



Proposed Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12VAC5-391
Regulation title	Rules and Regulations for the Licensure of Hospices
Action title	To implement HB1965 (2007) regarding hospice facilities
Date this document prepared	

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.

In 2003(HB1822), the hospice community was permitted to establish dedicated hospice facilities licensed as assisted living facilities. Such dual licensure has proven problematic for hospice providers with facilities currently licensed under that legislation. The strengthening of the assisted living facility regulation in 2006 widened the disparity between assisted living facilities and the hospice philosophy. Enactment of HB1965 (CHAP0391, 2007) places oversight for hospice facilities with the Virginia Department of Health, the designated state oversight authority for hospice programs. The legislation establishes that the continuity in hospice services provided in a patient's home also be provided in a dedicated facility. This change in law necessitates amending Part IV (12 VAC 5-391-440 et seq.) to expand the scope and breadth of the current standards addressing patient care and safety in hospice facilities. Currently the regulations do not offer adequate protections for medically fragile patients receiving care in the dedicated facilities. The department is also taking this opportunity to address some omissions in the regulation revised in 2005.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

The regulation is promulgated under the authority of § 32.1-162.5 of the Code of Virginia, which grants the Board of Health the legal authority “to prescribe such regulation governing the activities and services provided by hospices as may be necessary to protect the public health, safety and welfare.” Therefore, this authority is mandated. The passage of HB1965(CHAP0397, 2007) requires that sections of 12 VAC 5-391 be subsequently amended.

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.

This action will establish standards for those hospice providers seeking to establish dedicated board and care facilities for diagnosed terminally ill consumers receiving hospice care, but who can no longer remain in their own homes. The proposed regulations address patient care and safety, physical plant, maintenance and housekeeping, and emergency preparedness. The proposed amendments also rectify some omissions in the 2005 revised regulation

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the “Detail of changes” section.)

The department has developed facility regulatory standards replicating the patient safety and physical plant standards under which hospice facilities operated prior to the enactment of HB1965 (2007). Such facilities were dually licensed as an assisted living facility, a nursing facility or as a hospital and subject to the physical plant, safety, and maintenance and housekeeping standards as contained in the proposed amendments. The department expanded the existing hospice facility standards established in 2005 as part of the comprehensive revision of Regulations for the Licensure of Hospices. At that time, the department promulgated only those facility standards deemed essential to insure basic patient care. The department relied on national standards of care, the hospice facility regulations of other states, as well as Virginia’s other facility licensure standards when developing the proposed amendments.

Issues

Please identify the issues associated with the proposed regulatory action, 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 the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.

As stated previously, a segment of Virginia’s hospice community has endeavored to establish identifiable hospice facilities for some years. Until the passage of HB1965, those efforts proved unsuccessful because providers felt that dual licensure as an assisted living facility, nursing facility or hospital, as required, was overly burdensome and that the facility licensure regulations were not sufficiently flexible to implement services reflecting the hospice philosophy of care.

The 2005 comprehensive revision to the hospice licensure regulations included facility specific regulations, one of which required a registered nurse on duty on all shifts. Some hospice providers objected to this requirement. The department knew that a registered nurse on all shifts met with the hospice facility licensure provision in other states, as well as with federal hospice facility regulation. The department conducted a year long pilot study to gather data to assess the impact of this requirement. At the end of the study, it was mutually agreed that appropriate care could be provided without an RN on duty if an RN was on-call within 20 minutes. However, the department learned there were still objections to the proposed staffing requirements. Some facility providers, in fact, advocated for no RN staffing in the dedicated hospice facilities. The department believes that these objections are primarily based on costs. Hospice patient care advocates do not consider costs a legitimate reason for opposing the registered nurse on duty criteria. Advocates cite the complexities of terminal illnesses, such as Alzheimer’s Disease, and the potential for medication errors and adverse drug reactions as sufficient cause to require a registered nurse on duty on all shifts. The department believes that the agreed upon exception to the RN requirement for those facilities with six beds or less appropriately and adequately addresses the concerns of both parties.

No particular locality is affected more than another by this regulation. Promulgation of these amendments to 12VAC5-391 create no known advantages or disadvantages to the agency, the Commonwealth, or the hospice community. Every effort has been made to ensure the regulation protects the health and safety of patient receiving care in a hospice facility while allowing providers to be more responsive to the needs of their patients. Failure to implement the regulation will not negatively impact the overall provision of hospice care in Virginia.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which are more restrictive than applicable federal requirements. Include 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 statement to that effect.

A hospice facility receiving Medicare reimbursement must staff the facility with a registered nurse on all shifts and must meet the standards of the Life Safety Code (LSC) of the National Fire Protection Association. The department’s proposed amendments do not require that a hospice facility meet the LSC or that a registered nurse staff each shift. Therefore, the proposed amendments are less restrictive than federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There is no one locality disproportionately affected by this proposed regulation.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so by mail, email or fax to:

Carrie Eddy
 Senior Policy Analyst
 Office of Licensure and Certification
 Virginia Department of Health
 9960 Mayland Drive
 Richmond, Virginia 23233
 Tel: 804-367-2157
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Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last date of the public comment period.

