State Board of Health

12 VAC 5-391

Regulations for the Licensure of Hospices

Center for Quality Health Care Services and Consumer Protection
Virginia Department of Health
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Rules and Regulations for the Licensure of Hospices

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Virginia Department of Health
Center for Quality Health Care Services and Consumer Protection

Rules and Regulations for the Licensure of Hospices

Chapter 391.
Regulations for the Licensure of Hospice.

PART I.
DEFINITIONS AND GENERAL INFORMATION.

12 VAC 5-391-10. Definitions.

The following words and terms when used in these regulations shall have the following meaning unless the context clearly indicates otherwise.

"Activities of daily living" means bathing, dressing, toileting, transferring, bowel control, bladder control and eating/feeding.

"Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion or any other means, to the body of a patient by (i) a practitioner or by his authorized agent and under his supervision, or (ii) the patient at the direction and in the presence of the practitioner as defined in §54.1–3401 of Title 54.1 of the Code of Virginia.

"Administrator" means a person designated, in writing, by the governing body as having the necessary authority for the day-to-day management of the hospice program. The administrator must be a member of the hospice staff. The administrator, director of nursing, or another clinical director may be the same individual if that individual is dually qualified.

"Attending physician" means a physician licensed in Virginia, according to Chapter 29 of Title 54.1 (§54.1-2900 et seq.) of the Code of Virginia, or licensed in an adjacent state and identified by the patient as having the primary responsibility in determining the delivery of the patient's medical care. The responsibilities of physicians contained in this chapter may be implemented by nurse practitioners or physician assistants as assigned by the supervising physician and within the parameters of professional licensing.

"Available at all times during operating hours" means an individual is available on the premises or by telecommunications.

"Barrier crimes" means certain offenses specified in §32.1-162.9:1 of the Code of Virginia that automatically bar an individual convicted of those offenses from employment with a hospice program.

"Bereavement service" means counseling and support offered to the patient's family after the patient's death.

"Commissioner" means the State Health Commissioner.

"Coordinated program" means a continuum of palliative and supportive care provided to a terminally ill patient and their family, 24 hours a day, seven days a week.

"Core services" means those services that must be provided by a hospice program. Such services are: (i) nursing services, (ii) physician services, (iii) counseling services, and (iv) medical social services.

"Counseling services" means the provision of bereavement services, dietary services, spiritual and any other counseling services for the patient and family while the person is enrolled in the program.

"Criminal record report" means the statement issued by the Central Criminal Records Exchange, Virginia Department of State Police.

"Dedicated hospice facility" means an institution, place, or building providing room, board, and appropriate patient care 24 hours a day, seven days a week to individuals diagnosed with a terminal illness requiring such care pursuant to a physician's orders.

"Dispense" means to deliver a drug to the ultimate user by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling or compounding necessary to prepare the substance for that delivery as defined in §54.1-3401 of the Code of Virginia.

"Employee" means an individual who is appropriately trained and performs a specific job function for the hospice program on a full or part time basis with or without financial compensation.

"Governing body" means the individual, group or governmental agency that has legal responsibility and authority over the operation of the hospice program.

"Home attendant" means a nonlicensed individual performing personal care and environmental services, under the supervision of the appropriate health professional, to a patient in the patient's residence. Home attendants are also known as certified nursing assistants or CNAs, home care aides, home health aides, and personal care aides.

"Hospice" means a coordinated program of home and inpatient care provided directly or through an agreement under the direction of an identifiable hospice administration providing palliative and supportive medical and other health services to terminally ill patients and their families. A hospice utilizes a medically directed interdisciplinary team. A hospice program of care 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. Hospice care shall be available 24 hours a day, seven days a week.

"Inpatient" means services provided to a hospice patient who is admitted to a hospital or nursing facility on a short-term basis for the purposes of curative care unrelated to the diagnosed terminal illness. Inpatient does not mean services provided in a dedicated hospice facility.

"Interdisciplinary group" means the group responsible for assessing the health care and special needs of the patient and the patient's family. Providers of special services, such as mental health, pharmacy, and any other appropriate associated health services may also be included on the team as the needs of the patient dictate. The interdisciplinary group is often referred to as the IDG.

"Licensee" means a licensed hospice program provider.

"Medical director" means a physician currently licensed in Virginia, according to Chapter 29 (§54.1-2900 et seq.) of Title 54.1 of the Code of Virginia, and responsible for the medical direction of the hospice program.

"Medical record" means a continuous and accurate documented account of services provided to a patient, including the prescription and delivery of the treatment or care.

"Nursing services" means the patient care performed or supervised by a registered nurse according to a plan of care.

"Operator" means any individual, partnership, association, trust, corporation, municipality, county, local government agency or any other legal or commercial entity responsible for the day-to-day administrative management and operation of the hospice.

"Palliative care" means treatment directed at controlling pain, relieving other symptoms, and focusing on the special needs of the patient and family as they experience the stress of the dying process. Palliative care means treatment to enhance comfort and improve the quality of a patient's life during the last phase of his life.

"Patient" means a diagnosed terminally ill individual, with an anticipated life expectancy of six months or less, who, alone or in conjunction with designated family members or representatives, has voluntarily requested admission and been accepted into a licensed hospice program.

"Patient's family" means the hospice patient's immediate kin, including spouse, brother, sister, child or parent. Other relations and individuals with significant personal ties to the hospice patient may be designated as members of the patient's family by mutual agreement among the patient, the relation or individual.

"Patient's residence" means the place where the individual or patient makes his home.

"Person" means any individual, partnership, association, trust, corporation, municipality, county, local government agency or any other legal or commercial entity that operates a hospice.

"Plan of care" means a written plan of services developed by the interdisciplinary group to maximize patient comfort by symptom control to meet the physical, psychosocial, spiritual and other special needs that are experienced during the final stages of illness, during dying, and bereavement.

"Primary caregiver" means an individual that, through mutual agreement with the patient and the hospice program, assumes responsibility for the patient's care.

"Progress note" means a documented statement contained in a patient's medical record, dated and signed by the person delivering the care, treatment or service, describing the treatment or services delivered and the effect of the care, treatment or services on the patient.

"Quality improvement" means ongoing activities designed to objectively and systematically evaluate the quality of care and services, pursue opportunities to improve care and services, and resolve identified problems. Quality improvement is an approach to the ongoing study and improvement of the processes of providing services to meet the needs of patients and their families.

"Staff" means an employee who receives financial compensation.

"Supervision" means the ongoing process of monitoring the skills, competencies and performance of the individual supervised and providing regular face-to-face guidance and instruction.

"Terminally ill" means a medical prognosis that life expectancy is six months or less if the illness runs its usual course.

"The Center" means the Center for Quality Health Care Services and Consumer Protection of the Virginia Department of Health.

"Volunteer" means an employee who receives no financial compensation.

12 VAC 5-391-20. Reserved.

12 VAC 5-391-30. License.

A. A license to operate a hospice program is issued to a person.

B. The State Health Commissioner shall issue or renew a license to establish or operate a hospice program if the commissioner finds that the hospice program is in compliance with the law and this chapter.

C. A separate license shall be required for hospice programs maintained at separate locations, even though they are owned or are operated under the same management.

D. Every hospice program shall be designated by an appropriate name. The name shall not be changed without first notifying the center.

E. Licenses shall not be transferred or assigned.

F. Any person establishing, conducting, maintaining, or operating a hospice program without a license shall be guilty of a Class 1 misdemeanor according to § 32.1-27 of the Code of Virginia.

12 VAC 5-391-40. Exemption from licensure.

A. According to §32.1-162.2 of the Code of Virginia, this chapter is not applicable to a hospice 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 drug or material remedy, whether gratuitously or for compensation. Such a hospice shall comply with the statutes and regulations governing environmental protection and life safety.

B. The hospice program must file a request for exemption from licensure in writing to the Director of the Center for Quality Health Care Services and Consumer Protection. The request shall contain documentation explaining the hospice program's relationship to the practice of religious tenets of a recognized church or denomination.

