staff members on emergency call, including alternates and medical	**CHANGE:** The Board is proposing the following new requirements: **12VAC5-410-280. Emergency service.** A. Hospitals with an emergency department/service shall have 24-hour staff coverage and shall have at least one physician on call at all times. Hospitals without emergency service shall have written policies governing the handling of emergencies. B. No less than one registered nurse shall be assigned to the emergency service on each shift. Such assignment need not be exclusive of other duties, but must have priority over all other assignments. C. Those hospitals that provide ambulance services shall comply with Article 2.1 (§ 32.1-111.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia and 12VAC5-31. D. The hospital shall provide equipment, drugs, supplies, and ancillary services commensurate with the scope of anticipated needs, including radiology and laboratory services and facilities for handling and administering of blood and blood products. Emergency drugs and equipment shall remain accessible in the emergency department at all times. E. Current roster of medical staff members on emergency call, including alternates and medical specialists or consultants shall be posted in the emergency department. F. Hospitals shall make special training available, as required, for emergency department personnel. G. Toxicology reference material and poison antidote information shall be available along with telephone numbers of the nearest poison control centers. H. Each emergency department shall post notice of the existence of a human

		specialists or consultants shall be posted in the emergency department. F. Hospitals shall make special training available, as required, for emergency department personnel. G. Toxicology reference material and poison antidote information shall be available along with telephone numbers of the nearest poison control centers. H. Each emergency department shall post notice of the existence of a human trafficking hotline to alert possible witnesses or victims of human trafficking to the availability of a means to gain assistance or report crimes. This notice shall be in a place readily visible and accessible to the public, such as the patient admitting area or public or patient restrooms. The notice shall meet the requirements of § 40.1-11.3 C of the Code of Virginia. I. Every hospital with an emergency department shall establish protocols to ensure that security personnel of the emergency department receive training appropriate to the populations served by the emergency department. This training may include training based on a trauma-informed approach in identifying and safely addressing situations involving patients or other persons who pose a risk of harm to themselves or others due to mental illness or substance abuse or who are experiencing a mental health crisis. J. Each hospital with an emergency department shall establish a protocol for treatment of individuals experiencing a substance use-related emergency to include the completion of	trafficking hotline to alert possible witnesses or victims of human trafficking to the availability of a means to gain assistance or report crimes. This notice shall be in a place readily visible and accessible to the public, such as the patient admitting area or public or patient restrooms. The notice shall meet the requirements of § 40.1-11.3 C of the Code of Virginia. I. Every hospital with an emergency department shall establish protocols to ensure that security personnel of the emergency department receive training appropriate to the populations served by the emergency department. This training may include training based on a trauma-informed approach in identifying and safely addressing situations involving patients or other persons who pose a risk of harm to themselves or others due to mental illness or substance abuse or who are experiencing a mental health crisis. J. Each hospital with an emergency department shall establish a protocol for the treatment and discharge of individuals experiencing a substance use-related emergency, ~~to~~ which shall include ~~the completion of appropriate assessments or screenings~~ provisions for: 1. Appropriate screening and assessment of individuals experiencing substance use-related emergencies to identify medical interventions necessary for the treatment of the individual in the emergency department~~. The protocol may also include a process for patients who are discharged directly from the emergency department for the recommendation of~~; and 2. Recommendations for follow-up care following discharge for any patient identified as having a substance use disorder, depression, or mental health disorder, as appropriate, that may include for patients who have been treated for substance use-related emergencies, including opioid overdose, or other high-risk patients: ~~1. Instructions for distribution~~ a. The dispensing of naloxone or other opioid antagonist used for

