Virginia Regulatory Town Hall

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Final Regulation
Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12 VAC 5 – 391
Regulation title	Regulations for the Licensure of Hospices
Action title	Amendments addressing hospice facilities
Date this document prepared	October 28, 2009

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

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

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.

Statement of final agency action

Please 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.

On October 23, 2009, the State Board of Health, meeting in Richmond, passed a motion to adopt the final regulations discussed herein.

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 numbers, if applicable, and (2) promulgating entity, i.e., 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. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal 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 identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.

12VAC5-391-10: Amended 'bereavement services' amended to reference federal regulation; added definitions of 'adverse outcomes' and 'separate and distinct entrance' to clarify intent of regulatory requirements.

12VAC5-391-120 C: Added primary caregiver or family to 'convenience' prohibition; D and E: Switched placement of regulations and added language to clarify intent of respite and symptom management regulation.

12VAC5-391-160 H: Modified to reflect statutory language; K: Added 'pandemic disease outbreaks' to emergency preparedness planning

12VAC5-391-180 B: Amended to include 'applicable state laws and regulations' and change name of JCAHCO

12VAC3-391-300 F: Subsection added.

12VAC5-391-395 A: Amended to require reporting of adverse outcomes to OLC/VDH.

12VAC5-391-440 J: Added 'separate and distinct entrance' to divert traffic and noise away from patient care areas.

12VAC5-391-445C: Amended food service reference as not all facilities will meet the commercial kitchen threshold.

12VAC5-391-450 B: Amended to stipulate protection from 'avoidable' accidents, injuries and infections

12VAC5-391-480: added note regarding family provision of patient meals; D: Amended to provide for employment of dietary consultation

12VAC5-391-500 B: Added exclusion for service animals; D: correct syntax

12VAC5-391-510 D: Amended to add 'patient rooms' to areas requiring telephone access.

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 there are no disadvantages to the public or the Commonwealth, please indicate.

Some members of Virginia's hospice community have wished 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 (12VAC5-391) included minimum facility related regulations since a hospice facility would also have to be licensed as a nursing facility, a hospital or an assisted living facility. With the passage of HB1965 (2007), it was necessary to fully develop the requirements for the physical plant and facility portion of 12VAC5-391. In developing these amendments, OLC/VDH relied on the hospice facility regulations from other states, as well as other long term care facility regulations within Virginia, and the hospice facility conditions for participation of the Centers for Medicare and Medicaid (CMS). Part of that development was recognizing that the intent of these facilities is to mirror a residence rather than the more complex physical plant of a nursing facility or assisted living facility. However, there remain certain standards that are inherent in any communal living situation, regardless of the size and complexity of that facility. This is especially true when that facility is dedicated to the provision of medical care services. As part of it efforts to involve the various interested parties, OLC/VDH convened a stakeholder meeting to reach consensus on issues such as staffing, physical plant requirements, dietary and housekeeping. Stakeholders included: The Virginia Association of Home Care and Hospice, The Virginia Association of Hospice, The Virginia Health Care Association, the Virginia Association of Nonprofit Homes for the Aging, the Alzheimer's Association, the State Fire Marshall's Office, and OLC/VDH staff. OLC/VDH believes this is the first time that hospice providers participated in such a regulatory consensus meeting. OLC/VDH is confident that the resultant amendments offered herein are a reasonable compromise that assure appropriate quality patient care in a communal setting while ensuring that the regulations are not a barrier or intrusive to the operation of a hospice facility that is limited by the Code of Virginia to 16 or fewer beds.

The requirement for a registered nurse on duty on all shifts was considered problematic for some hospice providers. The most often cited reason for objecting to the regulation is cost. However, 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. Even though the regulation was consistent with hospice facility licensure provisions in other states as well as with federal hospice facility regulation, OLC/VDH agreed to reconsider the regulation. After conducting a pilot 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. The department believes that the agreed upon exception that a RN be available to respond to emergent calls within 20 minutes for those facilities with six beds or less appropriately addresses the concerns of both parties.

In addition to staffing, dietary/food services and pharmacy received attention during the public comment period, stating that such regulations were unnecessary and intrusive. OLC/VDH disagrees that such regulations are actually intrusive; rather they bring provider awareness to the complexities of operating a facility. That includes an awareness of various other Virginia laws and regulations that all facility providers, regardless of focus, must adhere to. Such laws and regulations have been legislatively established for the common welfare of Virginia's citizens. Exception was also taken to the requirement that adverse medication outcomes be reported to the department and that providers implement an active pressure ulcer reduction program. OLC/VDH considers both these issues important to the overall quality of care delivered. In light of national studies on medication errors and adverse outcomes, many states have implemented adverse event reporting requirements as one of their tools for monitoring compliance to nationally accepted standards of practice. OLC/VDH believes Virginia should be no different and cites §32.1-19C as its legal authority for establishing reporting requirements. Therefore, OLC/VDH is adding adverse event reporting as it revises all its program licensure regulations. Medication errors can indicate a system failure within a provider's organization that can also have serious quality of care consequences. The intent is to use the reports as a survey preparation tool, for data analysis for targeted provider training, and to identify those providers needing additional oversight support. Patient advocates declare that all pressure ulcers are avoidable, however the national rate remains high and Virginia's rate is in excess of that. Since 2005, reduction of pressure ulcers has been a Governor's key performance

reassure in VDH's strategic plan. As part of that ongoing requirement, OLC/VDH is adding a pressure ulcer regulation as it revises all its program licensure programs.

