Virginia Regulatory Town Hall

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Final Regulation
Agency Background Document

Agency name	Department of Health
Virginia Administrative Code (VAC) citation	12 VAC 5-391
Regulation title	Regulation for the Licensure of Hospice
Action title	Promulgation of final regulation
Document preparation date	April 7, 2005

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) 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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

12 VAC 5-391 Rules and Regulation for the Licensure of Hospice is a comprehensive revision of the Commonwealth's regulation addressing hospice programs. The purpose of the regulation is to assure quality health care and provide the necessary consistency in hospice care in order to protect public health, safety, and welfare. A hospice program provides care to meet the physical, psychological, social, spiritual and other special needs that are experienced during the final stages of illness, and during dying and bereavement. Because of the extensive revision to the current regulation (12 VAC 5-390), the Department proposed replacing the current hospice regulation, adopted in 1990, with the proposed regulation. To accomplish this, the current regulation is repealed as the proposed regulation is promulgated.

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 April 4, 2005, the State Board of Health voted to adopt the proposed regulation 12 VAC 5-391 (Rules and Regulations for the Licensure of Hospice) and concurrent repeal of the existing regulation 12 VAC 5-390.

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 Section 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. Such regulations shall include, but not be limited to, the requirements for: the qualifications and supervision of licensed and non-licensed personnel; the provision and coordination of inpatient care and home treatment and services; the management, operation, staffing and equipping of the hospice program; clinical and business records kept by the hospice; [and] procedures for the review of utilization and quality of care." Therefore, this authority is mandated.

The General Assembly has also recognized the need to update the regulation. In 1998, the General Assembly adopted Senate Joint Resolution 164 (SJR164), which requested the Board of Health to begin the process of reviewing and revising the regulation governing hospice.

Section 32.1-162.5 of the Code and SJR164 are available through the Virginia Division of Legislative Services LIS web site (http://leg1.state.va.us/lis.htm).

The proposed regulation does not exceed federal minimum requirements. The Office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed regulation and that it comports with applicable state law.

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.

The existing regulation governing hospice programs (12 VAC 5-390) has not been revised since first promulgated in 1990. Since then, the hospice industry has evolved and expanded. Responsible for regulating medical care facilities and related services, the Department recognized the need to update the regulation to reflect changes that have occurred in the hospice industry during the last decade. At the same time, the Department wanted to develop a more provider-oriented document. Simply revising the current regulation, however, would not achieve the goal of developing a document that could serve as a "customer service" manual while providing the necessary regulatory controls. The department, therefore, chose to replace the current regulations and promulgate a new regulation in its place. The approach used in

developing the proposed regulation was to strive for clarity, simplicity, avoiding overly burdensome criteria while meeting the requirements of the law.

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.

The Department has long recognized the need to update the current regulation governing hospice programs to: (i) address in greater detail the services that are unique to hospice programs such as volunteer services, bereavement counseling, family-focused service rather than patient-centered service, palliative versus curative care, and the interdisciplinary team approach to service provision, (ii) reorganize the regulation into a user-friendlier format, and (iii) reconcile the state regulatory requirements with the federal regulations, where appropriate to eliminate contradictions.

Because of the extent of the planned revisions, the Department has opted to replace the current hospice regulation (12 VAC 5-390). For example, the "General Information" section of the current regulation does not provide adequate instructions for obtaining and maintaining a license, responding to an inspection report, or conducting home visits. Other changes to be considered include implementing financial control standards; enhancing patient rights standards, including criminal record clearances, enhancing quality assurance standards, and adding standards for dedicated hospice facilities.

The regulation governs the licensure of hospices except those programs "established or operated for the practice of religious tenets of any recognized church or denomination which provides care and treatment for the sick by spiritual means without the use of any drugs or material remedy" pursuant to section 32.1-162.2 of the Code of Virginia.

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.

The proposed regulation (12 VAC 5-391) is intended to reflect the changes in the industry over the last decade while providing the necessary safeguards to assure safe, adequate and efficient hospice program operation. The primary advantage to the public and the provider community, as a result of that effort, is the enhancements made to the regulation that include:

1. Modifying the insurance or indemnity section of the regulation;
2. Adding "home visits" as part of the inspection;

3. Adding standards for "dedicated hospice facilities;"
4. Adding standards on pain management;
5. Updating the quality assurance criteria;
6. Adopting a biennial inspection protocol;
7. Coordinating standards to eliminate contradictions with federal certification requirements, i.e., Medicaid;
8. Correcting the medical record criteria to remove mistaken references and to reflect correct record keeping practices;
9. Ensuring the regulation is clearly understandable by updating the language and eliminating ambiguities providing clearer guidance for providers; and
10. Reorganizing the regulation into a user-friendly format. The new arrangement is logical and orderly, facilitating use of the regulation.

In addition, the fees charged for licensure have been restructured. State general funds and licensure service fess based on a hospice's annual budget finance the hospice licensure program. The Department conducts the annual licensure inspections of home care organizations, processes Medicare certifications for home health and hospice organizations, investigates complaints filed against hospice and home care providers, and conducts the inspection program for hospice programs. Historically, tax dollars have subsidized a disproportionate share of the licensure program and will continue to pay a major share of the cost of the program. A goal of recent Administrations has been to relieve the tax burdens on Virginia's citizens. One way to achieve relief is to have state licensing programs become more self-sufficient. The Department is increasing certain fees, establishing new fees, and adopting a biennial inspection protocol to better support the cost of the program. The Department acknowledges that the increases may seem dramatic, however, this is the first increase in fees since the regulation was fist promulgated in 1990. The proposed fee structure is based on the potential for action required by the Department regarding a program's licensure status, i.e., issuing initial and renewal licenses or as an assurance against late filing of licensure application paperwork. Even with a fee increase, the fees collected cover only 1/3 of the costs to conduct an inspection. The late fee is designed to be an incentive to file renewal applications on time and is not charged unless a complete and accurate application is received past the due date for filing a renewal application. The renewal period is timed to coincide with the expiration of the license. If a hospice fails to file a renewal application, it runs the risk of having its license expire.