		appropriate assessments or screenings to identify medical interventions necessary for the treatment of the individual in the emergency department. The protocol may also include a process for patients who are discharged directly from the emergency department for the recommendation of follow-up care following discharge for any identified substance use disorder, depression, or mental health disorder, as appropriate, that may include: 1. Instructions for distribution of naloxone; 2. Referrals to peer recovery specialists and community-based providers of behavioral health services; or 3. Referrals for pharmacotherapy for treatment of drug or alcohol dependence or mental health diagnoses. Statutory Authority §§ 32.1-12 and 32.1-127 of the Code of Virginia.	overdose reversal pursuant to subsection X of § 54.1-3408 at discharge; or b. Issuance of a prescription for and information about accessing naloxone or other opioid antagonist used for overdose reversal, including information about accessing naloxone or other opioid antagonist used for overdose reversal at a community pharmacy, including any outpatient pharmacy operated by the hospital, or through a community organization or pharmacy that may dispense naloxone or other opioid antagonist used for overdose reversal without a prescription pursuant to a statewide standing order. ~~2. Referrals~~ Such protocols may also provide for referrals of individuals experiencing a substance use-related emergency to peer recovery specialists and community-based providers of behavioral health services~~;~~, or to providers of pharmacotherapy for the treatment of drug or alcohol dependence or mental health diagnoses. ~~3. Referrals for pharmacotherapy for treatment of drug or alcohol dependence or mental health diagnoses.~~ Statutory Authority §§ 32.1-12 and 32.1-127 of the Code of Virginia. **INTENT:** The intent of the new requirements is to conform 12VAC5-410-10 *et seq*. to the Code of Virginia. **RATIONALE:** The rationale for the new requirements is that Code of Virginia § 32.1-127(B)(27) was amended to modify the minimum requirements for hospitals with an emergency department that are treating and discharging individuals experiencing a substance use-related emergency. **LIKELY IMPACT:** The likely impact of the new requirements is reduced confusion for regulants about what their obligations are regarding the treatment and discharge of individuals experiencing a substance use-related emergency.

410-1170	N/A	**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	**CHANGE:** The Board is proposing the following new requirements: **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. 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

		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. 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. 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	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. 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. 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

		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. 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	access to controlled substances within the outpatient surgical hospital pharmacy. F. During a declared public health emergency related to a communicable disease of public health threat, each hospital shall establish a protocol to allow patients 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 and the Centers for Medicare and Medicaid Services 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 patient pursuant to this subdivision to comply with all reasonable requirements of the hospital adopted to protect the health and safety of the person, patients, and staff of the hospital. Statutory Authority §§ 32.1-12 and 32.1-127 of the Code of Virginia. **INTENT:** The intent of the new requirements is to conform 12VAC5-410-10 *et seq*. to the Code of Virginia. **RATIONALE:** The rationale for the new requirements is that Code of Virginia § 32.1-127(B)(30) now requires the regulations for the licensure of hospitals to include minimum requirements about protocols that allow patients to receive visits from a rabbi, priest, minister, or clergy of any religious denomination or sect during public health emergencies related to communicable diseases. **LIKELY IMPACT:** The likely impact of the new requirements is reduced

		outpatient surgical hospital pharmacy. Statutory Authority §§ 32.1-12 and 32.1-127 of the Code of Virginia.	confusion for regulants about what their obligations are regarding visitation during a public health emergency.

Project 6875 - Fast-Track

Department Of Health

Amend Regulation to Conform to Chapters 219, 233, and 525 of the 2021 Acts of Assembly, Special Session I

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:

"Board" means the State Board of Health.

"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.

"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" 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.

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

"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 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.

"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.

"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 combinations known as digital assistants or virtual assistants.

"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 § 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.

"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 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 a medical environment exceeding the normal capability found in a physician's office, but do not require inpatient hospitalization.

"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.

"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.

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

Statutory Authority

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

Historical Notes

Derived from VR355-33-500 § 1.1, eff. July 28, 1993; amended, Virginia Register Volume 11, 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; Volume 37, Issue 14, eff. March 31, 2021.

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 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.

1. During a declared public health emergency related to a communicable disease of public health threat, each hospital shall establish a protocol to allow patients to receive visits from a rabbi, priest, minister, or clergy of a religious denomination or sect consistent with guidance from the Centers for Disease Control and Prevention and the Centers for Medicare and Medicaid Services and subject to compliance with an executive order, order of public health, department guidance, or other applicable federal or state guidance having the effect of limiting visitation.

a. The protocol may restrict the frequency and duration of visits and may require visits to be conducted virtually using interactive audio or video technology.

b. The protocol may require the person visiting a patient pursuant to subdivision F 1 of this section to comply with all reasonable requirements of the hospital adopted to protect the health and safety of the person, patients, and staff of the hospital.

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; 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 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. 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. 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.

L. Each hospital shall establish and implement policies to ensure the permissible access to and use of an intelligent personal assistant provided by a patient while receiving inpatient services. The policies shall ensure protection of health information in accordance with the requirements of the federal Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. § 1320d et seq., as amended.

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.

12VAC5-410-280. Emergency service.

A. Hospitals with an emergency department/service shall have 24-hour staff coverage and shall have at least one physician on call at all times. Hospitals without emergency service shall have written policies governing the handling of emergencies.