Even though the law provides for up to 16 beds, the size favored by most hospice providers appears to be 6 beds or less. OLC/VDH is mindful that history and experience have proven that smaller size facilities such as the size preferred by most hospice providers are not of a sufficient capacity to provide significant economies of scale. This is especially true for facilities providing medical care services. As a comparison, the smallest nursing facility is 18 beds with an average size of 114 beds. OLC/VDH recognizes that the intent of these facilities is to resemble a residence. Since these facilities will be located in residential neighborhoods, OLC/VDH also focused on addressing appropriate quality patient 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. Therefore, many of the regulations were modified to accommodate the planned smaller capacity of a hospice facility. 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.

No particular locality is affected more than another by this regulation. Promulgation of these amendments to 12VAC5-391 creates 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 patients 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.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar's office, please put an asterisk next to any substantive changes.

Section number	Requirement at proposed stage	What has changed	Rationale for change
10	Definition of 'bereavement services' as taken from 42CFR418.3 in narrative	Definition amended to reflect 42CFR418.3 Added 'adverse outcomes' and 'separate and distinct entrance	Since many hospice providers are Medicare certified, and Medicare remains the primary payer source for hospice services, it makes sense to assure that Virginia's regulatory definition of bereavement services comports with the federal definition. By citing the applicable regulation, the definition can be changed or modified without having to subsequently amend the state regulation. 'Adverse outcomes'

			added to clarify for providers when it is necessary to report medication errors to OLC. "Separate and distinct entrance' added to allow for administration of community hospice services from a facility, but traffic is to be diverted from patient care areas.
120	C: Convenience prohibition addresses only the hospice provider	C: Added 'primary caregiver' and 'family' D/E: Placement of language switched.	Result of public comment, added reinforce that the decision to enter a hospice facility is between the patient and the physician. Clarifies the intent that hospice facility providers are to accommodate the needs of those patients residing in their own dwellings that might need respite or symptom management to the extent that beds are available in the facility.
160	K: Includes only inclement weather and natural disasters to planning for emergencies	H: Amended to reflect statutory language K: 'Pandemic disease outbreaks' added	Amended to comport with statute. Adds pandemic diseases outbreaks to required planning for emergencies such as hurricanes or flu, conforms with Virginia's emergency planning efforts
180	Subsection D requires administrators to understand the interrelationship between state licensure programs and national and federal certification programs References the Joint Commission on Accreditation of healthcare organizations	Amended to include an understanding of applicable state laws and regulations. Amended to read: 'Joint Commission."	Ensures program administrators have knowledge of and a basic understanding of applicable Virginia laws and regulations and their interrelationship. Technical name change by the organization
300	Did not include regulation on pressure ulcers	Added subsection pertaining to pressure ulcer prevention	This is part of a national and VDH initiative to reduce pressure ulcers in

			Virginia. Since 2005, reduction of pressure ulcers has been a Governor's key performance measure in VDH's strategic plan. As a part of that ongoing requirement, OLC/VDH is adding this regulation as it revises all its program licensure regulations. The national rate of pressure ulcers is one of 2 areas of focus by CMS.
395	Stipulates actions to be taken in the event of a medication error or drug reaction	Amended to require reporting medication related adverse outcomes to OLC.	As the mandated oversight authority for hospice provider, OLC/VDH has a vested interest in events relating to quality of care such as mediation errors and drug reactions.
440	Did not require a separate staff entrance for community hospice programs	J: Added 'Separate and distinct entrance' requirement	Addresses a public comment by allowing providers the flexibility to provide community based program services from a hospice facility; while requiring traffic be divert from patient care areas.
445		Amended regarding food services applicability	Clarifies the applicability of the subsection as not all facilities will meet the commercial kitchen threshold of 13 or more unrelated persons.
450	Subsection B required that facility staff protect patients from accidents, injury or infection.	Amended to stipulate protection from avoidable accidents, injuries and infections	It was pointed out that it is an unrealistic expectation that staff protect patients from accident, injury or infection when caring for individuals whose physical condition may unavoidably result in an infection, injury or accident. However, some accidents, injuries and infections can be avoided if proper systems are in place. Therefore, the regulation was modified to reflect protections from avoidable accidents, injuries and infections.
480		Added note on family involvement	The note clarifies that

	Subsection D referenced only contracting for dietary consultation	in meals provision Allowed for employment of dietary consultation	families bring or preparing food at the facility are not subject to the subsection. The change provides clarification that a hospice facility provider may contract with or employ dietary consultation.
500	Dies not address service animals	Added exclusion of service animals Technical change in subsection D	Addresses a public comment that service animals are allowed anywhere the owner goes, including kitchens Syntax correction
510	Subsection D requires a telephone in each area where patients' are admitted with additional phone as necessary.	Specifies that phones shall also be available in patient rooms as well as common areas and where needed.	The amendment clarifies the intent of the regulation.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