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

<p>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures</p>	<p>State general funds (0100) and licensure fees fund the hospice licensure program. Fees are \$500 for each initial and renewal license. The average cost of conducting an inspection is \$1,800. In FY2007, VDH/OLC collected \$118,998 in total licensing fees, while licensing expenses totaled \$1,099,690; program/subprogram: 561/03. These expenditures are expected to be on-going.</p>
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<p>Projected cost of the regulation on localities</p>	<p>None, unless a locality operates a hospice program and wants to open a facility. Currently, there are no localities licensed to operate a hospice program.</p>
<p>Description of the individuals, businesses or other entities likely to be affected by the regulation</p>	<p>Hospice providers wishing to establish hospice facilities, businesses under contract to hospice facility providers.</p>
<p>Agency’s best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>There are currently 4 known providers of hospice facilities in Virginia: 3 licensed under DSS and 1 licensed as a hospital by VDH. It is expected that the ‘hospital’ facility will relinquish its hospital license in favor of the hospice facility license which is not as burdensome as hospital licensure. VDH knows that there are currently 2 facilities in the funding/proposal stages. In addition, we are aware of an expressed general interest in establishing such facilities.</p>
<p>All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.</p>	<p>Promulgation of the proposed amendments will not inhibit the offering of hospice services in Virginia. A hospice facility accommodates a business decision made by the hospice provider. The costs of operating a dedicated hospice facility will not affect bed availability for those hospice recipients who can no longer stay in their homes.</p>

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. 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 regulation.

The regulation is clearly and directly mandated by law.

Regulatory flexibility analysis

Please 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) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of 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 proposed regulation.

The hospice community in Virginia includes both large hospice organizations, generally associated with health care systems, and smaller independent or stand alone hospice organizations. However, the

proposed regulations do not require that a hospice provider establish a hospice facility in order to operate in Virginia. That is a business decision determined by the hospice provider as an added service to their clients. In developing the proposed regulations, the state focused on addressing appropriate quality patient care, consistent with state and national standards of care, in a facility type that will not have the visibility experienced by their larger counterparts, i.e., assisted living facilities, nursing facilities or palliative care units in hospitals. Because these facilities will be located in residential areas, it is necessary to assure that the state and public/private entities recognize that the smaller sized facilities preferred by most hospice providers are not of a sufficient capacity to provide significant economies of scale to operate a facility efficiently.

Public comment

Please summarize all comments received during public comment period following the publication of the NOIRA, and provide the agency response.

Commenter	Comment	Agency response
Andrew parker President American Hospice	No facility should be allowed to operate and serve citizens of the Commonwealth of Virginia unless there is a Registered Nurse on duty, providing direct patient care. There needs to be a trained clinical professional who can case manage any patient care contingency on a real-time, face-to-face basis.	Thank you for supporting our efforts.
Marcia Tetterton Executive Director Virginia Association for Home Care and Hospice (VAHCH)	We are requesting an amendment to §12VAC5-391-450...to require that only one licensed nurse be on duty when six or fewer patients are present...Given the complexity of the hospice patient's terminal illness coupled with compounding disease states, we believe that nurse are best suited to deliver the timely and appropriate medication and care for hospice patients...the role of a hospice nurse is critical to quality end of life care.	As evidenced in 12VAC5-391-450 C, OLC has adopted this recommendation.
Kathy Clements, RN Executive Director Hospice of the Rapidan (HR)	While HR wants to consider this new service for our community we must also consider the impact this new service will have on our small hospice. One factor that concerns us is the cost of staffing this facility...ask that hospices be granted the same responsibility that hospitals and nursing facilities currently have, to determine the appropriate staffing mix by the patient needs...request that [the levels of care provided] not be made more restrictive in regulation.	Whether or not a provider determines to open a facility is a business decision to be made by the provider. However, providing institutional care (regardless of physical plant of that facility) is costly. While we are sensitive to that, we cannot adopt patient care standards based solely on cost. We believe the proposed staffing language is an appropriate compromise, assuring quality patient care with reasonable cost. Thank you for the comment regarding levels of care, especially since it points out a misunderstanding about the amendments. In