B. No less than one registered nurse shall be assigned to the emergency service on each shift. Such assignment need not be exclusive of other duties, but must have priority over all other assignments.

C. Those hospitals that provide ambulance services shall comply with Article 2.1 (§ 32.1-111.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia and 12VAC5-31.

D. The hospital shall provide equipment, drugs, supplies, and ancillary services commensurate with the scope of anticipated needs, including radiology and laboratory services and facilities for handling and administering of blood and blood products. Emergency drugs and equipment shall remain accessible in the emergency department at all times.

E. Current roster of medical staff members on emergency call, including alternates and medical specialists or consultants shall be posted in the emergency department.

F. Hospitals shall make special training available, as required, for emergency department personnel.

G. Toxicology reference material and poison antidote information shall be available along with telephone numbers of the nearest poison control centers.

H. Each emergency department shall post notice of the existence of a human trafficking hotline to alert possible witnesses or victims of human trafficking to the availability of a means to gain assistance or report crimes. This notice shall be in a place readily visible and accessible to the public, such as the patient admitting area or public or patient restrooms. The notice shall meet the requirements of § 40.1-11.3 C of the Code of Virginia.

I. Every hospital with an emergency department shall establish protocols to ensure that security personnel of the emergency department receive training appropriate to the populations served by the emergency department. This training may include training based on a trauma-informed approach in identifying and safely addressing situations involving patients or other persons who pose a risk of harm to themselves or others due to mental illness or substance abuse or who are experiencing a mental health crisis.

J. Each hospital with an emergency department shall establish a protocol for the treatment and discharge of individuals experiencing a substance use-related emergency, ~~to~~ which shall include ~~the completion of appropriate assessments or screenings~~ provisions for:

1. Appropriate screening and assessment of individuals experiencing substance use-related emergencies to identify medical interventions necessary for the treatment of the individual in the emergency department~~. The protocol may also include a process for patients who are discharged directly from the emergency department for the recommendation of~~; and

2. Recommendations for follow-up care following discharge for any patient identified as having a substance use disorder, depression, or mental health disorder, as appropriate, that may include for patients who have been treated for substance use-related emergencies, including opioid overdose, or other high-risk patients:

~~1. Instructions for distribution~~ a. The dispensing of naloxone or other opioid antagonist used for overdose reversal pursuant to subsection X of § 54.1-3408 at discharge; or

b. Issuance of a prescription for and information about accessing naloxone or other opioid antagonist used for overdose reversal, including information about accessing naloxone or other opioid antagonist used for overdose reversal at a community pharmacy, including an outpatient pharmacy operated by the hospital, or through a community organization or pharmacy that may dispense naloxone or other opioid antagonist used for overdose reversal without a prescription pursuant to a statewide standing order.

~~2. Referrals~~ The protocols may also provide for referrals of individuals experiencing a substance use-related emergency to peer recovery specialists and community-based providers of behavioral health services~~;~~, or to providers of pharmacotherapy for the treatment of drug or alcohol dependence or mental health diagnoses.

~~3. Referrals for pharmacotherapy for treatment of drug or alcohol dependence or mental health diagnoses.~~

Statutory Authority

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

Historical Notes

Derived from VR355-33-500 § 2.12, eff. July 28, 1993; amended, Virginia Register Volume 11, Issue 8, eff. April 1, 1995; Volume 22, Issue 8, eff. January 25, 2006; Volume 35, Issue 4, eff. November 14, 2018; Volume 36, Issue 23, eff. August 6, 2020.

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. 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.

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. 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.

F. During a declared public health emergency related to a communicable disease of public health threat, each hospital shall establish a protocol to allow patients to receive visits from a rabbi, priest, minister, or clergy of a religious denomination or sect consistent with guidance from the Centers for Disease Control and Prevention and the Centers for Medicare and Medicaid Services and subject to compliance with an executive order, order of public health, department guidance, or other applicable federal or state guidance having the effect of limiting visitation.

1. The protocol may restrict the frequency and duration of visits and may require visits to be conducted virtually using interactive audio or video technology.

2. The protocol may require the person visiting a patient pursuant to this subdivision to comply with all reasonable requirements of the hospital adopted to protect the health and safety of the person, patients, and staff of the hospital.

Statutory Authority

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

Historical Notes

Derived from VR355-33-500 § 4.3, eff. July 28, 1993; amended, Virginia Register Volume 11, 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.