C. The hospice program shall be notified in writing that the exemption from licensure has been registered.

D. Exempt hospice programs shall remain subject to complaint investigations in keeping with state law.

12 VAC 5-391-50. License application; initial and renewal.

A. The center will provide prelicensure consultation and technical assistance to any person regarding the licensure process. The purpose of such consultation is to explain the regulation and to review an applicant's proposed hospice program plans, forms, and other documents, as they relate to the regulation. Prelicensure consultations can be arranged after an initial application has been filed.

B. Licensure applications are obtained from the center. The center shall consider an application complete when all requested information and the appropriate fee, stated in 12 VAC 5-391-70, are submitted. If the center finds the application incomplete, the applicant will be notified in writing of the incomplete application.

An incomplete application shall become inactive six months after it is received by the center. Applicants must reapply for licensure with a completed application and application fee. An application for a license may be withdrawn at any time.

C. A completed application for initial licensure must be submitted at least 60 days prior to the hospice program's planned opening date to allow the center time to act on the application.

D. The activities and services of each applicant or licensee of a hospice license shall be subject to an inspection by the Center to determine if the hospice program is in compliance with the provisions of this chapter and state law. Hospice programs submitting an initial application shall receive an announced inspection prior to accepting patients.

E. Licenses are renewed annually. The center shall make renewal applications available at least 60 days prior to the expiration date of the current license.

F. The hospice program shall submit the completed renewal application form along with any required attachments and the application fee by the date indicated in the cover letter. Providers operating dedicated hospice facilities shall include a copy of the facility deficiency report and plan of correction from their latest facility licensure inspection when applying to renew their hospice program license.

G. It is the hospice program's responsibility to complete and return the renewal application to assure timely processing. Should a current license expire before a new license is issued, the current license shall remain in effect provided a complete and accurate application was filed on time.

H. Providers operating a dedicated hospice facility shall maintain compliance with the applicable licensure regulations described in 12 VAC 5-391-120. Failure to maintain compliance may be taken into consideration in the center's decision to renew a hospice program license.

12 VAC 5-391-60. Changes to or re-issuance of a license.

A. It is the responsibility of the hospice program's governing body to maintain a current and accurate license, including appropriate facility licensure if the hospice program operates a dedicated hospice facility.

B. A hospice program shall give written notification 30 working days in advance of any proposed changes that may require the reissuance of the license. Notices shall be sent to the attention of the Director of the Center for Quality Health Care Services and Consumer Protection.

The following circumstances require the reissuance of a license and payment of a fee:

1. A change in ownership or operator;
2. A change in hospice program name; or
3. Relocation of the hospice program's administrative office.

C. The center will evaluate written information about any planned changes in operation that affect the terms of the license or the continuing eligibility for a license. A licensing

representative may inspect the hospice program during the process of evaluating a proposed change.

D. The hospice program will be notified in writing whether a license can be reissued or a new application is needed.

12 VAC 5-391-70. Fees.

A. The center shall collect a fee of $500 for each initial and renewal license. Fees shall accompany the licensure application and are not refundable.

B. A processing fee of $250 shall be collected for each reissuance or replacement of a license and shall accompany the written request for re-issuance or replacement.

C. In addition, a late fee of $50 shall be collected for a hospice program's failure to file a renewal application by the date specified.

12 VAC 5-391-80. On-site inspections.

A. A center representative shall make periodic unannounced on-site inspections of the hospice program as necessary, but not less often that biennially. The hospice program shall be responsible for correcting any deficiencies found during any on-site inspection, including deficiencies found during announced initial inspections. Compliance with all standards will be determined by the center according to applicable law. The administrator will be notified whenever any item in the plan of correction is determined to be unacceptable.

B. The hospice program shall make available to the center representative any necessary records and shall allow access to interview the agents, employees, contractors, and any person under its control, direction or supervision.

C. After the on-site inspection, the center representative shall discuss the findings of the inspection with the administrator or designee.

D. The administrator shall submit, within 15 working days from the date of the deficiency report, an acceptable plan for correcting any deficiencies found during an on-site inspection. The plan of correction shall contain:

1. A description of the corrective action or actions to be taken and the personnel to implement and monitor the corrective action;
2. The expected correction date;
3. A description of the measures implemented to prevent a recurrence of the violation; and
4. The signature of the hospice program's administrator.

E. The administrator shall be responsible for assuring the plan of correction is implemented and monitored so that compliance is maintained.

F. Completion of corrective actions shall not exceed 45 working days from the last day of the inspection.

12 VAC 5-391-90. Home visits.

A. As part of any inspection, a center representative may conduct home visits subject to obtaining consent from the patient and the patient's family or caretaker.

B. The hospice program shall be responsible for arranging inhome visits with patients, family members, and caregivers for the center representative.

C. The hospice program shall explain clearly to the patient, patient's family or caretaker, that a home visit is voluntary and that refusal to consent to a home visit will in no way affect the patient's care.

12 VAC 5-391-100. Complaint investigation.

A. The center has the responsibility to investigate any complaints regarding alleged violations of this chapter and applicable law.

B. Complaints may be received in written or oral form and may be anonymous.

C. When the investigation is complete, the licensee and the complainant, if known, will be notified in writing of the findings of the investigation.

D. The administrator shall submit an acceptable plan for correcting any deficiencies found during a complaint investigation.

E. The administrator will be notified in writing whenever any aspect of the plan of correction is determined to be unacceptable.

F. The administrator shall be responsible for assuring the plan of correction is implemented and monitored so that compliance is maintained.

12 VAC 5-391-110. Criminal records checks.

A. Section 32.1- 162.9:1 of the Code of Virginia requires hospice providers, as defined in § 32.1-162.1 of the Code, to obtain a criminal record report on applicants for compensated employment from the Virginia Department of State Police. Section 32.1-162.9:1 also requires that all applicants for compensated employment in a hospice program provide a sworn statement regarding their criminal history.

B. The criminal record report shall be obtained within 30 days of compensated employment. It is the hospice program's responsibility to ensure that its compensated employees have not been convicted of any of the barrier crimes listed in §32.1-162.9:1 of the Code of Virginia.

C. The hospice program shall not accept a criminal record report dated more than 90 days prior to the date of compensated employment.

D. Only the original criminal record report shall be accepted. An exception is permitted for hospice programs using temporary staffing agencies for the provision of substitute staff. The hospice program shall obtain a letter from the temporary staffing agency containing the following information:

1. The name of the substitute staffing person;
2. The date of employment by the temporary staffing agency; and
3. A statement verifying that the criminal record report has been obtained within 30 days of employment, is on file at the temporary staffing agency, and does not contain any barrier crimes listed in § 32.1-162.9:1 of the Code of Virginia.

E. A criminal record report remains valid as long as the compensated employee remains in continuous service with the same hospice program.

F. A new criminal record report shall be required when an individual terminates compensated employment at one hospice program and begins compensated employment at another hospice program. The following exceptions are permitted:

1. When an employee transfers, within 30 days, to a hospice program owned and operated by the same entity. The employee's file shall contain a statement indicating that the original criminal record report has been transferred or forwarded to the new work location
2. A criminal record report for an individual who takes a leave of absence will remain valid as long as the period of separation does not exceed six consecutive months. If a period of six consecutive months has passed, a new criminal record report and sworn disclosure statement are required.

G. The sworn disclosure statement shall be completed by all applicants for compensated employment. The sworn disclosure statement shall be attached to and filed with the criminal record report.

H. Any applicant denied compensated employment because of convictions appearing on his criminal record report shall be provided a copy of the report by the hiring hospice program.

I. All criminal records reports shall be confidential and maintained in locked files accessible only to the administrator or designee.

J. Further dissemination of the criminal record report and sworn disclosure statement information is prohibited other than to the commissioner's representative or a federal or state authority or

court as may be required to comply with an express requirement of law for such further dissemination.