No particular locality is affected more than another by this regulation. There are no disadvantages to the public, the Commonwealth, or the hospice industry as a result of the proposed regulation. Every effort has been made to ensure the regulation protects the health and safety of patients receiving hospice services while allowing providers to be more responsive to the needs of their patients. Failure to implement the regulation would cause the current regulation, which is outdated and not reflective of current industry practices, to remain in effect.

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	Definitions section	1. Added a definition for activities of daily living and counseling services 2. Amended the definitions of "administrator," "attending physician, "core services," "criminal record, " "home attendant," "inpatient," "medical record," "patient," "progress note," "staff," and "volunteer" 3. Deleted definition of "immediate"	1. Because the term "activities of daily living" was added to 12 VAC 5-391-400.A, a definition was added to provide clarity; a definition of "counseling services," a core hospice service, was previously omitted. 2. Changes are technical to provide additional clarity and do not alter the intent of the definition. 3. "Immediate" deleted and "within 24 hours" substituted in 12 VAC 5-391-280.J
20	Responsibility of the department	Deleted section	Does not conform to regulatory guidelines
50	License application; initial and renewal	C. Amended "organization's" to read hospice program's E. Amended "send a renewal application" to read "make renewal applications available"	C. Corrected for consistency. E. Acknowledges an operational change by the Center regarding licensure applications.
80	On-site inspections	A. Added periodic biennial inspection. Added "according to applicable law"	Allows flexibility in program administration and does not jeopardize patient safety Provider request
90	Home visits	A. Added subject to obtaining consent from the patient and patient's family or caretaker.	Provides clarification that patient consent is needed prior to a visit by an inspector.
120	Dedicated hospice facilities"	A. Changed 22 VAC 40-71-10 to read 22 VAC 40-71 D. and E. Added dedicated after "No" and before "hospice" in each subsection	A. Technical change D. Provided for clarity

Section number	Requirement at proposed stage	What has changed	Rationale for change
130	Variances	F. Sentence rewritten	Grammatical correction
150	Surrender of a license to the Center	Return was substituted for "surrender" in the section title and subsection A	Provider request -"return" seen as less punitive than "surrender"
160	Management and administration	I. This does not mean that a hospice program must accept new clients on an emergency basis during non-business hours was added. J. Deleted "in a patient's residence."	I. Clarifies that providers are not required to accept new clients during non-business hours, standardizing the requirement with the proposed home care regulation. J. Not necessary.
170	Governing body	B. Amended subsection regarding periodic review of program bylaws. C. Deleted ", when appropriate"	B. Amendment is technical and clarifies the intent of the requirement. C. Requested by a provider.
180	Administrator	C. Added effective date	Technical change
190	Written policies and procedures	C. 14. "§ 63.2-106" changed to § 63.2-1606 of the Code of Virginia	Corrects incorrect Code citation.
200	Financial controls	A. Inserted separate before "working budget" in the 2nd sentence.	To clarify that providers operating dedicated hospice facilities should have a working budget separate from a budget used for the program services.
210	Personnel practices	I.8 Changed "Infection-control" to read Infection control	Technical change
220	Indemnity coverage	B.2. Deleted "Blanket"	A technical change for clarification
240	Patient rights	B.8. Deleted "hospice"	Typo
250	Complaints	A.3. Changed to read "adult protective services unit of the local social services department	Technical change
260	Quality improvement	C. Added confidentiality to candidate's abilities and sensitivity in 2nd paragraph.	Provider request.
280	Medical record system.	J. Changed "immediate" to within 24 hours	Provider suggestion.
300	Hospice services	B. Deleted "spiritual support or counseling", "bereavement support", and "dietary or nutritional support." Renumbered remaining list F. Inserted "§54.1-3300 et seq." and "§ 54.3400 et seq.	B.Considered part of "Counseling services," see definition added in 12 VAC 5-391-10. F. Technical change
330	Medical direction	B. Admitting was substituted for "clinical"	Correcting incorrect usage.
350	Home attendant services	A.7. Deleted "and federal	Correcting incorrect

Section number	Requirement at proposed stage	What has changed	Rationale for change
		guidelines"	citation of federal regulations.
		F.1, 2, 4, and 5. Deleted "hospice"	Correcting technical errors
		F.6. Added: Have satisfactorily completed training using the "Personal Care Training Curriculum," Dated 2003, of the Department of Medical Assistance Services. However, the training is permissible for volunteers only.	Added to assist providers with training of nonprofessional volunteers.
360	Medical social services	A. Reduced requirement for experience from "3" years to 2 years. Inserted effective date	Compromise with request from providers for 1 year of experience. Technical change.
400	Volunteer services	A. Added activities of daily living; deleted "care and"	To clarify that volunteers, after training, can assist with these activities for patients. Clarifies that families receive only support from hospice providers.
430	Pharmacy services	C.5. Changed "." to ;	Corrects incorrect punctuation as required by the Style Manual.
440	General facility requirements	G. Added permitting and the nearest regional permitting office for; deleted "a permit"	Corrects an incorrect citation
450	Required staffing	B. Deleted "have 2 or more registered nurses and 2 or more direct care staff, as appropriate to the needs of the patients, on duty at all times;" Added be based on the assessed needs of the patients in the facility. Deleted 2nd paragraph.	Provider request
460	Pharmacy services	H. deleted ; Relettered remaining subsections	Corrects a technical error
480	Food services	C. Added pursuant to 12 VAC 5-391-230	Cross references prior section for clarity.
500	Pet care	Added A and B to subsections	Technical changes for clarity.