Commenter	**Comment**	**Agency response**
Marcia Tetterton Executive Director, Virginia Association of Home Care and Hospice	Thank you for the opportunity to voice our support of the proposed regulations for the Licensure of Hospice [facilities]. As you are aware, a group of providers met several times to discuss the regulatory revision and the proposed regulations reflect the general nature of those meetings. The [Association] looks forward to moving forward with the regulations. Additional modifications have been made to make the hospice facility regulations consistent with current health care practices, such as requiring reporting of medical errors and drug reactions, a pressure ulcer prevention program plan and a [clarification regarding] false advertising. These modifications are appropriate and should be made.	Thank you.

Brenda Clarkson Executive Director, Virginia Association for Hospices (VAH)	12VAC5-391-10: Suggest: insert 'patient and/or family before and' after offered to the.	The definition has been amended to reference 42 CFR 418.3.
	12VAC5-391-120.C: Replace patient's physician with 'hospice [IDG]'	OLC/VDH disagrees and believes this regulation as written is an important and vital requirement. In addition to the ethical concerns related to provider self-referral, in Virginia there are also legal prohibitions regarding self-referral to provider owned entities. OLC/VDH also believes that a patient's decision to move to a hospice facility is a decision between the patient and physician, without pressure from the provider who has a financial interest in the decision. Once the decision has been made by the patient and his physician, then the facility provider can become involved.
	12VAC5-391-180: After Centers for, insert "Medicarcomments on the intended regulatory action e and Medicaid Services. Strike *JCAHO* as programs are choosing to obtain accreditation from other accrediting organizations.	OLC/VDH disagrees, the words 'such as' included in the regulation indicate the references to CMS and The Joint Commission are examples. It is apparent from the questions and comments that VDH staff routinely receive that many hospice providers, regardless of their size and organizational complexity, do not understand the relationship between licensure and national certification or accrediting organizations. Nor is there comprehensive understanding of the interrelationship with other applicable state laws and regulations. In Virginia, hospice programs *must* be licensed in order to conduct business. All certification or accrediting programs are voluntary on the part of the provider and are not necessary to operate a hospice business in Virginia.
	12VAC5-391-300. [C. Replace] hospitals with 'facilities' and 'receiving short-term in-patient hospice care' allowing for admission to a nursing facility.	OLC/VDH disagrees. A nursing facility is not an appropriate admission setting for handling medical complications that might arise.
	12VAC5-391-440.J.: Suggest adding 'and administrative offices of the hospice.'	OLC/VDH disagrees; the intent of the regulation is to limit the amount of non-facility patient traffic through patient care areas. However, we understand that some programs may want to consolidate administrative offices at the facilities. Therefore, the regulation has been amended to require a separate and distinct entrance when providing community based hospice care from the facility, so that traffic is diverted away from facility patient care areas.
	12VAC5-391-450.C. Strike after 'to meet the needs of each patient.'	OLC/VDH disagrees. The regulation was discussed and the language carefully vetted at the public stakeholder meeting; consensus was

		reached on the proposed amendments to the regulation.
	12VAC5-391-460.D.: [strike reference to consultant pharmacist], Insert: "ensure that the interdisciplinary group confers with an individual with education and training in drug management as defined in hospice policies and procedures, who is an employee of or under contract with the hospice to ensure that drugs and biologicals meet each patient's needs. The provided pharmacist services must include evaluation of a patient's response to medication therapy, identification of potential adverse drug reactions, and recommended appropriate corrective action.'	As stated in 12VAC5-391-130 regarding variances, OLC/VDH cannot waive the regulations of another state agency or to any requirements in federal, state or local laws.
	12VAC5-391-460.E.: Suggest [replacing] 'a pharmacist' with 'the pharmacist.'	There does not appear to be any advantage to such a change.
	12VAC5-391-460.H.: Suggest [replacing] 'a pharmacist licensed in Virginia' with 'a licensed pharmacist.'	As stated in 12VAC5-391-130 regarding variances, OLC/VDH cannot waive the regulations of another state agency or to any requirements in federal, state or local laws.
	12VAC5-391-480: VAH considers the entire chapter burdensome to the point of inhibiting the development of small hospice facilities that are designed to take the place of a person's own home and recommends it be eliminated. VAH recommends language similar to the new Medicare conditions of Participation	OLC/VDH disagrees. When a provider decides to offer facility services, the provider also accepts the responsibility to meet state and national standards for operating that facility. History and experience have shown 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. That fact is not impacted by regulatory compliance requirements which are designed to protect the health, safety and welfare of hospice patients.
	12VAC5-391-500.D.3: Strike: recommended or	OLC/VDH disagrees. This section as presented in the proposed regulation was expanded from the working draft at the request of VAH. Any pet residing in a communal environment such as a hospice facility should have all immunizations, recommended as well as required.
	12VAC5-391-510: Replace: areas to which patients are admitted with 'patient room'	The regulation has been amended.
Sue Ranson President Good Samaritan Hospice President of the Virginia	12VAC5-391-120.C: Replace patient's physician with 'hospice [IDG]'	OLC/VDH disagrees and believes this regulation as written is an important and vital requirement. In addition to the ethical concerns related to provider self-referral, in Virginia there are also legal prohibitions regarding self-referral to provider owned entities.