12 VAC 5-391-120. Dedicated hospice facilities.

A. Providers seeking to operate a dedicated hospice facility shall comply with the appropriate facility licensing regulation as follows:

1. Up to five patient beds, facilities shall be licensed as:
   a. An assisted living facility pursuant to 22 VAC 40-71,
   b. A hospital pursuant to 12 VAC 5-410; or
   c. A nursing facility pursuant to 12 VAC 5-371; or
2. Six or more patient beds, facilities shall be licensed as
   a. An assisted living facility, pursuant to 22 VAC 40-71, with a classified Use Group of I-2;
   b. A hospital pursuant to 12 VAC 5-410; or
   c. A nursing facility pursuant to 12 VAC 5-371.

Facilities to be licensed as a hospital or a nursing facility shall obtain the applicable Certificate of Public Need (COPN).

B. Only patients diagnosed terminally ill shall be admitted to a dedicated hospice facility. The facility shall admit only those patients whose needs can be met by the accommodations and services provided by the facility.

C. Admission to a dedicated hospice facility shall be the decision of the patient in consultation with the patient's physician. No patient shall be admitted to a hospice facility at the discretion of, or for the convenience of, the hospice provider.

D. No dedicated hospice facility shall receive for care, treatment, or services patients in excess of the licensed bed capacity. However, facilities licensed as a nursing facility may provide temporary shelter for evacuees displaced due to a disaster. In those cases, the facility may exceed the licensed capacity for the duration of that emergency only provided the health, safety, and well being of all patients is not compromised and the center is notified.

E. No dedicated hospice facility provider shall add additional patient beds or renovate facility space without first notifying the center and the applicable facility licensing authority. Center notifications must be in writing to the Director of the Center for Quality Health Care Services and Consumer Protection.

F. The center will not accept any requests for variances to this section.

12 VAC 5-391-130. Variances.

A. The center can authorize variances only to its own licensing regulations, not to regulations of another agency or to any requirements in federal, state, or local laws.

B. A hospice program may request a variance to a particular regulation or requirement contained in this chapter when the standard or requirement poses a special hardship and when a variance to it would not endanger the safety or well being of patients. The request for a variance must describe the special hardship to the hospice program and to the patients it serves. When applicable, the request should include proposed alternatives to meet the purpose of the requirements that will ensure the protection and well being of patients. At no time shall a variance approved for one individual be extended to general applicability. If a variance is denied, expires, or is rescinded, routine enforcement of the regulation or portion of the regulation shall be resumed. The hospice program may at any time withdraw a request for a variance.

C. The center shall have the authority to waive, either temporarily or permanently, the enforcement of one or more of these regulations provided safety, patient care and services are not adversely affected. The center may attach conditions to the granting of the variance in order to protect persons in care.

D. The center may rescind or modify a variance when: (i) conditions change; (ii) additional information becomes known which alters the basis for the original decision; (iii) the hospice program fails to meet any conditions attached to the variance; or (iv) results of the variance jeopardize the safety, comfort, or well being of persons in care.

E. Consideration of a variance is initiated when a written request is submitted to the Director of the Center for Quality Health Care Services and Consumer Protection. The center shall notify the hospice program in writing of the receipt of the request for a variance.

F. The licensee shall be notified in writing if the requested variance is denied.

G. The hospice program shall develop procedures for monitoring the implementation of any approved variance to assure the ongoing collection of any data relevant to the variance and the presentation of any later report concerning the variance as requested by the center.

12 VAC 5-391-140. Revocation or suspension of a license.

A. The commissioner is authorized to revoke or suspend any license if the licensee fails to comply with the provisions of Article 7 (§32.1-162.1 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia or the regulations of the board.

Providers operating a dedicated hospice facility shall also maintain compliance with the applicable licensure regulations as described in 12 VAC 5-391-120. Failure to maintain compliance may be taken into consideration when the commissioner decides to revoke or suspend a hospice program license.

B. If a license is revoked, the commissioner may issue a new license when the conditions upon which revocation was based have been corrected and compliance with all provisions of the law and this chapter has been achieved.

C. Suspension of a license shall in all cases be for an indefinite time. The suspension may be lifted and rights under the license fully or partially restored at such time as the commissioner determines that the interests of the public will not be jeopardized by resumption of services.

D. When a license is revoked or suspended, the hospice program shall cease operations. If the hospice program continues operating, the commissioner may request the Office of the Attorney General to petition the circuit court of the jurisdiction in which the hospice program is located for an injunction to cease operations.

12 VAC 5-391-150. Return of a license.

A. The circumstances under which a license must be returned include, but are not limited to (i) change in ownership or operator, (ii) change in hospice program name, (iii) relocation of the administrative office, (iv) discontinuation of any core services, and (v) establishment a dedicated hospice facility.

B. The licensee shall notify its patients and the center in writing 30 days prior to discontinuing any services.

C. If the hospice program is no longer operational, or the license is revoked or suspended, the license shall be returned to the center within five working days. The licensee is responsible for notifying its patients and the center where all medical records will be located.

PART II.
ADMINISTRATIVE SERVICES.

12 VAC 5-391-160. Management and administration.

A. No person shall establish or operate a hospice program, as defined in § 32.1-162.1 of the Code of Virginia, without having obtained a license.

B. The hospice program must comply with:

1. This chapter (12 VAC 5-391);
2. Other applicable federal, state or local laws and regulations; and
3. The hospice program's own policies and procedures.

When applicable regulations are similar, the more stringent regulation shall take precedence.

C. The hospice program shall submit or make available reports and information necessary to establish compliance with this chapter and applicable law.

D. The hospice program shall permit representatives from the center to conduct inspections to:

1. Verify application information;
2. Determine compliance with this chapter;
3. Review necessary records and documents; and
4. Investigate complaints.

E. The hospice program shall notify the center 30 working days in advance of changes effecting the hospice program, including the:

1. Location of the administrative office or mailing address of the hospice program;
2. Ownership or operator;
3. Services provided;
4. Administrator;
5. Hospice program name;
6. Establishment of a dedicated hospice facility; and
7. Closure of the hospice program.

F. The current license from the department shall be posted for public inspection.

G. Service providers or individuals under contract must comply with the hospice program's policies and this chapter, as appropriate.

H. The hospice program shall not use any advertising that contains false, misleading or deceptive statements or claims, or false or misleading disclosures of fees and payment for services.

I. The hospice program shall have regular posted business hours and be fully operational during business hours. Patient care services shall be available 24 hours a day, seven days a week. This does not mean that a hospice program must accept new clients on an emergency basis during non-business hours.

J. The hospice program shall accept a patient only when the hospice program can adequately meet that patient's needs.

K. The hospice program must have an emergency preparedness plan in case of inclement weather or natural disaster to include contacting and providing essential care to patients, coordinating with community agencies to assist as needed, and maintaining current information on patients who would require specialized assistance.

12 VAC 5-391-170. Governing body.

A. The hospice program shall have a governing body that is legally responsible for the management, operation and fiscal affairs of the hospice program. The governing body of the hospital, nursing facility or home health agency that operates a hospice shall include in its internal organizational structure an identifiable unit of hospice services.

B. The governing body shall adopt written by-laws describing the hospice program structure, including the:

1. Hospice program's objectives;
2. Scope of services;
3. Relationship of the hospice program's services to other services operated by the governing body, if applicable, or by written agreement with the governing body of an affiliated medical service provider; and
4. Establishment of a quality improvement committee.

At least every two years, the governing body shall review and approve necessary changes to the hospice program's bylaws.

C. The governing body shall review annually and approve the recommendations of the quality improvement committee.

12 VAC 5-391-180. Administrator.

A. The governing body shall appoint as administrator an individual who has evidence of at least one year of training and experience in direct health care service delivery with at least one year, within the last five years, of supervisory or administration management experience in hospice care or a related health care delivery system.