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
Hospice of the Piedmont	391-360.A: Per federal regulations, the employee who provides social work as part of the IDT must be a social worker and cannot be a sociologist or psychologist. Counselors with various degrees can be employed in the provision of bereavement services only.	That may be true and providers receiving federal reimbursement are expected to comply with federal standards. However the inclusion of "sociologist" and "psychologist" in the standard is to provide flexibility for providers experiencing difficulty in hiring qualified individuals for their programs because of the shortage of available social workers.
	391-450: Hospice patients in residential facilities are followed by a case manager nurse and full IDG as are all patients in hospice no matter where they reside. Therefore staffing requirements may be too restrictive.	The standard was modified to allow providers to determine staffing levels based on the assessed needs of the patients in a dedicated facility. However, it is important to remember that providing hospice services to persons in residential facilities cannot be equated to actually operating a facility. Those hospice providers desiring to operate a dedicated hospice facility cannot expect to utilize the same personnel to cover both the facility and the program's home-based patients.
Pat Foutz BCC Hospital	There is no mention of volunteer services as a "core service" Are volunteer services only a suggested part or a mandated part?	The commenter is confusing the hospice "philosophy" with "core" services. Volunteers are an integral part of the hospice philosophy and are addressed in the regulation. However, volunteers are not a core service. Rather, volunteers would be used to provide core services.
James Giordano, Ph.D. Hospice of Central Virginia	391-10: Concerned that "dedicated hospice facility" may be construed to apply to contractual arrangement a provider may have with a hospital or nursing facility for the provision of inpatient services. Suggest a clarification in the definition to distinguish between existing contractual agreements and dedicated hospice facilities.	The provider community can be assured that the Center's inspection staff will not confuse "dedicated hospice facilities" with the contractual facilities associated with the hospice program to provide inpatient services.
	391-150.B: Suggest rewording to read: "An incomplete application shall become inactive within 6 months after it is received by the Center, unless deemed complete. If deemed inactive, applicants must reapply."	If an application is complete, it cannot be considered incomplete. The intent of the standard is to inform applicants that incomplete applications are void after 6 months and the applicant must reapply.

Commenter	Comment	Agency response
James Giordano, Ph.D. cont'd.	391-50.E: Suggest extending the term of licensure from 1 year to 2 years to mitigate the impact of the fee increase and help reduce the administrative burden involved in reapplying for a license ever year.	The Code of Virginia (§ 32.1-162.3) requires that hospice licenses be renewed annually. Therefore, the term of licensure cannot be changed without first amending the Code. It is important to remember that licensure fees have not been increased since first established in 1990. Current fees cover only 1/3 of the costs of the mandated licensure program, meaning that Virginia's taxpayers, many of whom do not utilize hospice services, are carrying the burden of paying for a program. The increase in fees is to address that inequity.
	391-80.A: Suggest adding "according to applicable law"	Agreed
	391-80.B: The program shall make available "any necessary records" which may involve confidential or privileged materials unrelated to requirements posed by the regulation. Suggest adding: "those records directly related to program compliance under the regulation and not otherwise protected from disclosure."	The commenter is confusing access to records by government officials with release of records to the public. The Code of Virginia (§ 32.1-25) stipulates that the State Health Commissioner, and his authorized designees (i.e., Center inspectors), has the right to inspect clinical and business records necessary to determine compliance with the regulation and the laws of the Commonwealth. In addition, the Center is a governmental oversight authority and, therefore, is not a "business associate" for the purposes of HIPAA.
	391-90.A requires the program to explain that home visits are voluntary, it should also indicate "with the consent of the patient's family or caretaker."	Consent of the patient and family is a given, the intent of the standard is to address client fears of retaliation *by the program* for speaking with inspectors. However, consent of the patient has been added.
	391-120 references to "hospice facility" or a "hospice facility provider" should read "dedicated hospice facility" for clarification.	The section is titled "*Dedicated* hospice facilities" (emphasis added) indicating that the requirements of the entire section are explicit for dedicated hospice facilities. However, "dedicated" has been added to subsections D and E as suggested.
	391-170.B: Suggest adding "resolutions or other governing documents to describe the hospice structure "	The intent of the standard is to ensure that the program's governing body reviews applicable management and operational policies of the organization. The dictionary definition of "bylaw" reads: "A rule or law governing the internal affairs on an organization," which would include "resolutions or other governing documents describing the hospice program structures."
	391-180.C: Suggest that "another clinical director" be considered.	Agreed – "or another clinical director" was added to the definition of Administrator in section 391-10.

Commenter	Comment	Agency response
James Giordano, Ph.D. cont'd.	391-220.B.2: Suggest amending as follows: Medical malpractice insurance covering the hospice program and all health providers who are employees of the hospice program with limits of liability no less that the maximum limit of liability imposed on such health care providers pursuant to § 8.01-581.15 of the Code of Virginia.	With the deletion of the word "blanket," we believe the standard is clear as originally stated.
	391-230.A: suggest: "Such contracts may include the use of licensed hospitals or nursing home inpatient beds from a separately licensed hospital or nursing facility. Such arrangement will not be considered a dedicated hospice facility."	The commenter is confusing "dedicated hospice facilities" with medical care facilities licensed as hospitals or nursing facilities. The definition of "dedicated hospice facility" is contained in 12 VAC 5-391-10 and is quite clear. All hospice providers are required to have contracts with hospitals or nursing facilities for the care of hospice patients needing inpatient care, which has not changed from the current regulation.
	391-230.D: seems to subject employees of a hospital or nursing facility to a separate criminal record check.	The law is quite clear regarding the requirements for criminal records checks (§ 32.1-162.9:1). The standard reflects the intent of the law.
	391-280.F: the requirements in this section may not necessarily apply to each patient, seems overly prescriptive, and may conflict with federal certification requirements.	The requirements in the section are minimal; many patient records may contain entries not listed in the section. A comparison of the requirements with the federal standards shows no conflict; the state regulation provides more detail to assist providers with the actual content of a patient record whereas the federal regulation provide only "broad scope" language. Since Center staff answer questions regarding the content of a patient record, we chose to be inclusive rather than exclusive in the content of the standard.
	391-360.A: Three years experience for social workers seems stringent. Suggest 1 year.	We do not believe that 1 year experience as suggested is adequate to address the needs of patients facing end of life decisions. The standard was reduced to 2 years experience.
	450.B: The minimum staffing levels for dedicated hospice facilities seem tighter than regulations in other states.	Actually, the language of the standard came directly from a sister state's hospice facility regulation. However, the standard has been modified.
	General comment: there are references to "business" and "working" days throughout the draft. Please be consistent.	The commenter is confusing the use of the two words; each word is used appropriately within the context of the standard in which it is found.
Bedford Hospice Care	391-180.D: how would they be available? Telecommunications?	A definition of "available at all times during operating hours," included in 12 VAC 5-391-10, reads: "an individual is available on the premises *or by telecommunication*." (emphasis added)