Association of Hospices		
	12VAC5-391-140: strike: dedicated	Thank you, but section 140 is not part of this regulatory action. However, note of the comment has been made for future regulatory amendments.
	12VAC5-391-120.E: strike to the extent possible Add: 'These services may be provided under contract with other facilities that meet regulatory requirements for short-term inpatient care.'	OLC/VDH disagrees. This regulation was discussed and the language carefully vetted at the public stakeholder meeting held to reach consensus on the proposed amendments. However, OLC/VDH believes there is confusion regarding this regulation and has amended it for clarity. The intent is to require those providers that also operate a hospice facility to provide any needed respite and symptom management for their patients remaining in their own homes, should the patient or family need such services in a facility. Regardless of the living situation of the patient, however, the hospice program is responsible for providing respite and symptom management to their clients. Failure to provide respite and symptom management may result in a cited deficiency or nonrenewal of a license.
	12VAC5-391-180: Strike after state licensure add: 'governmental regulatory organizations'	OLC/VDH disagrees as explained above.
	12VAC5-391-440J: Add: 'or for other hospice services provided by the hospice.'	The regulation has been amended to require a separate and distinct entrance when providing community based hospice care from the facility, so that traffic is diverted away from facility patient care areas.
	12VAC5-391-445C: Strike this section	OLC/VDH disagrees. As stated in 12 VAC5-391-30, OLC/VDH cannot waive the regulation of another agency or any requirements of federal, state or local laws. Any facility with 13 or more beds must obtain a commercial kitchen license. Hospice facility law allows for up to 16 beds in which case compliance with becomes 12VAC5-421 is mandatory. However, OLC/VDH has modified the regulation for clarity.
	12VAC5-391-450. Strike B and C. Replace with: 'The facility must have sufficient nursing staff to provide nursing and related services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care. The nursing needs of patients may be met by the hospice's home care nursing staff as long as the patient's	OLC/VDH disagrees. This regulation was discussed and the language carefully vetted at the public stakeholder meeting and consensus was reach on the proposed amendments.

	needs are met. A registered nurse must be available 24/7 and able to respond to emergent calls within twenty minutes.'	
	12VAC5-391-460.Strike D. Replace with: Each facility shall ensure "that the interdisciplinary group confers with an individual with education and training in drug management as defined in hospice policies and procedures and State law, who is an employee of or under contract with the hospice to ensure that drugs and biologicals meet each patient's needs." (42 CFR 418.106(a) The provided pharmacist services must include evaluation of the patient's response to medication therapy, identification of potential adverse drug reactions, and recommended appropriate corrective action."	As stated in 12VAC5-391-130 regarding variances, OLC/VDH cannot waive the regulations of another state agency or to any requirements in federal, state or local laws.
	12VAC5-460.H. Strike	OLC/VDH disagrees. There is a need for such regulation in light of the numerous medications patients are given and the potential for severe adverse reactions or complications. OLC/VDH believes such reporting is essential to ensuring quality patient care. However, we have added a definition of adverse outcome to clarify when a report to the OLC is necessary.
	12VAC5-391-480. B. Strike assigned food service	OLC/VDH disagrees and believes the regulation has been misinterpreted. For smaller bed facilities, it is expected that staff would wear many hats. The intent of the regulation is to assure that regardless of the size of the facility, staff and patients know who can assist in preparation of meals and snacks. For larger facilities, this might require dedicated food service staff.
	12VAC5-391-480.[C] After: licensed by [VDH]. Insert: 'If meals are routinely provided by a food service establishment,' there	OLC/VDH disagrees. Unless food is prepared on the premises of the facility, all catered food shall be obtained from a food vendor licensed by the department. That is current law. OLC/VDH also believes this regulation is even more important in light of the recent increase in food borne illnesses affecting Virginians and any potential impact on compromised immune systems. However, this regulation does not apply to meals prepared by a patient's family members and brought to the patient.
	12VAC5-391-480.D. After shall contract, insert 'or employ'; strike a consulting; strike food service personnel, insert 'staff'; strike shall,	OLC/VDH agrees to add 'or employ'; however, other changes offered do not enhance or improve the regulation as currently written.