B. The administrator shall be responsible for the day-to-day management of the hospice program, including but not limited to:

1. Organizing and supervising the administrative functions of the hospice program;
2. Maintaining an on-going liaison with the governing body, the professional personnel and staff;
3. Employing qualified personnel and ensuring adequate employee orientation, training, education and evaluation;
4. Ensuring the accuracy of public information materials and activities;
5. Implementing an effective budgeting and accounting system;
6. Maintaining compliance with applicable laws and regulations and implementing corrective action in response to reports of hospice program committees and regulatory agencies;
7. Arranging and negotiating services provided through contractual agreement; and
8. Implementing the policies and procedures approved by the governing body.

C. An individual who meets the qualifications of subsection A of this section shall be designated in writing to perform the duties of the administrator when the administrator is absent from the hospice program.

Hospice programs shall have one year from November 1, 2005 to ensure that the individuals currently designated meet the qualifications of subsection A of this section.

D. The administrator or alternate shall be available at all times during operating hours and for emergency situations.

12 VAC 5-391-190. Written policies and procedures.

A. The hospice program shall implement written policies and procedures approved by the governing body.

B. All policies and procedures shall be reviewed at least annually, with recommended changes submitted to the governing body for approval, as necessary.

C. Administrative and operational policies and procedures shall include, but are not limited to:

1. Administrative records;
2. Admission and discharge criteria;
3. Informed consent;
4. Advance directives, including Durable Do Not Resuscitate Orders;
5. Patient rights;
6. Pain assessment and management;
7. Medical supplies and appliances including drugs and biologicals, disposal of controlled drugs when no longer needed by patients, and handling of medications procured from a pharmacy of the patient's choice;

8. Contract services;
9. Transfer of patients to an inpatient facility including arrangements for an ambulance and the patient escort, when appropriate, to the facility by a professional staff member of the hospice program;
10. Medical social services;
11. Quality improvement;
12. Communicable and reportable diseases;
13. Post mortem activities;
14. Mandated reporting of abuse, neglect, and exploitation pursuant to §63.2-1606 of the Code of Virginia;
15. Medical records, including confidentiality;
16. Record retention, including termination of services;
17. Supervision and delivery of services;
18. Interdisciplinary group duties and responsibilities;
19. Bereavement and spiritual services;
20. Volunteer services;
21. Infection control;
22. Special services;
23. Emergency preparedness;
24. Handling consumer complaints; and
25. Approved variances.

D. Financial policies and procedures shall include, but are not limited to:

1. Admission agreements;
2. Data collection and verification of services delivered;
3. Methods of billing for services by the hospice program and contractors;
4. Patient notification of changes in fees and charges;
5. Refund policy and correction of billing errors; and
6. Collection of delinquent patient accounts.

E. Personnel policies and procedures shall include, but are not limited to, a:

1. Written job description specifying responsibility, qualifications, and authority for each job classification;
2. Process for obtaining a criminal background check;
3. Process for maintaining an accurate, complete and current personnel record for each employee;
4. Process for verifying current professional credentials and training of employees, or independent contractors;
5. Process for annually evaluating employee performance and competency;
6. Process for verifying that contractors and their employees meet the personnel qualifications of the hospice program; and
7. Process for reporting licensed and certified medical personnel for violations of the licensing or certification to the appropriate Board within the Department of Health Professions.

F. Admission and discharge policies and procedures shall include, but are not limited to:

1. Criteria for accepting patients;
2. The process for assessing a patient and maintaining a plan of care;
3. Criteria for determining discharge from hospice and referral to other agencies or community services; and
4. Process for notifying patients of intent to discharge or refer, including:
   a. Oral and written notice and explanation of the reason for discharge or referral;
   b. The name, address, telephone number and contact name at the referral hospice program; and
   c. Documentation in the medical record of the referral or notice.

G. Policies shall be made available for review, upon request, to patients and their designated representatives.

H. Policies and procedures shall be readily available for staff use at all times.

12 VAC 5-391-200. Financial controls.

A. The hospice program shall document financial resources to operate based on a working budget showing projected revenue and expenses.

Hospice programs operating dedicated hospice facilities shall have financial resources to operate based on a separate working budget showing projected revenue and expenses.

B. All financial records shall be kept according to generally accepted accounting principles (GAAP).

C. All financial records shall be audited at least triennially by an independent certified public accountant or audited as otherwise provided by law.

D. The hospice program shall have documented financial controls to minimize risk of theft or embezzlement.

12 VAC 5-391-210. Personnel practices.

A. Personnel management and employment practices shall comply with applicable state and federal laws and regulations.

B. The hospice program shall design and implement a staffing plan that reflects the types of services offered and shall provide qualified staff in sufficient numbers to meet the assessed needs of all patients, including those patients residing in the provider's hospice facility, if applicable.

C. Employees and contractors shall be licensed or certified as required by the Department of Health Professions.

D. The hospice program shall implement a mechanism to verify professional credentials.

E. Any person who assumes the responsibilities of any staff position or positions shall meet the minimum qualifications for that position or positions. Professional staff may be assigned multiple job responsibilities provided the individual is appropriately qualified.

F. The hospice program shall obtain the required sworn statement and criminal record check for each compensated employee as specified in §32.1-162.9:1 of the Code of Virginia.

G. Each employee position shall have a written job description that includes:

1. Job title;
2. Duties and responsibilities required of the position;
3. Job title of the immediate supervisor; and
4. Minimum knowledge, skills, and abilities or professional qualifications required for entry level.

H. Employees shall have access to their current position description. There shall be a mechanism for advising employees of changes to their job responsibilities.

I. New employees and contract individuals shall be oriented commensurate with their function or job-specific responsibilities. Orientation shall include:

1. Objectives and philosophy of the hospice program;
2. Confidentiality practices;
3. Patient rights;
4. Mandated reporting of abuse, neglect and exploitation;
5. Applicable personnel policies;
6. Emergency preparedness procedures;
7. Infection control practices and measures; and
8. Applicable laws, regulations, and other policies and procedures that apply to specific positions and specific duties and responsibilities.

J. The hospice program shall implement a policy for evaluating employee performance.

K. Individual staff development needs and plans shall be a part of the performance evaluation.

L. The hospice program shall provide opportunities for and record participation in staff development activities designed to enable staff to perform the responsibilities of their positions.

M. All individuals who enter a patient's home for or on behalf of the hospice program shall be readily identifiable by employee nametag.

N. The hospice program shall maintain an organized system to manage and protect the confidentiality of personnel files and records.

O. Employee personnel records, whether hard-copy or electronic, shall include:

1. Identifying information;
2. Education and training history;
3. Employment history;
4. Results of the verification of applicable professional licenses or certificates;
5. Results of reasonable efforts to secure job-related references and reasonable verification of employment history;
6. Results of performance evaluations;
7. A record of disciplinary actions taken by the hospice program, if any;
8. A record of adverse action by any licensing bodies and hospice programs, if any;
9. A record of participation in staff development activities, including orientation;
10. The criminal record check; and
11. A signed job description.

P. Each employee personnel record shall be retained in its entirety for a minimum of three years after termination of employment.

Q. Personnel record information shall be safeguarded against loss and unauthorized use.

R. Employee health-related information shall be maintained separately within the hospice program's personnel files, but may be maintained in a separate secure section for confidentiality.

12 VAC 5-391-220. Indemnity coverage.

A. The governing body shall ensure the hospice program and its contractors have appropriate indemnity coverage to compensate patients for injuries and losses resulting from services provided.

B. To protect the interests of patients, employees, and the hospice program from risks of liability, there shall be indemnity coverage to include:

1. General liability insurance covering personal property damages, bodily injuries, product liability, liable and slander of at least $1 million comprehensive general liability per occurrence; and
2. Malpractice insurance for all nursing and medical professional employees consistent with §8.01-581.15 of the Code of Virginia.

12 VAC 5-391-230. Contract services.

A. If the hospice program contracts for services there shall be a written agreement for the provision of those services.

B. The written agreement shall include, but is not limited to:

1. The services to be furnished by each party to the contract;
2. The contractor's responsibility for participating in developing plans of care;
3. The manner in which services will be controlled, coordinated, and evaluated by the hospice program;
4. The procedures for submitting clinical and progress notes, scheduling of visits, and periodic patient evaluation;
5. The process for payment for services furnished under the contract; and
6. Adequate indemnity coverage.