Commenter	Comment	Agency response
Bedford Hospice Care cont'd.	391-190.E.1: clarify authority	Clarification is not necessary, as the standard is not requiring a different interpretation of "authority" than can be found in any readily available dictionary.
	391-430.D: what type of training in infusion therapy	Infusion therapy is a specific medical procedure, not subject to "types" of training.
	391-450.A. why? Neither adult home nor ICF/MRs require this level of care	It is not appropriate to compare dedicated hospice facilities with adult homes or ICF/MRs. Since a dedicated hospice facility would be providing services to individuals who can no longer care for themselves and who are in the last stages of life, it is expected and appropriate that a registered nurse be available to respond to the medical needs of the dying.
Bell-Jo Rodgers Hospice Support Care of Williamsburg	391-10: Suggest differentiating between "hospice" which is a philosophy and the provider of that service.	The definition of hospice included in section 10 is a reiteration of state law, specifically § 32.1-162.1, and therefore, cannot be changed without legislative intervention. However, the term "hospice program" is used consistently throughout the text of the regulation to indicate the entity providing the services to the patient.
	The provisions in 391-300.F and 391-430 are new and would impose requirements upon hospice organizations that do not currently exist.	While the Center acknowledges that the requirements may be new to the commenter, the requirements themselves are not new, but a part of the laws and regulation of the Board of Pharmacy. The Center worked closely with the Executive Director for the Board on the language of those standards to assure compliance with the pharmacy laws and regulations. Hospice providers are not exempt from the responsibility of knowing the laws and regulations of other state agencies that are applicable to the services the hospice program provides.
Lori Showalter, Jeanne Apgar, Julie Smith, Linda King	391-400: Clarify that volunteers can assist patients with the activities of daily living. What are volunteers allowed to do regarding patient care?	Agree and added "including the "activities of daily living" to the standard, to clarify the duties of volunteers.
Unknown	391-350.D: clarify that direct supervision is not required every 2 weeks, but indirect supervision.	We believe the standard is clear as written.
	391-300.A: What about respite and continuous care?	If families require a respite, then it is expected that the hospice provider would arrange for respite of the patient. Such care should be addressed in the provider policies. If continuous care in needed, then it is expected that providers would follow current practices for determining the environment that is in the best interest of the patient, which may not mean a dedicated hospice facility.

Commenter	Comment	Agency response
	391-300.C: Add “dedicated hospice facility”	No, dedicated hospice facilities would not be providing inpatient services as defined in the regulation. Patients needing curative care should be transferred to a hospital or nursing facility.
	391-330.B: Medical director may not have clinical privileges at a hospital or nursing facility. Suggest using ”admitting.”	Agree – will substitute “admitting” for “clinical” in the standard.
Eve Bargmann, M.D. University of Virginia Health System	391-450: 1 RN round the clock for each 3-5 patients is a level of staffing not achieved by acute care hospitals, much less hospices.	That is an incorrect assumption. Hospitals would most certainly be required to have an RN on duty around the clock for 3-5 patients, if that was the number of patients in the hospital. Since a dedicated hospice facility would be providing services to individuals who can no longer care for themselves and who are in the last stages of life, it is expected and appropriate that a registered nurse be available to respond to the medical needs of the dying.
	391-460.H: must all chronic medications be stopped on admission to the facility? If so, this could cause much patient suffering.	That is certainly not the intent of the standard, which has been deleted.
Dee Eadie Northern Hospital of Surry County	391-160.I: where are the business hours to be posted, in the office, in admission paperwork.	There are several places where a program can post their hours. Examples include, but are not limited to: the main office door, the program’s web site, on the answering machine, on program brochure and advertising. The intent of the standard is to assist consumers in accessing the services offered.
	391-160.J: hospice patients are also admitted in hospitals and nursing facilities	That is certainly true. However, the standard is directed at the admission practices of hospice providers, not hospitals or nursing facility providers.
	391-200.D: please elaborate	The standard addresses a programs’ ability to safeguard against the misuse of its finances and to remain financially able, not just clinically able, to provide the care to the patients it has admitted to its services.
	391-210.C and D are new: need more info	The standards address a program’s oversight responsibility regarding the services it contracts out to other care providers. The program must have procedures in place to assure that its admitted patients still get the services they need should a contract care provider fail to or cannot provide a service as described in a patient’s plan of care. A hospice provider is not relieved from providing needed services should a contract service provider be unable to provide those services for whatever reason.
	391-350: visit with a CNA present still a requirement?	No, the CNA does not have to be present.

Commenter	Comment	Agency response
Dee Eadie, cont'd.	391-370.C: suggest "offer" as some family members refuse bereavement services	The standard addresses the length of time a program is expected to provide bereavement services, if the family chooses to accept those services after the death of their loved one. A family is under no obligation to accept the services from the program. Refusal of such services need only be noted in the patient's record.
	391-370.430: Interstate compact?	We do not understand the intent of the comment. However, it is expected that an entity hiring nursing staff would be in compliance with the laws and regulation of the Board of Nursing, including those related to the interstate compact requirements.