	insert 'may';	
	12VAC5-391-480. Strike E – O. Replace with "Food shall be stored, prepared, and served in an area and manner that promotes hygiene, safety and patient satisfaction.'	OLC/VDH disagrees. As explained under 'Issues' above, these regulations have been carefully considered and moderated to accommodate the smaller size facility preferred by providers, while still meeting the minimum national, state and community standards for facility operation, without being onerous or burdensome to providers. When a provider decides to offer facility services, the provider also accepts the responsibility for operating that facility in a manner that meets or exceeds standards or expectations.
	As I ponder the intention of regulations surrounding hospice facilities (which I see more as "residences"), my hope is that we can go back to the original conversations about why hospices want to have hospice residences: some hospice patients just cannot stay at home to die and prefer to be in a place that is like a home (not a facility) for the end of their journey. I do not question the need for regulations. I do wonder, however, if parts of these proposed regulations (especially those regarding food service), would more than likely discourage hospices from carrying forward their vision to have a residence, thus failing to meet a significant community need. I have a vision that someday Good Samaritan Hospice will have a hospice "residence", or a hospice "house" for 4-5 patients. It is also my hope that these regulations will encourage us to move forward with that vision.	OLC/VDH recognizes that the intent of these facilities is to look like a residence. However, these entities are medical care facilities as defined in the Code of Virginia. When a provider decides to offer facility services, the provider also accepts the responsibility to meet state, national and community standards for operating that facility. In developing the proposed regulations, OLC/VDH relied on the available hospice facility regulations of other states, replicating many of those standards in this endeavor. Since these facilities will be located in residential areas, OLC/VDH also focused on addressing appropriate quality patient 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. Therefore, many of the regulations were moderated to accommodate the planned smaller capacity of a hospice facility. History and experience have shown 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, regardless of focus. That fact is not impacted by regulatory compliance requirements. 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. There is nothing in these regulations that prevents Good Samaritan from moving forward with their vision for a hospice facility.
Sharon Britt Hospice of the Piedmont	12VAC5-391-160.L: should read 'the hospice facility' not the hospice program	OLC/VDH disagrees. Section 160 and that regulation are applicable to all hospice providers, not just facility providers.
Pat Bishop Blue Ridge	We agree with most of the comments that will be sent from the	OLC/VDH disagrees as explained previously.

Hospice	VAH. Some of the proposed regulations may be difficult and cost prohibitive for some hospices, especially smaller hospices…in particular the requirements for dietary services may be difficult for smaller hospices to meet.	
Kathy Clement Hospice of the Rapidan	12VAC5-391-120: This should be the decision of the patient and the caregiver in consultation with the hospice IDG and the patient's attending physician as needed.	OLC/VDH disagrees as explained previously.
	12VAC5-391-180: Strike reference to JACHO. This may be seen as an endorsement by some hospices as the appropriate accrediting body	OLC/VDH disagrees, the words 'such as' included in the regulation indicate the references to CMS and The Joint Commission are examples.
	12VAC5-391-300: To have a preventive pressure ulcer prevention program required by the state regulations seems to disregard the type of patients hospice programs are caring for. Suggest instead a program focused on decubitus ulcer prevention when possible and appropriate that is included in the regular teaching program that is done with families and caregivers to support them in their care for their loved ones.	OLC/VDH suggests that the suggested family/caregiver program would be part of any hospice program's overall program to prevent program acquired pressure ulcers. Patient advocates declare all pressure ulcers are avoidable, however the national rate remains high and Virginia's rate is in excess of the national rate. Since 2005, reduction of pressure ulcers has been a Governor's key performance measure in VDH's strategic plan. As a part of that ongoing requirement, OLC/VDH is adding this regulation as it revises all its program licensure regulations. The national rate of pressure ulcers is one of 2 areas of focus by CMS.
	12VAC5-391-395: In order to obtain palliation of symptoms such as pain, hospice patients may receive high doses of medications with an occasional side effect, of that high dosing, being an undesirable outcome. What will be done with this report within [OLC/VDH], how will it be used and what authority rests… to collect this information.	OLC/VDH's understands that the combinations of medications used by some hospice patients can resulted in unintended outcomes through no fault of the provider. However, OLC also believes medication errors can indicate a system failure within a provider's organization that can have serious quality of care consequences and is adding adverse event reporting to all its program licensure regulations as they are revised. We cite §§ 32.1-19.C and 32.1-162.5 as the statutory authority to be informed when adverse outcomes result. The intent is to use the reports as a survey preparation tool, data analysis of type and frequency of medication errors for targeted provider training, and to identify those providers needing additional oversight support. To assist in determining when adverse outcomes should be reported, we have added a definition of 'adverse outcomes' in section 10.
	12VAC5-391-440.I: Hospice providers should have the flexibility to … determine community need	The regulation has been modified to allow for the provision for other hospice patient care services to be administered from the facility