C. The hospice program shall have procedures for providing patient services in the event the contractor is unable to comply with the plan of care.

D. The contractor shall conform to applicable hospice program policies and procedures as specified in the contract, including the required sworn statement and criminal record check.

12 VAC 5-391-240. Patient rights.

A. The hospice program shall establish and implement written policies and procedures regarding the rights of patients. A copy of the patient's rights shall be displayed in the hospice office for public review.

B. Written procedures to implement the policies shall ensure that each patient is:

1. Treated with courtesy, consideration and respect;
2. Assured the right to privacy;
3. Assured confidential treatment of his medical and financial records as provided by law;
4. Free from mental and physical abuse and property exploitation;
5. Assured the right to participate in the planning of his care, including appropriate assessment and management of pain and the right to refuse services;
6. Served by individuals who are properly trained and competent to perform their duties;
7. Assured the right to voice grievances and complaints related to hospice program services without fear of reprisal;
8. Advised, before care is initiated, of the extent to which payment for services may be expected from federal or state programs, and the extent to which payment may be required from the patient;

9. Advised orally and in writing of any changes in fees for services that are the patient's responsibility. The hospice program shall advise the patient of these changes as soon as possible, but no later than 30 calendar days from the date the hospice program became aware of the change;
10. Provided with advance directive and Durable Do Not Resuscitate Order information prior to start of services; and
11. Given five days oral and written notice when the hospice program determines to terminate services.

C. At the time of admission, patient rights shall be reviewed with patients and primary caregivers who shall receive a written summary of the policies. The review shall be documented in the patient's record.

D. Before care is initiated, the hospice program shall inform the patient, orally and in writing, of the general nature of hospice care and policies of the hospice program, including, but not limited to:

1. The type and frequency of service or services to be delivered, the purpose of the service or services, and the name of the individual supervising the service or services;
2. Any anticipated effects of treatment, as applicable:
3. A schedule of charges for services;
4. The method of billing and payment for services, including the:
   a. Services to be billed to third party payers;
   b. Extent to which payment may be expected from third party payers known to the hospice program;
   c. Services that may not be covered by third party payers;
5. The charges that the individual may have to pay;
6. The requirements of notice for cancellation or reduction in services by the hospice program and the patient; and
7. The refund policies of the hospice program.

12 VAC 5-391-250. Complaints.

A. The hospice program shall establish and maintain complaint handling procedures that specify the:

1. System for logging receipt, investigation and resolution of complaints;
2. Format of the written record;
3. Method in which the adult protective services unit of the local social services department is to be informed and for what complaints; and
4. Description of the appeal rights if a complainant is not satisfied with the resolution.

B. The hospice program shall designate staff responsible for complaint resolution, including:

1. Complaint intake, including acknowledgment of complaints;
2. Investigation of the complaint;
3. Review of the investigation of findings and resolution of the complaint; and
4. Written notification to the complainant of the proposed resolution within 30 days from the date of receipt of the complaint.

C. The patient or his designee shall be given a copy of the hospice program's procedures for filing a complaint at the time of admission to service. The hospice program shall provide each patient or his designee with the name, mailing address, and telephone number of the:

1. Hospice program contact person;
2. State Ombudsman; and
3. Center for Quality Health Care Services and Consumer Protection.

D. The hospice program shall maintain documentation of all complaints received and the status of each complaint from date of receipt through its final resolution. Records shall be maintained from the date of the last licensure inspection and for no less than three years.

12 VAC 5-391-260. Quality improvement.

A. The hospice program shall implement an on-going, comprehensive, integrated, self-assessment program of the quality and appropriateness of care provided, including services provided under contract. The quality improvement program shall address actual patient outcomes (results of care), clinical, administrative, and cost-of-care issues. The findings shall be used to correct identified problems and revise policies and practices, as necessary. Exclusive concentration on administrative or cost-of-care issues does not fulfill this requirement.

B. The following areas shall be evaluated to identify unacceptable or unexpected trends or occurrences that influence patient outcomes (results of care):

1. Staffing patterns and clinical performance;
2. Admissions and discharges;
3. Supervision appropriate to the level of service;
4. Emergency preparedness plan;
5. Medical records;
6. Appropriateness and effectiveness of pain management;
7. Patient satisfaction and complaint resolution;
8. Infection control;
9. Staff concerns; and
10. Provision of services appropriate to patient needs.

C. The administrator or governing body shall designate a quality improvement committee, which is responsible for the oversight and supervision of the quality improvement program. The committee shall consist of:

1. A physician with association with the hospice program;
2. A member of the administrative staff;
3. Representatives of each of the services provided by the hospice program, including contracted services; and
4. An individual with demonstrated ability to represent the rights and concerns of patients. The individual may be a member of the hospice program's staff, a patient, or a patient's family member.

In selecting members of this committee, consideration shall be given to a candidate's abilities and sensitivity to issues relating to confidentiality, quality of care and services provided to hospice patients.

D. Measures shall be implemented to resolve important problems or concerns that have been identified. Health care practitioners, as well as administrative staff, shall participate in the resolution of the problems or concerns that are identified.

E. Results of the quality improvement program shall be reported annually in writing to the governing body and the administrator, and to the staff as appropriate. The report shall be acted upon by the governing body and the hospice program. All corrective actions shall be documented.

12 VAC 5-391-270. Infection control.

A. The hospice program shall implement a program to reduce the risk of infection.

B. Infection control activities shall include, but are not limited to:

1. Staff, patient, patient family or caregiver education regarding infection risk-reduction behaviors;
2. Use of universal precautions;
3. Handling, storing, processing and transporting of regulated medical waste according to applicable procedures;
4. Handling, storing, processing and transporting supplies and equipment in a manner that prevents the spread of infection; and
5. Monitoring of staff performance of infection control practices.

C. Accumulated waste, including all contaminated sharps, dressings, or similar infectious waste, shall be disposed of in a manner compliant with the OSHA Bloodborne Pathogens standard (29 CFR 1910.1030).

D. Dedicated hospice facilities shall have provisions for isolating patients with infectious diseases.

12 VAC 5-391-280. Medical record system.

A. The hospice program shall maintain an organized medical record system according to accepted standards of practice. Written policies and procedures shall specify retention, reproduction, access, storage, content, and completion of the record.

B. Medical record information shall be safeguarded against loss or unauthorized use.

C. Medical records shall be confidential. Only authorized personnel shall have access as specified in state and federal law.

D. Provisions shall be made for the safe storage of the original record and for accurate and legible reproductions of the original.

E. Policies shall specify arrangements for retention and protection of records if the hospice program discontinues operation and shall provide for notification to the center and the patient of the location of the records.

F. An accurate and complete medical record shall be maintained for each patient receiving services and shall include, but shall not be limited to:

1. Patient identifying information;
2. Identification of the attending physician;
3. Admitting information, including a patient history;
4. A psychosocial and spiritual assessment, including information regarding composition of the household, safety issues in the physical environment, coping skills of the family and the patient, and identification of the individuals to be instructed in the care of the patient;
5. Physical assessment;
6. Documentation and results of all medical tests ordered by the physician or other health care professionals and performed by the hospice program's staff;
7. Physician's orders;
8. The plan of care including, but not limited to, the type and frequency of each service to be delivered by hospice program or contract service personnel and appropriate assessment and management of pain;
9. Medication sheets that include the name, dosage, frequency of administration, route of administration, date started, changed or discontinued for each medication, and possible side effects;
10. Copies of all summary reports sent to the attending physician;
11. Documentation of patient rights review;
12. Services provided, including any volunteer services; and
13. A discharge summary that includes continuing symptom management needs.

G. Signed and dated progress notes by each individual delivering service shall be written on the day the service is delivered and incorporated in the medical record within seven working days.

