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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 March 31, 2022.

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.