Commenter	Comment	Agency response
Susan Hogg Virginia Association of Hospice	391-10, "administer": does "controlled substance" mean all medications including OTC or strictly prescribed medications?	No, controlled substance does not include OTC medications.
	"full-time:" if an administrator only works 4 days a week or is shared by 2 programs, this may cause a problem	"full-time" was stricken from the standard.
	"attending physician:" need to include physicians working for the federal government in VA facilities. Also need to add nurse practitioners	No need to include military physicians, they are exempt under § 54.1-2901.17 of the Code and may practice in Virginia using their home state license. Language on nurse practitioners and physician's assistance was added.
	"core services:" remove dietary as a core service	Agreed, dietary is considered an element under the broader term of "counseling."
	"Criminal record report:" doesn't say Virginia State Police. Must this be the state police? Sometimes more advantageous to get a national report.	For the purposes of the regulation, the law requires only a report from the Virginia State Police. However, nothing prevents a provider from conducting a national report if they choose.
	"employee;" including volunteer corps, correct?	Yes, volunteers are employees without financial compensation.
	"Home attendant;" shouldn't this include CNA, it is believed most providers use CNAs.	Yes, CNA is added to the definition.
	"Immediately:" 24 hours does not sound immediate, suggest "by end of shift" or deleting definition and changing 391-280.J as it is the only place were immediate is used.	Agree, will delete definition and change 391-280.J. However, we disagree to the restrictive ness of "at the end of each shift." A provider may make such a policy decision if they choose to do so.
	"Medical record" and "progress note;" suggest changing "written" to documented, to allow for technology.	Agreed.
	"supervision:" remove "face-to-face" or clarify that this is not in patient's home for sup visits.	Do not agree - How else is a supervisor to assess the performance of an employee if not by "face-to-face guidance and instruction"?
	391-30.C: propose a definition of "hospice programs maintained at separate locations" to read "where patient and employee records are kept."	Do not agree. The law requires that each hospice program have a separate license. Therefore, each hospice would keep its own patient/employee records, even though owned or operated under the same management.

Commenter	Comment	Agency response
Susan Hogg Virginia Association of Hospice, cont'd.	391-70: recommend $100 –150 for renewal and re-issuance/ replacement or return to tiered approach	Do not agree. It is important to remember that licensure fees have not been increased since first established in 1990. Current fees cover only 1/3 of the costs of the mandated licensure program, meaning that Virginia's taxpayers, many of whom do not utilize hospice services, are carrying the burden of paying for the program. The increase in fees is to address that inequity.
	391-80.D: change to "date of the center's written letter and deficiency report" so that provider don't "start the clock" at the exit interview.	Do not agree – The sole purpose of the exit conference is to allow providers an opportunity to begin correcting deficiencies as quickly as possible after an inspection. Therefore, providers are expected to "start the clock" at the exit interview. As with any licensing program, hospice providers are expected to be in compliance with the applicable laws and regulations at all times, not only as a result of responding to deficiencies identified by an on-site inspection.
	391-80.G: change to "Center's written letter and deficiency report" as its best to work from a final report.	Do not agree. The purpose of the exit conference is to allow providers an opportunity to begin correcting deficiencies as quickly as possible after the inspection. It is not unreasonable to expect that deficiencies be corrected within 45 days of the *exit conference,* since providers are expected to remain in compliance with the standards *at all times* and not just as a result of deficiencies identified by an on-site inspection.
	391-110: want a national report permitted if law permits such.	The law does not prohibit a national report now; it requires only a check using the Criminal Records Exchange of the Virginia State Police. In fact § 19.2-392.02, grants permissive authority for providers to access the national criminal database of the FBI through the Virginia State Police, which is cheaper than using a commercial vendor to conduct the search.
	391-110.F.1: suggest adding "or other department"	Why? The standard has no impact on "other departments" owned or operated by the same entity." Such other departments would be required to follow the regulation under which they are licensed, if so required. This regulation has no authority "over another agency or any requirements in federal, state, or local laws."

Commenter	Comment	Agency response
Susan Hogg Virginia Association of Hospice, cont'd.	391-120.B: Oppose - providers may have to admit non-hospice residents for the facility to be economically viable.	It has been difficult to determine just how the hospice community perceives "dedicated hospice facilities." However, the original purpose for creating dedicated hospice facilities was to provide an environment catering to the unique needs of persons in the end stages of life. Admitting non-hospice persons to such a facility appears to contradict that purpose. In addition, our research showed that such facilities in other states are designed for the exclusive use of persons needing hospice services according to an order of their physician. That does not allow for the admission of non-hospice persons to such a facility.
	391-150.A change "surrender" to "return" – surrender sounds too punitive	Agreed
	391-160.E: Add "whenever possible" after "program" as it is feasible that an administrator could be fired and 30 days notice would not be possible, or add to E.4	Do not agree – the sole reason for the standard is provider failure to inform the Center of changes within their organization, such as Administrators leaving on their own accord. The standard emphasizes the obligation of hospice providers to keep the Center informed of changes affecting the basis for their license.
	391-190.C.9: end sentence at "when appropriate." Staffing is not sufficient to commit professional staff member to always accompany patient.	Do not agree – the standard allows the provider to determine when it is appropriate for a professional staff member, as opposed to a paraprofessional staff member, to accompany a patient to an inpatient facility.
	391-220: if the contractor is unable to provide the services, another team member will perform the duties.	That is the intent of the standard.
	391-240.B.11: giving 5 days notice to terminate services has never been practical.	The intent of the standard is to assure that patient's are given minimal notice of intended discharge in order to make plans for continuing care, including financial plans if they become ineligible for Medicare. It is not expected that providers would "carry the patient without billing," which is not fraud as suggested. Providers would be within their rights to expect rendered services to be paid for by the patient or patient's family. The standard is not applicable to patients opting to terminate services.
	391-240.D.4.a,b,c: please use the term insurance companies instead of third party payers. This term is misleading as it is not always third in line.	The "third party payers" term is a generally accepted business term meaning any source of income that is not from a patient's personal finances or from public reimbursement programs. It is not intended to mean only insurance companies or that the payer is "third in line."
	391-260.C.4: add confidentiality	Agreed