	and what other parts of the program to place within the facility.	
	12VAC5-391-440.J.: Suggest adding 'and administrative offices of the hospice.' Seems to be ruling out that program administrative offices and the facility can be together.	The reader is correct; the intent of the regulation is to limit non-facility related traffic, including the program's administrative office. The facility is a residence for terminally ill persons, not the administrative office for the program. However, the regulation has been amended to require a separate and distinct entrance when providing community based hospice care from the facility, so that traffic is diverted away from facility patient care areas.
	12VAC5-391-450.C.: Suggest [ending] at "the hospice shall have sufficient numbers of trained and supervised staff to meet the needs of each patient.'	OLC/VDH disagrees as explained previously.
	12VAC5-391-460.E.: Suggest [replacing] 'a pharmacist' with 'the pharmacist.'	OLC/VDH disagrees as explained previously.
	12VAC5-391-460.H.: Suggest [replacing] 'a pharmacist licensed in Virginia' with 'a licensed pharmacist.'	OLC/VDH disagrees as explained previously.
	12VAC5-391-460.J.: Suggest striking whole regulation or requiring that the drug container must be intact and sealed from the pharmacy with no signs of tampering.	OLC/VDH is unable to impose requirements on entities that are within the regulatory arena of another state agency, in this case, the Board of Pharmacy.
	12VAC5-391-480: Suggest [using the food preparation language] that is closer to federal regulations … especially in some of our smaller rural areas. Much of this section reads… like regulations for nursing homes or assisted living facility.. does not take into account [hospice patients] with decreasing appetites and variable intake needs.	OLC/VDH's suggests there is some confusion regarding the focus of this section. OLC is aware that hospice patients have a decreased appetite and variable intake needs, especially those in the active stages of the dying process. The approach taken in developing this section was to assure proper food handling across the broad spectrum of potential hospice facility providers, from the small 4 bed facilities to the larger 16 bed facilities. Since these facilities will been caring for two or more unrelated persons, the regulations proposed are the minimum needed to assure proper food handling.
Beverley Soble Vice President Regulatory Affairs Virginia Health Care Association	12VAC5-391-450.B: suggest inserting 'avoidable' after and protected from	OLC/VDH agrees and has made the change.
Judy Mathews, RN, MSN Augusta Healthcare	[The 2005 revised regulation removed the Joint Commission deemed status provision.] I would like to see the exemption for licensure survey put back into the hospice regulations.	Thank you for the comment, however the provision was removed from regulation as deemed status is not permitted by law.

Becky Bowers-Lanier Legislative Consultant Macaulay & Burtch, PC On behalf of the Executive Director and the Board of Directors of the Virginia Association of Hospices and Palliative Care	12VAC5-391-300: after 'arise' insert: <u>that are unrelated to the terminal diagnosis or require treatment in a hospital.</u> This clarifies 'medical complications and assists [providers] in determining the events that would necessitate transfer to hospitals.	OLC/VDH disagrees; medical complications are individual to each patient and subject to onsite observation and assessment of medical personnel providing care.
	12VAC5-391-300.F: insert after 'ulcers': <u>whenever possible and palliate associated pain and discomfort</u>	OLC/VDH suggests that 'palliating associated pain and discomfort' would be part of any hospice program's overall program to prevent program acquired pressure ulcers. Patient advocates declare all pressure ulcers are avoidable, however the national rate remains high and Virginia's rate is in excess of the national rate. Since 2005, reduction of pressure ulcers has been a Governor's key performance measure in VDH's strategic plan. As a part of that ongoing requirement, OLC/VDH is adding this regulation as it revises all its program licensure regulations. The national rate of pressure ulcers is one of 2 areas of focus by CMS
	12VAC5-391-395.A: strike the second sentence. We believe tat creating a mandatory adverse drug reaction reporting system through regulation goes beyond the scope of statutory authority of the Board of health and therefore, we oppose the requirement on that basis.	OLC/VDH's understands that the combinations of medications used by some hospice patients can resulted in unintended outcomes through no fault of the provider. However, OLC also believes medication errors can indicate a system failure within a provider's organization that can have serious quality of care consequences and cites§§32.1-19.C and 32.1-162.5 as the statutory authority to be informed when adverse outcomes result. We have added a definition of 'adverse outcomes' to assist providers in determining when negative outcomes are appropriate for reporting. OLC is adding adverse event reporting to all its program licensure regulations as they undergo revision.
	12VAC5-391-440 J: add after 'care': <u>and related hospice services</u>	The regulation has been modified to allow for the provision for other hospice patient care services to be administered from the facility
	12VAC5-391-480.A: add: <u>The hospice must furnish meals to each patient that are:</u> 1. <u>Consistent with the patient's plan of care,</u>	OLC/VDH's suggests there is some confusion regarding the focus of this section. There is nothing in the section that prohibits families of hospice patients from providing favorite foods and beverages. In addition, OLC is aware that