		fact, the proposed regulation were specifically designed to provide just the opposite, flexibility for the provider to address all levels of care within the facility without having to transfer a patient to a more institutional setting, i.e., hospital or nursing facility. Therefore, the proposed regulations do not limit the levels of care that can be proved within a hospice facility.
Becky Bowers-Lanier, EdD, MPH Legislative Consultant Virginia Association for Hospices, Inc.	Staffing requirements should be determined by the needs of the patients. We believe that language similar to [that] in licensure of hospitals and nursing facilities should suffice...Request that the OLC consider adding to the definitions...the types of care that hospice facilities may render, again depending on the needs of the patients.	We believe the proposed staffing language is appropriate to assure quality patient care. We believe the commenter is confusing state and federal processes. The federal process (Medicare) has already determined 4 levels of care, i.e., (i) home care, (ii) continuous care, (iii) inpatient care, and (iv) respite care. We have designed the regulations specifically to allow flexibility for the provider to address all levels of care within the facility.
Neysa R. Summers VP, Community Services, Augusta Medical Center	There is not a constant need for a 24/7 RN or 24/7 RN/LPN plus a second staff member, regardless of patient needs...if the regulation stands, it will serve to hamper other development in the state and diminish the resources communities have to serve this population.	The staffing standard as initially proposed met with federal certification regulations as well as with similar regulations in other states that allow hospice facilities. It should be noted that not all states allow hospice facilities and some states require a certificate of public need. In preparation for the work group meeting held on Dec. 5, VDH/OLC received notice from Judy Matthews, Executive Director of Hospice of the Shenandoah (i.e., the hospice program of the Augusta Medical Center) that she agrees with the proposed amendment regarding staffing. Refer to 12VAC5-391-450 C.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

There is no direct impact on the family or family stability.

Detail of changes

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

For changes to existing regulations, use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
10		Definitions	<p>Added 'hospice facility' based on passage of HB1965;</p> <p>Amended 'inpatient' for consistency between regulatory chapters and to clarify meaning of inpatient care for hospice providers</p> <p>Added 'medication error' in response to added new section</p>
120		Addresses in the required interface for dual licensure as a hospice provider and as assisted living, a nursing facility or hospital. Also addresses regulations specific to the provision of hospice facility care.	<p>Amended the section to repeal interface with other licensing criteria;</p> <p>Adds a requirement that hospice facilities provide respite and symptom management services to their community patients needing such services. This reinforces a basic tenet of hospice patient care.</p>
150		Addresses circumstances under which a licensed must be returned to VDH	Adds hospice facility to the list of circumstances, so that VDH is aware of changes affecting a provider's license.
160		Addresses management and demonstration of the hospice	<p>Adds hospice facility to the list of changes under which to notify VDH of changes to a hospice license;</p> <p>Adds a requirement that a facility encourage and facilitate the availability of flu shots to correct an omission in the 2005 revised regulation in support of state and national flu prevention initiatives.</p>
180		Addresses the requirements for individuals hired as administrator and designated assistant administrators	Adds a requirement that the administrator have operational knowledge of state hospice laws and regulations and the interrelationship between such laws/regulations and voluntary accreditation/certification by national organizations. Believed to be necessary knowledge to effectively operate and hospice program.

			Amends (relaxes) the criteria for the individual serving as backup to the administrator. Consistent with the criteria for the assistant administrator for home care organizations.
300		Addresses the overall provision of hospice services in the community	Clarified transfer to a hospital as a result of provider confusion and passage of HB1965; Added transportation in cases of emergency, moved from 12VAC5-391-440.
	395		Section added to address an omission in the 2005 revised regulation. With the numbers and types of medications prescribed to hospice patients, there is the concern for medication errors. The section provides expectations regarding actions when such errors occur.
440		Addresses general facility requirements	Adds criteria regarding design and construction of hospice facilities consistent with the 2006 standards of the American Institute of Architects addressing hospice facilities, Consistent with similar regulations for nursing facilities and hospitals. Adds stipulation that hospice facilities can provide only hospice care to assure that the facilities are not used for other purposes to generate revenue. Determined necessary in response to provider emphasis on costs of operation.
	445		New section added to address additional building regulations and standards as a result of passage of HB1965. Consistent with facility criteria for other licensed facility types.
	446		New section added addressing financial controls and patient funds as a result of passage of HB1965. Consistent with GAAP and patient funds accountability for other licensed facility types.
450		Address required minimum staffing	Section amended to allow 1 licensed staff person for six or fewer beds; result of compromise between differing factions in the hospice industry.
460		Addresses pharmacy services	Amended to assure consistency with pharmacy laws and regulations (18VAC110-20)
480		Address dietary and food service	Section amended to added additional dietary requirements resulting from passage of HB1965. Consistent with dietary criteria for other licensed facility types.
	485		New section added addressing maintenance and housekeeping as a result of passage of HB1965. Consistent with similar criteria for other licensed facility types.

	495		New section added addressing transportation as a result of passage of HB1965. Consistent with similar criteria for other licensed facility types.
500		Addresses pet care	Amended to provide clarity regarding expectations for pet visitors and resident pets. Section expanded at request of hospice facilities providers participating in work group discussions.
	510		New section added, as a result of passage of HB1965, to address resident/staff safety and preparedness for emergencies resulting from natural or man-made disasters. Consistent with similar criteria for other licensed facility types. Supports state and national preparedness initiatives.

Enter any other statement here