H. All services provided to the patient by the hospice program shall be documented in the patient's medical record.

I. Entries in the medical record shall be current, legible, dated and authenticated by the person making the entry. Errors shall be corrected by striking through and initialing.

J. Verbal orders shall be documented within 24 hours in the medical record by the health care professional receiving the order and shall be countersigned by the health professional initiating the order according to the procedures of the hospice program.

K. Originals or reproductions of individual patient medical records shall be maintained in their entirety for a minimum of five years following discharge or date of last contact unless otherwise specified by state or federal requirements. Records of minors shall be kept for at least five years after the minor reaches 18 years of age.

12 VAC 5-391-290. Discharge.

A. Patients shall receive five days oral and written notice of a transfer or discharge initiated by the hospice program except under the following circumstances:

1. When a medical emergency exists;
2 For the welfare of the patient or the welfare of employees; or
3. The welfare of other patients in a dedicated hospice facility operated by the hospice program.

B. The hospice program shall make all arrangements necessary to assure continuing care and services including a discharge summary for the receiving hospice or provider.

PART III.
HOSPICE PROGRAM SERVICES.

Article 1.
Hospice Services.

12 VAC 5-391-300. Hospice services.

A. Each hospice shall provide a coordinated program of services encompassing the hospice philosophy that:

1. The unit of care consists of the patient, the primary caregiver, and the patient's family;
2. Emphasizes in-home care;
3. A designated interdisciplinary group supervises the patient's care;
4. A patient's physical pain will be appropriately assessed and managed;
5. Services are available 24 hours a day, 7 days a week;
6. Inpatient care is provided in an atmosphere as home-like as practical;
7. Bereavement services are available to the family after the death of the patient; and
8. Trained volunteers are utilized to perform specific job functions in the hospice service delivery system.

B. Specific services provided according to the plan of care shall include:

1. Nursing services;
2. Counseling services;
3. Medical social services;
4. Physician services;
5. Physical therapy, occupational therapy, speech-language pathology;
6. Home attendant services;
7. Short-term inpatient care; and
8. Medical appliances and supplies, including drugs and biologicals, relevant to the patient's terminal illness.

C. Inpatient services shall be provided in a licensed hospital or nursing facility.

D. There shall be written agreement with an inpatient facility for the transfer of patients if medical complications arise. Such agreement shall include, but is not limited to, interagency communication processes and coordination of the patient's plan of care, and shall clearly identify the services to be provided by the facility and the hospice while the patient is at the inpatient facility.

E. All prescription drugs shall be prescribed and properly dispensed to patients according to the provisions of Chapters 33 (54.1-3300 et seq.) and 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia and the regulations of the Virginia Board of Pharmacy, except for the

prescription drugs authorized by §54.1-3408 of the Drug Control Act, such as epinephrine for emergency administration, normal saline and heparin flushed for the maintenance of IV lines, and adult immunizations, which may be given by a nurse pursuant to established protocol.

12 VAC 5-391-310. Interdisciplinary group or IDG.

A. The hospice program shall designate an interdisciplinary group or groups to provide or supervise the care and services offered by the hospice program. The IDG shall consist of:

1. The patient, the patient's primary caregiver, and patient's family;
2. The attending physician;
3. The medical director;
4. A registered nurse;
5. The social worker;
6. The pastoral or other counselor; and
7. Volunteers, if applicable.

B. The IDG shall:

1. Establish a coordinated plan of care for the services, supplies and medical appliances required for each patient;
2. Provide or supervise the care and services delivered; and
3. Periodically reassess each patient and update the patient's plan of care, as needed.

C. The IDG shall establish policies governing the day-to-day provision of the care and services. If the hospice program utilizes multiple IDGs, one IDG shall be designated in advance as responsible for establishing those policies.

12 VAC 5-391-320. Plan of care.

A. At the time of a patient's admission to the hospice program, the IDG shall develop and maintain a plan of care, including but not limited to:

1. Identification of the primary caregiver, or an alternative in the absence of a primary caregiver, to ensure the patient's needs will be met;
2. The patient's diagnosis and prognosis;
3. Assessment of the patient's family medical, physical, psychosocial, spiritual and bereavement needs, identification of the services required to meet those needs and plans for providing the services through the IDG, contractual providers, and community resources;
4. A comprehensive assessment of pain, as warranted by the patient's condition and the scope of services provided by the hospice program;
5. Services to be provided, including: (i) specific procedures, (ii) treatment modalities, and (iii) frequency and duration of the services ordered;
6. Special dietary or nutritional needs, when applicable;

7. Medical equipment, supplies, medications, and specialized therapies when applicable;
8. Identification of the members of the staff designated to carry out the plan of care; and
9. Physician orders, including any orders to change the plan when appropriate.

B. Services shall be provided according to the patient's plan of care. The plan of care shall be updated at intervals determined by the IDG and specified in the plan.

C. The plan of care shall be reviewed, approved and signed by the patient's attending physician or the hospice program's medical director after consultation with the patient's attending physician.

D. The attending physician shall be notified immediately of any changes in the patient's condition that indicates a need to alter the plan of care.

12 VAC 5-391-330. Medical direction.

A. There shall be a medical director, who shall be a physician licensed by the Virginia Board of Medicine, responsible for the overall direction and management of the medical component of care. The individual shall have training and experience in the psychological and medical needs of the terminally ill.

B. The medical director shall have admitting privileges at one or more hospitals and nursing facilities that provide inpatient service to the hospice program's patients.

C. The duties and responsibilities of the medical director shall include at least the following:

1. Consulting with attending physicians regarding pain and symptom management;
2. Reviewing patient eligibility for hospice services according to the law and the hospice program's admission policies;
3. Acting as a medical resource to the IDG;
4. Coordinating with attending physicians to assure a continuum of medical care in cases of emergency or in the event the attending physician is unable to retain responsibility for the patient's care;
5. Acting as medical liaison with physicians in the community; and
6. Determining, in consultation with the patient's physician, when a patient can no longer remain at home and should be moved to a congregate living facility of the patient's choosing.

12 VAC 5-391-340. Nursing services.

A. All nursing services shall be provided directly or under the supervision of a registered nurse, currently licensed by the Virginia Board of Nursing, who has education and experience in the needs of the terminally ill. Duties and responsibilities of the supervising nurse shall include:

1. Assuring that nursing services delivered are provided according to established hospice program policies;
2. Assuring that nursing services are available 24 hours a day, 7 days a week and that licensed practical nurses and home attendants work under the direct supervision of a registered nurse;
3. Participating in the development and implementation of orientation and in-service training hospice programs for all levels of nursing staff employed by the hospice program;
4. Acting as nurse liaison with staff and other agencies, hospice programs and individuals that have contractual agreements to provide nursing services;
5. Participating in quality improvement reviews and evaluations of the nursing services provided; and
6. Directing or supervising the delivery of nursing services.

B. Nursing services shall include, but are not limited to:

1. Assessing a patient's needs and admission for service as appropriate;
2. Working with the IDG to develop a plan of care;
3. Implementing the plan of care;
4. Obtaining physician's orders when necessary;
5. Providing those services requiring substantial and specialized nursing skill;
6. Educating the patient and patient's family in the care of the patient, including pain management;
7. Evaluating the outcome of services;
8. Coordinating and communicating the patient's physical or medical condition to the IDG;
9. Preparing clinical notes; and
10. Supervising licensed practical nurses and home attendants providing delegated nursing services.

C. A registered nurse shall coordinate the implementation of each patient's plan of care.

D. If nursing duties are delegated, the hospice program shall develop and implement an organizational plan pursuant to 18 VAC 90-20-420 through 18 VAC 90-20-460 of the Virginia Administrative Code.