	nutritional needs and therapeutic diet 2. Palatable, attractive and served at the proper temperature 3. Obtained, stored, prepared, distributed and served under sanity conditions. And striking subsections B and D through O We recommend simpler language that is less burdensome for hospices and which does not prevent families from participating in providing favorite food and beverages to hospice patients.	hospice patients have a decreased appetite and variable intake needs, especially those in the actively dying. The approach taken in developing this section was to assure proper food handling across the broad spectrum of potential hospice facility providers, from the small 4 bed facilities to the larger 16 bed facilities. Since these facilities will been caring for two or more unrelated persons, the regulations proposed are the minimum needed to assure proper and safe food handling.
Sherry Confer Deputy Director Virginia Office for Protection and Advocacy	The Virginia Office for Protection and Advocacy appreciates the Office of Licensure and Certification's (OLC) effort to enhance protections for patients receiving hospice services yet reinforcing efforts to maximize the patients' independence, and to require providers to exercise good business sense while providing a service that is based on dignity and respecting personal decisions of the patients.	Thank you.
	12VAC5-391-120: VOPA recommends that this exemption include at the discretion of or for the convenience of the primary caregiver or family. That is not to say that we do not support using the hospice facility for respite services	OLC/VDH agrees and modified the regulations accordingly.
	12VAC5-391-160.B: VOPA recommends that OLC specify the Americans with Disabilities Act, the Virginians with Disabilities Act, and the Health Care Decisions Act at a minimum. Providers may already be aware of the regulations and best practices specific to hospice services, but other laws and regulations impact the provision of services in general. 12VAC5-391-160.D: VOPA recommends that the OLC address including the patient, primary caregiver and family in the inspection process They could	The three Acts listed are certainly important to patient dignity and quality care. To list all applicable laws in regulation is not recommended lest an equally important reference be omitted. Compliance with all applicable laws and regulations is contained in the Virginia laws for hospice as well as within the regulation in 3 places. However, OLC/VDH will file this comment and monitor consumer complaints for potential future action. OLC/VDH agrees that the inspection process is more than a document review exercise and believes that patients and families are given an opportunity to participate in the inspection process via the home visit as well as by filing

	participate in determining compliance or investigating complaints. This will clarify that the inspection is much more than a document review. 12VAC5-391-160.K: The Department of Health has taken the lead with educating the public about the H1N1 virus pandemic potential. VOPA suggests that the emergency preparedness plans include addressing pandemic and outbreak situations in addition to the natural disasters.	complaints. Both these avenues to participate can be accomplished anonymously if desired. Consumers may also participate in the regulatory process via public participation as required in the APA. The regulation has been amended.
	12VAC5-391-180.C: VOPA recommends that the OLC specify that addressing complaints and monitoring the complaint process be identified as a responsibility of the administrator.	OLC/VDH considers complaint monitoring part of the administrator's duty to organize and supervise the administrative functions of the organization. However, OLC/VDH will file this comment and monitor consumer complaints for potential future action.
	12VAC5-391-300.C: VOPA recommends that the patient, primary caregiver, and family be made aware in advance that this agreement is in place. This will increase the patient's involvement in the planning of their care and will help to optimize their choice of hospital providers.	OLC/VDH considers that, in addition to being a critical aspect of quality patient care, a hospital transfer agreement serves as a marketing tool that should be part of any program's admission practices and public information program. However, OLC/VDH will file this comment and monitor consumer complaints for potential future action.
	12VAC5-391-395: VOPA strongly supports the OLC in including these proposed regulations. This is an important safeguard that increases patient protection and requires the provider to review and modify if necessary procedures and duties; basic quality assurance strategies.	Thank you.
	12VAC5-391-440: VOPA recommends that the ADA and VDA be noted here. Although the Uniform Statewide Building Code includes aspects of the ADA, the ADA also includes reasonable accommodations.	The Acts listed are certainly important to patient dignity and quality care. OLC/VDH can assure consumers that state and federal disability acts are inherent parts of national and state building codes as well as part of the AIA standards required by OLC/VDH. However, OLC/VDH will file this comment and monitor consumer complaints for potential future action.
	12VAC5-391-450: VOPA strongly supports the OLC's effort to ensure that appropriate staffing levels are provided. Facility based hospice services are provided by people and people must be <u>at the facility</u> in order to provide the services. These	Thank you.

	patients are in the end-stages of terminal illnesses and conditions and they are individuals. There is no guarantee that a care plan can be developed to address every need of a unique individual as he or she faces this phase of their life. Staff must be available to respond. In addition, this is a minimal safeguard in the event a patient wanders, a hydrating tube gets clogged, a smoke detector alarms and so on.	
	12VAC5-391-500: There needs to be clarification that service animals for people with disabilities are not pets and are thus not confined in the same manner as other animals which are merely pets. Services animals are allowed in any area where the resident is allowed, including dining areas. Service animals must be permitted at every facility, regardless of its pet policy.	Thank you, the section has been clarified to allow for service animals.
	This portion of the Hospice regulations makes no mention of the need to prevent, monitor, and report incidents of alleged abuse, neglect, or exploitation. We recommend that OLC add such requirements while including language that alerts providers, patients, primary caregivers, and family members to these issues. Also, we recommend that OLC clarify the expectation that patient confidentiality be protected.	That is correct, only those portions of the regulation regarding the provision of care in a facility were opened for amendment. However, a hospice facility provider is subject to the regulations of the entirety of 12VAC5-391, abuse, neglect, and exploitation are covered elsewhere. This comment will be kept on file for review when we seek to revise the entire regulation.
	The proposed regulations specifically address accessibility issues regarding physical barriers (12VAC5-391-440A), they fail to address non-physical barriers. Of particular concern are effective communication access issues for persons with low-literacy abilities and those who are deaf or hard of hearing. Hospices and their staffs have an obligation to provide effective communication between the Hospice staff and the patient, the primary caregiver, and other family members – including the need to use sign language interpreters, language translators,	Thank you for the suggestion. Only those portions of the regulation regarding the provision of care in a facility were opened for amendment. However, a hospice facility provider is subject to the regulations of the entirety of 12VAC5-391, patient rights are covered elsewhere. OLC is adding patient communications to all its program licensure regulations as they undergo revision. This comment will be kept on file for review when we seek to revise the entire regulation.

	and low-level reading materials as necessary. We think that the regulations should directly acknowledge this effective communication obligation.	