Commenter	Comment	Agency response
Susan Hogg Virginia Association of Hospice, cont'd.	391-270.D: have polices to address both types of and protocols for isolation of patients with infectious diseases."	The intent of the standard includes policies, as policies would need to be in place in order to have provisions for isolation of patients, if needed.
	391-280.F.want assurance that spiritual assessment may be part of another discipline's document, especially if spiritual services are nor requested by the patient.	There seems to be some confusion regarding the applicability of the regulation. The standard is not applicable to the patient, but to the provider. If a patient chooses to forgo the spiritual component of care, that is their right and choice. Refusal of such service need only be noted in the patient's record.
	391-280.G: suggest "documented within 24 hours of services," rather than 7 working days.	Disagree – it is not clear why the hospice community requests a tighter control than proven necessary. However, a provider is certainly able to set such a standard of practice for his program, as long as it's documented in the program's medical records procedures.
	391-280.J: strike "immediately" and insert "by the end of shift" after "in the medical record.	It is not clear why the hospice community requests a tighter control than proven necessary. However, a provider is certainly able to set such a standard of practice for his program, as long as it's documented in the program's medical records procedures.
	391-280.K: Thought minor records were kept 5 years or until the child would have reached 18, whichever is greater. Please check code and clarify.	The standard is correct as written. Providers have the option for keeping records longer than 5 years if they desire to do so. However, providers should be aware that state law requires that death records be kept for 10 years following the death.
	391-290.A: Insert "whenever possible" after "program." Add "4. Leaves service area" and "Admits to a non-contract facility."	There seems to be some confusion regarding the applicability of the regulation. The standard is not applicable to the patient, but to the provider. If a patient chooses to leave the service area or enter a non-contract facility, that is their right and choice. Such activities need only be documented in the patient's record.
	391-300.B: Critical, change "shall" to "may." B.7: concerned about the term "home attendant"	Do not agree – theses are the core services each program is to provide for their patients based on the patient's assessed needs. However, the standard was modified to correct the listing of services. Because of the confusion regarding the numerous and contradictory terms used to identify the program's paraprofessional staff, the Center developed the generic terms "home attendant" to encompass all non-professional personnel providing services to hospice patients. "Home attendant" is defined in section 10 of the regulation.

Commenter	Comment	Agency response
Susan Hogg Virginia Association of Hospice, cont'd.	391-300.C: Need to list "dedicated hospice facility" in keeping with the other changes to these regulations.	That is not correct. The intent of the standard is to assure that patients needing curative care not related to their terminal illness receive those services in the appropriate medical environment. It would be expected that the hospice provider would continue to provide hospice services to the patient admitted to a hospital or nursing facilities for the duration of the patient's stay in that facility.
	391-330.G: Medical directors may not have clinical privileges at the facility where contracts are held. Suggest removing this requirement.	For the purposes of admission, the medical director of the hospice program must have a professional link to the program's contract facilities. However, we agree that "clinical" is not appropriate and will substitute "admitting."
	391-350.D: Will get much more accurate, honest feedback on CNA services if RN can ask about satisfaction without the aide present.	That is the intent of the standard.
	391-350.F. 1, 2, 4: we do not know what these programs are 350-F.3: Since certification is mentioned here, it should also be added in the definition of home attendant	Will delete "hospice" Agree and have added "CNAs to the definition.
	391-360.A: Suggest striking "with major studies" and "sociology and psychology" Decrease 3 years to 1 year.	Do not agree. The inclusion of "sociologist" and "psychologist" in the standard is to address the current shortage of available social workers and the difficulty some providers have in hiring qualified individuals for their programs. We do not believe that 1 year experience is enough, however, we are willing to compromise with 2 years experience.
	391-370.C: a number of families refuse this services, recommend adding "unless refused by the family"	That is not necessary. Bereavement services for 1 year after death is a core hospice service and the standard addresses the expectation of the hospice provider, not the patient's family. The provider needs only notate the refusal of services by the family in the patient's medical record to be in compliance with the standard.
	391-380: Can dietary and nutritional counseling be provided through contract?	Yes.
	391-400.A: This means we can use volunteers if they have been properly trained as outlined in policies, correct?	Yes. However, for clarity, we have added "including the activities of daily living" and added a definition for "activities of daily living" in section 10.
	391-410.D: suggest adding" via consultation with other members of the IDG by phone or team meeting.	That is not necessary – the standard is clear as written. How members of an IDG communicate is up to the hospice provider to decide through its policies.

Commenter	Comment	Agency response
Susan Hogg Virginia Association of Hospice, cont'd.	391-440: The state must differentiate between inpatient and residential facilities to allow hospices to create the proper environment and for the facilities to become economically feasible.	It has been difficult to determine just how the hospice community perceives "dedicated hospice facilities." However, the original purpose for creating dedicated hospice facilities was to provide an environment catering to the unique needs of persons in the end stages of life. We have been quite clear in our discussions with the hospice industry regarding the establishment of dedicated facilities in Virginia. To clarify our intent, we have adjusted the definition of "inpatient" in section 10 of the regulation. However, that clarification does not prevent a provider from establishing a facility for the care of those facing the end of their lives.
	391-440.B: this is a good entry	Thank you.
	391-540.A. Oppose, a RN would only need to be on call. If Medicare should change its position on this, we would hate to see licensure {continue to] require one.	We disagree. We have understood from the hospice community that the purpose of establishing dedicated facilities was for the care of individuals *who could no longer care for themselves* – that requires medical oversight. The fact that Medicare currently requires RN oversight only serves to strengthen our argument that RN oversight is needed and, therefore, should be required. If Medicare should change its position, we will gladly revisit the issue.
	391-450.B: Oppose the detail here. Recommend the [provider] be required to have a staffing plan which delineates the ratios based on the bed type and acuity levels of patients.	As stated in your own comments "acuity has so much to do with the needs in hospice," we couldn't agree more. However, we will modify the standard to allow provider to determine staffing needs, based on the assessed needs of the patients, for facilities over 6 beds.