E. Licensed practical nurses shall be currently licensed by the Virginia Board of Nursing.

F. The services provided by a licensed practical nurse may include, but are not limited to:

1. Delivering nursing services according to the hospice program's policies and standard nursing practices;
2. Assisting the registered nurse in performing specialized procedures;
3. Assisting the patient with activities of daily living, including the teaching of self-care techniques;
4. Preparing equipment and supplies for treatment that requires adherence to sterile

or aseptic techniques; and

5. Preparing clinical notes.

12 VAC 5-391-350. Home attendant services.

A. Services of the home attendants may include, but are not limited to:

1. Assisting patients with (i) activities of daily living; (ii) ambulation and prescribed exercise; (iii) other special duties with appropriate training and demonstrated competency;
2. Assisting with oral or topical medications that the patient can normally self-administer;
3. Taking and recording vital signs as indicated in the plan of care;
4. Measuring and recording fluid intake and output;
5. Recording and reporting to the health care professional changes in the patient's physical condition, behavior or appearance;
6. Documenting services and observations in the medical record; and
7. Performing any other duties that the attendant is qualified to do by additional training and demonstrated competency, within state guidelines.

B. Prior to the initial delivery of services, the home attendant shall receive specific written instructions for the patient's care from the appropriate health care professional responsible for the care.

C. Home attendants shall work under the supervision of the appropriate health care professional responsible for the patient's care.

D. The nurse responsible for supervising the home attendant shall make visits to the patient's home as frequently as necessary, but not less than every two weeks. The results of each visit shall be documented in the medical record.

E. Relevant in-service education or training for home attendants shall consist of at least 12 hours annually. In-service training may be in conjunction with on-site supervision.

F. Home attendants shall be able to speak, read and write English and shall meet one of the following qualifications:

1. Have satisfactorily completed a nursing education program preparing for registered nurse licensure or practical nurse licensure;
2. Have satisfactorily completed a nurse aide education program approved by the Virginia Board of Nursing;
3. Have certification as a nurse aide issued by the Virginia Board of Nursing;
4. Be successfully enrolled in a nursing education program preparing for registered nurse or practical nurse licensure and have currently completed at least one nursing course which includes clinical experience involving patient care; or
5. Have satisfactorily passed a competency evaluation that meets the criteria of 42 CFR 484.36 (b); or

6. 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.

12 VAC 5-391-360. Medical social services.

A. Social services shall be provided according to the plan of care under the direction of a qualified social worker who holds, at a minimum, a bachelor's degree with major studies in social work, sociology, or psychology from a four year college or university accredited by the Council on Social Work Education and has at least two years experience in case work or counseling in a health care or social services delivery system.

The hospice program has one year from November 1, 2005 to ensure the designated individual meets the qualifications of this standard.

B. The duties of the social worker may include, but are not limited to:

1. Conducting a complete psychosocial assessment of the patient and family and participating in the development of the plan of care at the time of patient's admission;
2. Delivering or supervising the delivery of social services to the patient or the patient's family;
3. Reviewing and updating the plan of care as often as necessary;
4. Obtaining physician's orders for services, as necessary;
5. Assisting the patient and family with identifying and accessing community resources;
6. Reporting any changes in the emotional, social, or financial condition of the patient or family to the attending physician;
7. Acting as consultant to hospice program staff;
8. Participating in the quality improvement reviews and evaluation of social services;
9. Preparing clinical notes; and
10. Participating in discharge planning.

12 VAC 5-391-370. Spiritual counseling and bereavement services.

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

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

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

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

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

12 VAC 5-391-380. Dietary or nutritional counseling

Dietary or nutritional counselors shall meet the requirements of 18 VAC 75-30 pursuant to Chapter 27.1 (§54.1-2730 et seq.) of Title 54.1 of the Code of Virginia and have at least two years experience in a health care food or nutrition delivery system

12 VAC 5-391-390. Therapy services.

A. Physical therapy, occupational therapy, or speech therapy services shall be provided under the direction of an appropriately qualified therapist licensed or certified as required in Virginia. The therapy services provided may include, but are not limited to:

1. Assessing patient needs;
2. Participating, as necessary, in developing a patient's plan of care;
3. Implementing therapy services as documented in a patient's plan of care;
4. Evaluating the outcome of the services provided;
5. Educating the patient and family regarding the therapy services provided;
6. Providing therapy service consultation to other health care professionals;
7. Coordinating and communicating with the IDG regarding changes in the patient's needs;
8. Supervising therapy assistants and home attendants as appropriate;
9. Preparing clinical notes; and
10. Obtaining physician orders, when necessary.

B. The occupational therapy assistant shall practice under the supervision of a licensed occupational therapist.

C. The physical therapy assistant shall be currently licensed by the Virginia Board of Physical Therapists and shall practice under the supervision of a licensed physical therapist.

D. Duties of therapy assistants shall include, but are not limited to:

1. Performing services planned, delegated, and supervised by the appropriately licensed or certified therapist; and
2. Preparing clinical notes.

12 VAC 5-391-400. Volunteer services.

A. The hospice program shall utilize trained volunteers to provide patient care, including the activities of daily living, and family support.

B. The hospice program shall have a plan delineating training, responsibilities, and supervision of all volunteers.

C. The hospice program shall demonstrate evidence of ongoing continuing education and recruitment activities for volunteers.

Article 2.
Other Special Services.

12 VAC 5-391-410. Other special services.

A. Other special services may be offered at the option of the hospice program and may include, but are not limited to:

1. Respiratory therapy; and
2. Pharmacy therapy.

B. Special services may be provided by hospice program employees or through contractual arrangements with individuals or programs that are licensed or certified as required by law.

C. A patient's need for special services shall be documented in the plan of care prepared by the IDG.

D. The special service provider shall assess the patient's need, assist in the development of the plan of care, and provide services according to the plan of care.

E. The special service provider shall participate in the review and update of the plan of care.

F. The special service provider shall instruct the patient, family members, and hospice staff, as appropriate, in assisting with the treatments.

G. Special services provided shall be documented in the medical record.

H. The special service provider shall provide consultative services and in-service training to hospice program staff as needed.

12 VAC 5-391-420. Respiratory therapy.

Respiratory therapy services shall be provided by a respiratory therapist licensed in Virginia. The duties of the respiratory therapist shall include:

1. Assessing patient needs;
2. Participating with the IDG in developing a plan of care;
3. Implementing a plan of care and revising as necessary;
4. Evaluating the outcome of the care provided;
5. Educating the patient and family;
6. Providing consultation to other health care professionals;
7. Coordinating and communicating with the IDG regarding changes in the patient's needs;
8. Preparing clinical notes; and
9. Obtaining physician orders, when necessary.

12 VAC 5-391- 430. Pharmacy services.

A. All prescription drugs shall be prescribed and properly dispensed to the patient according to the provisions of the Chapters 33 (§ 54.1-3300 et seq.) and 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia and the regulations of the Virginia Board of Pharmacy, except for prescription drugs authorized by §54.1-3408 of the Drug Control Act, such as epinephrine for emergency administration, normal saline and heparin flushes for the maintenance of IV lines, and adult immunizations, which may be given by a nurse pursuant to established protocol.

B. Home attendants may assist only with those topical and oral medications that the patient would normally self administer. Any other drug shall be administered only by a licensed nurse or physician assistant.

C. The hospice program shall develop written policies and procedures for the administration of infusion therapy medications, that include, but are not limited to:

1. Developing a plan of care;
2. Initiation of medication administration based on a prescriber's order and monitoring of the patient for response to the treatment and any adverse reactions or side effects;
3. Assessment of any factors related to the home environment that may affect the prescriber's decisions for initiating, modifying, or discontinuing medications;
4. Communication with the prescriber concerning assessment of the patient's response to therapy, any other patient specific needs, any significant change in the patient's condition;
5. Communication with the patient's provider pharmacy concerning problems or needed changes in a patient's medication;
6. Maintaining a complete and accurate record of medications prescribed, medication administration data, patient assessments, any laboratory tests ordered to monitor response to drug therapy and results, and communications with the prescriber and pharmacy provider;

7. Educating or instructing the patient, family members, or other caregivers involved in the administration of infusion therapy in the proper storage of medication, in the proper handling of supplies and equipment, in any applicable safety precautions, in recognizing potential problems with the patient, and actions to take in an emergency; and
8. Initial training and retraining of all hospice program staff providing infusion therapy.