Enter any other statement here

All changes made in this regulatory action

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

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
10		Definitions	Added 'hospice facility' based on passage of HB1965; Amended 'inpatient' for consistency between regulatory chapters and to clarify meaning of inpatient care for hospice providers Added 'medication error' in response to added new section
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.	Amended the section to repeal interface with other licensing criteria; 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.
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	Adds hospice facility to the list of changes under which to notify VDH of changes to a hospice license; 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.

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.

Section number	**Requirement at proposed stage**	**What has changed**	**Rationale for change**
10	Definition of 'bereavement services' as taken from 42CFR418.3 in narrative	Definition amended to reflect 42CFR418.3 Added 'adverse outcomes' and 'separate and distinct entrance	Since many hospice providers are Medicare certified, and Medicare remains the primary payer source for hospice services, it makes sense to assure that Virginia's regulatory definition of bereavement services comports with the federal definition. By citing the applicable regulation, the definition can be changed or modified without having to subsequently amend the state regulation. 'Adverse outcomes' added to clarify for providers when it is necessary to report medication errors to OLC. "Separate and distinct entrance' added to allow

			for administration of community hospice services from a facility, but traffic is to be diverted from patient care areas.
120	C: Convenience prohibition addresses only the hospice provider	C: Added 'primary caregiver' and 'family' D/E: Placement of language switched.	Result of public comment, added reinforce that the decision to enter a hospice facility is between the patient and the physician. Clarifies the intent that hospice facility providers are to accommodate the needs of those patients residing in their own dwellings that might need respite or symptom management to the extent that beds are available in the facility.
160	K: Includes only inclement weather and natural disasters to planning for emergencies	H: Amended to reflect statutory language K: 'Pandemic disease outbreaks' added	Amended to comport with statute. Adds pandemic diseases outbreaks to required planning for emergencies such as hurricanes or flu, conforms with Virginia's emergency planning efforts
180	Subsection D requires administrators to understand the interrelationship between state licensure programs and national and federal certification programs References the Joint Commission on Accreditation of healthcare organizations	Amended to include an understanding of applicable state laws and regulations. Amended to read: 'Joint Commission."	Ensures program administrators have knowledge of and a basic understanding of applicable Virginia laws and regulations and their interrelationship. Technical name change by the organization
300	Did not include regulation on pressure ulcers	Added subsection pertaining to pressure ulcer prevention	This is part of a national and VDH initiative to reduce pressure ulcers in Virginia. Since 2005, reduction of pressure ulcers has been a Governor's key performance measure in VDH's strategic plan. As a part of that ongoing

			requirement, OLC/VDH is adding this regulation as it revises all its program licensure regulations. The national rate of pressure ulcers is one of 2 areas of focus by CMS.
395	Stipulates actions to be taken in the event of a medication error or drug reaction	Amended to require reporting medication related adverse outcomes to OLC.	As the mandated oversight authority for hospice provider, OLC/VDH has a vested interest in events relating to quality of care such as mediation errors and drug reactions.
440	Did not require a separate staff entrance for community hospice programs	J: Added 'Separate and distinct entrance' requirement	Addresses a public comment by allowing providers the flexibility to provide community based program services from a hospice facility; while requiring that traffic be diverted from patient care areas.
445		Amended regarding food services applicability	Clarifies the applicability of the subsection as not all facilities will meet the commercial kitchen threshold of 13 or more unrelated persons.
450	Subsection B required that facility staff protect patients from accidents, injury or infection.	Amended to stipulate protection from avoidable accidents, injuries and infections	It was pointed out that it is an unrealistic expectation that staff protect patients from accident, injury or infection when caring for individuals whose physical condition may unavoidably result in an infection, injury or accident. However, some accidents, injuries and infections can be avoided if proper systems are in place. Therefore, the regulation was modified to reflect protections from avoidable accidents, injuries and infections.
480	Subsection D referenced only contracting for dietary	Added note on family involvement in meals provision Allowed for employment of dietary consultation	The note clarifies that families bring or preparing food at the facility are not subject to the subsection. The change provides clarification that a hospice

	consultation		facility provider may contract with or employ dietary consultation.
500	Does not address service animals	Added exclusion of service animals Technical change in subsection D	Addresses a public comment that service animals are allowed anywhere the owner goes, including kitchens Syntax correction
510	Subsection D requires a telephone in each area where patients' are admitted with additional phone as necessary.	Specifies that phones shall also be available in patient rooms as well as common areas and where needed.	The amendment clarifies the intent of the regulation.

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.

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 anticipated direct impact on the family or on family stability.