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
12VAC5-390-10	12VAC5-391-10	Definitions	Definitions were modified, deleted, or added to reflect the proposed document
	12VAC5-391-	Same as above	*Result of comment period*: 1. Added a

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
	10		definition for activities of daily living and counseling services. Because the term "activities of daily living" was added to 12 VAC 5-391-400.A, a definition was added to provide clarity; a definition of "counseling services," a core hospice service, was previously omitted. . 2. Amended the definitions of "administrator," "attending physician, "core services," "criminal record, " "home attendant," "inpatient," "medical record," "patient," "progress note," "staff," and "volunteer." Changes are technical to provide additional clarity and do not alter the intent of the definition. 3. Deleted definition of "immediate" "Immediate" deleted and "within 24 hours" substituted in 12 VAC 5-391-280.J
	20	Responsibility of the department	Deleted -does not conform to regulatory guidelines
12VAC5-390-20	12VAC5-391-40, 60, 130, 140, 150	General information	Not adequate to properly inform applicants of administrative requirements for licensure; new sections added address respectively: responsibility of the department, exemption from licensure, changes to or re-issuance of a license, variances, revocation and suspension of a license, and surrender of a license
12VAC5-390-30	12VAC5-391-70	Application fee	Fees are not adequate to cover the costs of the licensing program. Fees were restructured and cover initial and renewal licenses, late fees, and license re-issue or replacement. Section realigned.
12VAC5-390-40	12VAC5-391-30, 160,	Requirements, general	Not adequate to inform applicants of expectations as a licensed provider; new sections added clarify the license process and management and administration.
12VAC5-390-50 & 60	12VAC5-391-50	Initial license, License renewal	Sections consolidated to facilitate use of the regulation.
	12VAC5-391-50		*Result of comment period*: C. Amended "organization's" to read hospice program's – correct for consistency E. Amended "send a renewal application" to read "make renewal applications available"
12VAC5-390-70	12VAC5-391-60	License re-issue	Section modified to reflect actual practice and logically realigned.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12VAC5-390-80 & 90	12VAC5-391-80, 100	On-site inspection, Plan of correction	New sections developed to address actual practice: on-site inspections and complaint investigations
	12VAC5-391-80		*Result of comment period*: Added biennial inspection protocol for program administration; added "according to applicable law" – provider request.
	12VAC5-391-90	N/A	Section added addressing home visits, a consumer quality of care enhancement.
	12VAC5-391-90		*Result of comment period*: A. Added subject to obtaining consent from the patient and patient's family or caretaker. Provides clarification that patient consent is needed prior to a visit by an inspector.
	12VAC5-391-110	N/A	New section added gives direction for obtaining a criminal record check for compensated employees. Result of Code change.
	12VAC5-391-120	N/A	New section added to provide directions on establishment of dedicated facilities.
	12VAC5-391-120		*Result of comment period*: A. Changed code citation – technical change D. and E. Added dedicated after "No" and before "hospice" in each subsection. Provided for clarity.
	12VAC5-391-130		*Result of comment period:* F. Sentence rewritten for grammatical correctness.
12VAC5-390-100, 110 & 120	N/A	Certification of hospice, Accreditation of hospice, and Acceptance of certification and accreditation	Removed from the regulation, as the Code of Virginia does not provide for recognition of certification or accreditation in lieu of licensed, referred to a "deemed status."
	12VAC5-391-150		*Result of comment period*: Return was substituted for "surrender" in the section title and subsection A. Provider request – "return" seen as less punitive than "surrender"
12VAC5-390-130	12VAC5-391-160	Organization	The section was consolidated into section addressing management and administration of the hospice program.
	12VAC5-391-160		*Result of comment period*: I. Added This does not mean that a hospice program must accept new clients on an emergency basis during non-business hours to clarify that providers are not required to accept new clients during non-business hours, standardizing the requirement with the proposed home care regulation. J. Deleted "in a patient's residence." Not necessary.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12VAC5-390-140 & 150	12VAC5-391-170	Governing body, Responsibilities	Sections were consolidated into one section on the Governing Body.
	12VAC5-391-170		*Result of comment period*: B. Amended subsection regarding periodic review of program bylaws. Amendment is technical and clarifies the intent of the requirement. C. Deleted ", when appropriate" as requested by a provider.
	12VAC5-391-180	Administrator	Added effective date – technical change
	12VAC5-391-210	Personnel practices	Fixed technical error
12VAC5-390-160	12VAC5-391-220	Insurance and bonding	Section was adjusted to remove incorrect application of law; now reflects appropriate requirements for assuring indemnity coverage and eases restrictive and overly burdensome criteria currently imposed on licensees. Section logically realigned to facilitate use of the regulation.
	12VAC5-391-220		*Result of comment period*: B.2. Deleted "Blanket" - a technical change for clarification
12VAC5-390-170	12VAC5-391-180	Administrative management	Section was realigned and updated to reflect industry standards for administering a hospice program
12VAC5-390-180	12VAC5-391-190, 200, 210	Policies and procedures	Section was realigned and language modified; two new sections added addressing financial solvency and personnel policies.
	12VAC5-391-190		*Result of comment period*: C. 14. "§ 63.2-106" changed to § 63.2-1606 of the Code of Virginia to correct an incorrect Code citation.
	12VAC5-391-200		*Result of comment period*: A. Inserted separate before "working budget" in the 2nd sentence to clarify that providers operating dedicated hospice facilities should have a working budget separate from a budget used for the program services.
12VAC5-390-190, 200, 210, 270	12VAC5-192-190, 290	Administrative and financial controls, Personnel policies and procedures, Admission and discharge, Service policies and procedures	Sections were consolidated and appropriately realigned.
12VAC5-390-220	12VAC5-391-230	Contract services	Section was updated and ambiguities removed, section logically realigned.
12VAC5-390-230, 260	12VAC5-391-280	Medical records, record retention	Sections were consolidated, incorrect Code citation was removed; ambiguities removed and language updated.
	12VAC5-391-		*Result of comment period*: J. Changed