D. The hospice program shall employ a registered nurse, who holds a current active license with the Virginia Board of Nursing, has completed training in infusion therapy, and has the knowledge, skills, and competencies to safely administer infusion therapy, to supervise medication administration by staff. This person shall be responsible for ensuring compliance with applicable laws and regulations, adherence to the policies and procedures related to administration of medications, and conducting periodic assessments of staff competency in performing infusion therapy.

PART IV.
Dedicated Hospice Facilities.

12 VAC 5-391-440. General facility requirements.

A. In addition to the facility licensure requirements in 12 VAC 5-391-120, providers of dedicated hospice facilities shall maintain compliance with the standards of this section.

B. All construction of new buildings and additions, renovations or alterations of existing buildings for occupancy as a dedicated hospice facility shall comply with applicable state and federal laws and regulations.

All buildings shall be inspected and approved as required by the appropriate regional state fire marshal's office or building and fire regulatory official. Approval shall be a Certificate of Use and Occupancy indicating the building is classified for its proposed licensed purpose.

C. The facility shall provide 24-hour nursing services sufficient to meet the total nursing needs according to individual plans of care, including treatments, medication, and diet as prescribed, of the patients and shall keep patients comfortable, clean, well-groomed, and protected from accident, injury, and infection.

D. The facility must have space for private patient family visiting and accommodations for family members after a patient's death. Patients shall be allowed to receive guests, including small children, at any hour.

E. Patient rooms must be at grade level or above, enclosed by four ceiling high walls, and can house one or more patients. Each room shall be equipped for adequate nursing care, the comfort and privacy of patients, and with a device for calling the staff member on duty.

F. Designated guest rooms for family members or patient guests and beds for use by employees of the facility shall not be included in the bed capacity of a hospice facility provided such beds and locations are identified and used exclusively by staff, volunteers or patient guests.

Employees shall not utilize patient rooms nor shall bedrooms for employees be used by patients.

G. Waste storage shall be located in a separate area outside or easily accessible to the outside for direct pickup or disposal. The use of an incinerator shall require permitting from the nearest regional permitting office for the Department of Environmental Quality.

H. The facility shall assist in obtaining transportation, when necessary, to obtain medical and psychiatric care, routine and emergency dental care, diagnostic or other services outside the facility.

I. The facility shall provide, or arrange for under written agreement, laboratory, x-ray, other diagnostic services, as ordered by the patient's physician.

J. There shall be a plan implemented to assure the continuation of essential patient support services in case of power outages, water shortage, or in the event of the absence from work of any portion of the workforce resulting from inclement weather or other causes.

12 VAC 5-391-450. Required staffing.

A. Each shift must include at least one registered nurse providing direct patient care.

B. Minimum staffing for a hospice facility with five patient beds shall consist of one registered nurse and one additional direct care staff member on duty at all times. Staffing for hospice facilities with 6 or more beds shall be based on the assessed need of the patients in the facility.

12 VAC 5-391-460. Pharmacy services.

A. Provision shall be made for the procurement, storage, dispensing, and accounting of drugs and other pharmacy products. This may be by arrangement with an off-site pharmacy, but must include provisions for 24-hour emergency service.

B. The dedicated facility shall comply with the Virginia Board of Pharmacy regulations related to pharmacy services in long-term care facilities, i.e., Part XII (18VAC110-20-530 et seq.) of the Virginia Board of Pharmacy Regulations.

C. Each dedicated hospice facility shall develop and implement policies and procedures for the handling of drugs and biologicals, including procurement, storage, administration, self-administration and disposal of drugs.

D. Each facility shall have a written agreement with a qualified pharmacist to provide consultation on all aspects of the provision of pharmacy services in the facility.

The consultant pharmacist shall make regularly scheduled visits, at least monthly, to the facility for a sufficient number of hours to carry out the function of the agreement.

E. Each prescription container shall be individually labeled by the pharmacist for each patient or provided in an individualized unit dose system.

F. No drug or medication shall be administered to any patient without a valid verbal order or a written, dated and signed order from a physician, dentist or podiatrist, nurse practitioner or physician assistant, licensed in Virginia.

G. Verbal orders for drugs or medications shall only be given to a licensed nurse, pharmacist or physician.

H. Each patient's medication regimen shall be reviewed by a pharmacist licensed in Virginia. Any irregularities identified by the pharmacist shall be reported to the physician and the director of nursing, and their response documented.

I. Medication orders shall be reviewed at least every 60 days by the attending physician, nurse practitioner, or physician's assistant.

J. Prescription and nonprescription drugs and medications may be brought into the facility by a patient's family, friend or other person provided:

1. The individual delivering the drugs and medications assures timely delivery, in accordance with the facility's written policies, so that the patient's prescribed treatment plan is not disrupted;
2. Each drug or medication is in an individual container; and
3. Delivery is not allowed directly to an individual patient.

In addition, prescription medications shall be:

4. Obtained from a pharmacy licensed by the state or federal authority; and
5. Securely sealed and labeled by a licensed pharmacist according to 18 VAC 110-20-330 and 18 VAC 110-20-340.

12 VAC 5-391-470. Restraints.

A. Periodic or continuous mechanical or physical restraints during routine care of a patient shall not be permitted, nor shall patients be restrained for employee convenience or as a substitute for care, treatment, or services. In cases of extreme emergencies, when a patient is a danger to himself or others, mechanical or physical restraints may be used as ordered by a physician or other health care provider.

B. Only those devices specifically designed as restraints may be used. Makeshift restraints shall not be used under any circumstances.

12 VAC 5-391-480. Food service.

A. The facility shall provide dietary services to meet the daily nutritional needs of patients.

B. If the facility has patients requiring medically prescribed special diets, the menus for such diets shall be planned by a dietitian qualified according to Chapter 27.1 (§54.1-2730 et seq.) of Title 54.1 of the Code of Virginia, or shall be reviewed and approved by a physician. The facility shall provide supervision of the preparation and serving of any special diets.

C. When meals are catered to a hospice facility, such meals shall be obtained from a food service establishment licensed by the Virginia Department of Health. There shall be a current written contract with the food service establishment pursuant to 12 VAC 5-391-230.

12 VAC 5-391-490. Laundry services.

A. A quantity of linens shall be available at all times to provide for proper care and comfort of residents.

B. Linens and other laundry must be handled, stored and processed to control the spread of infection.

C. Clean linen shall be stored in a clean and dry area accessible to patient rooms.

D. Soiled linen shall be stored in covered containers in separate, well-ventilated areas and shall not accumulate in the facility.

E. Soiled linen shall not be sorted, laundered, rinsed or stored in bathrooms, patient rooms, kitchens or food storage areas.

F. Soiled linen shall not be placed on the floor.

G. Arrangement for laundering patient's personal clothing shall be provided. If laundry facilities are not provided on premises, commercial laundry services shall be utilized.

H. Laundry facilities shall include:

1. A soiled laundry receiving, holding, and sorting room with hand-washing lavatory; and
2. A clean laundry storage, issuing, and holding room or area.

I. On-premise laundry service facilities shall include:

1. A laundry processing room with commercial-type equipment capable of processing seven days needs within a regularly scheduled workweek and a hand-washing lavatory;
2. A storage space for laundry supplies; and
3. A clean laundry inspection and mending room or area.

12 VAC 5-391-500. Pet care.

A. If the facility chooses to permit pets, healthy animals that are free of fleas, ticks and intestinal parasites, have been screened by a veterinarian prior to entering the facility, have received required inoculations and that represent no apparent threat to the health, safety, and well-being of the patients may be permitted provided they are properly cared for and the pet and its housing or bedding are kept clean.

B. Pets shall not be allowed near patients with pet allergies or patients choosing not to be disturbed by animals. Pets shall not be allowed in dining and kitchen areas when food is being prepared or served.