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
	280		"immediate" to within 24 hours. Provider request.
	12VAC5-391-250	N/A	New section added to address proper and timely response to consumer complaints.
12VAC5-390-240	12VAC5-391-240	Patient rights'	Criteria modified to reflect industry standards, ambiguities were removed. B.8. Deleted "hospice" – fixing technical error
	12VAC5-391-250	Complaints	A.3. Changed to read "adult protective services unit of the local social services department – fixing a technical error
12VAC5-390-250	12VAC5-391-260	Quality assurance	Section modified to reflect current industry standards regarding improvement of services to patients. Ambiguities were removed.
	12VAC5-391-260		*Result of comment period*: C. Added confidentiality to candidate's abilities and sensitivity in 2nd paragraph. Provider request.
	12VAC5-391-270	N/A	New section added addressing infection control.
12VAC5-390-280	12VAC5-391-300, 320, 200	Provision of services	Not adequate to inform applicants of expectations regarding the provision of hospice services. The section was divided into 3 sections to appropriately address expectations.
	12VAC5-391-300		*Result of comment period*: B. Deleted "spiritual support or counseling", "bereavement support", and "dietary or nutritional support"; renumbered remaining list. Considered part of "Counseling services," see definition added in 12 VAC 5-391-10.
12VAC5-390-290	12VAC5-391-330	Plan of care	Section was consolidated into new section
	12VAC5-391-330		*Result of comment period*: B. Admitting was substituted for "clinical" to correct incorrect usage.
	12VAC5-391-310	N/A	Regulation does not appropriately identify one of the core services of hospice care, the interdisciplinary team. The new section provides criteria identify one of the uniqueness of hospice.
12VAC5-390-300	12VAC5-391-310	Medical director required	Section updated and ambiguities removed
12VAC5-390-310, 320, 300	12VAC5-391-340	Nursing services, Registered nurses, licensed practical nurses.	Sections were consolidated to facilitate use.
12VAC5-390-340, 360	12VAC5-391-350	Nursing assistants, treatment performed by nursing assistants	Sections consolidated and updated to reflect industry standards, quality of care expectations, and eliminate contradictions with federal regulations.
12VAC5-	12VAC5-391-	Contract nursing services	Section was consolidated.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
390-350	230		
12VAC5-390-370	12VAC5-391-350	Other care attendants.	Section was consolidated.
	12VAC5-391-350		*Result of comment period*: A.7. Deleted "and federal guidelines" Correcting incorrect citation of federal regulations. F.1, 2, 4, and 5. Deleted "hospice" between "education" and "program" Correcting technical errors F.6. Added: Have satisfactorily completed training using the "Personal Care Aide Training Curriculum," dated 2003, of the Department of Medical Assistance Services. However, the training is permissible for volunteers only to assist providers with training of nonprofessional volunteers.
12VAC5-390-380, 390, 400, 410, 420	12VAC5-391-360	Article 5. Social services.	Current regulation does not appropriately identify one of the core services of hospice care, social services. The new section appropriately identified this core service and allows 1 year for providers to comply with this new requirement.
	12VAC5-391-360		*Result of comment period*: A. Reduced requirement for experience from "3" years to 2 years. Compromise with request from providers for 1 year of experience. Inserted effective date – technical change
12VAC5-390-430, 440	12VAC5-391-370	Article 6. Spiritual Counseling and Bereavement services	Sections were consolidated and updated.
12VAC5-390-450	12VAC5-391-300	Inpatient services	Section was consolidated.
12VAC5-390-460	12VAC5-391-400	Other special services	Section was amended.
	12VAC5-391-400		*Result of comment period*: A. Added activities of daily living to clarify that volunteers can assist with these activities for hospice patients. Deleted "care and" to clarify that families receive only support from hospice providers.
12VAC5-390-470, 480, 490, 500, 510, 520, 530, 540, 550	12VAC5-391-370	Article 2. Physical therapy services; Article 3. Occupational therapy; Article 4. Speech Therapy	Sections were repetitive and duplicative; sections were consolidated
12VAC5-390-560, 570, 580	12VAC5-391-380	Article 5. Specialized nutrition support	Sections were consolidated and updated.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12VAC5-390-590, 600, 610, 620	12VAC5-391-430	Article 6. Intravenous therapy services	Sections were consolidated and updated.
	12VAC5-391-430		*Result of comment period*: C.5. Changed "." To ";" to correct punctuation as required by the Style Manual.
12VAC5-390-630, 640, 650, 660	12VAC5-391-420	Article 7. Respiratory Therapy Services	Sections were consolidated and updated.
	12VAC5-391-440, 450, 460, 470, 480, 490, 500	N/A	Current regulation does not include standards for dedicated hospice facilities, new sections were added respectively addressing: general facility requirements, required staffing, pharmacy services, restraints, food services, laundry services, and pet care.
	12VAC5-391-440		*Result of comment period:* G. Added permitting and the nearest regional permitting office for; deleted "a permit" t correct an incorrect citation
	12VAC5-391-450		*Result of comment period*: B. Deleted "have 2 or more registered nurses and 2 or more direct care staff, as appropriate to the needs of the patients, on duty at all times;" Added be based on the assessed needs of the patients in the facility. Section moved to 230-110; non-measurable standards were deleted. 2nd paragraph. Provider request
	12VAC5-391-460		*Result of comment period:* H. deleted; Relettered remaining subsections correcting a technical error
	12VAC5-391-480		*Result of comment period:* C. Added pursuant to 12 VAC 5-391-230. Cross references prior section for clarity.
	12VAC5-391-500		*Result of comment period:* Added A and B to subsections – technical changes for clarity

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability.

There is no direct impact to the family as a result of the proposed regulation.