WEST VIRGINIA
SECRETARY OF STATE
BETTY IRELAND
ADMINISTRATIVE LAW DIVISION

Form #4

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OFFICE OF WEST VIRGINIA SECRETARY OF STATE

NOTICE OF RULE MODIFICATION OF A PROPOSED RULE

AGENCY: DHHR Office of Health Facility Licensure and Certification TITLE NUMBER: 64

CITE AUTHORITY: W. Va. Code § 16-51

AMENDMENT TO AN EXISTING RULE: YES X NO ____

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 54

TITLE OF RULE BEING AMENDED: Hospice Licensure Rule

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: ____

TITLE OF RULE BEING PROPOSED: ____

THE ABOVE PROPOSED LEGISLATIVE RULES, FOLLOWING REVIEW BY THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE, IS HEREBY MODIFIED AS A RESULT OF REVIEW AND COMMENT BY THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE. THE ATTACHED MODIFICATIONS ARE FILED WITH THE SECRETARY OF STATE.

Martha Yeager Walker
Authorized Signature

#6.60

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Hospice Licensure Rule

Type of Rule: x Legislative _____ Interpretive _____ Procedural

Agency: **HEALTH AND HUMAN RESOURCES**

Address: **Health and Human Resources**
1 Davis Square, Suite 101
Charleston, WV 25301-1799

Phone Number: **558-1500** Email: anitabarnhouse@wvdhhr.org

Fiscal Note Summary

Summarize in a clear and concise manner what effect this measure will have on costs and revenues of state government.

There is no fiscal impact by this Rule because it is only a replacement for the current Hospice Licensure Rule

Fiscal Note Detail

Show over-all effect in Item 1 and 2 and, in Item 3, give an explanation of Breakdown by fiscal year, including long-range effect.

Effect of Proposal	Fiscal Year		
	2007 Increase/Decrease (use"-")	2008 Increase/Decrease (use"-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0	0	0
Personal Services			
Current Expenses			
Repairs and Alterations			
Equipment			
Other			
2. Estimated Total Revenues			

3. Explanation of above estimates (including long-range effect):

Please include any increase or decrease in fees in your estimated total revenues.

Memorandum

Please identify any areas of vagueness, technical defects, reasons the proposed rule **would not** have a fiscal impact, and/or any special issues **not** captured elsewhere on this form.

Date

Agency

Department of Health and Human Resources

Authorized Representative

Martha Yeager Walker

Martha Yeager Walker
Secretary

TITLE 64
LEGISLATIVE RULES
DEPARTMENT OF HEALTH

SERIES 54
HOSPICE LICENSURE RULE

§ 64-54-1. General.

1.1. Scope - This legislative rule establishes general standards and procedures for the licensure of hospice programs in West Virginia.

1.2. Authority. - W. Va. Code §16-5I.

1.3. Filing Date. -

1.4. Effective Date. -

1.5. Repeal of Former Rule. - This legislative rule repeals and replaces Licensure of Hospice Care Programs, West Virginia Department of Health and Human Resources Legislative Rules, 64CSR54, effective 1989.

1.6. Applicability - This rule applies to any person, partnership, association or corporation and any local governmental unit or any division, department, board or agency thereof establishing, conducting, managing or operating a hospice. The hospice shall be in compliance with the standards in this rule and shall be evaluated independently from compliance with other licensure standards. A hospice may share staff, space, physical facilities and equipment or other components only if the requirements of each applicable rule are satisfied in full.

1.7. Enforcement - This rule is enforced by the Secretary of the West Virginia Department of Health and Human Resources or his or her other lawful designee.

1.8. Purpose - The purpose of this rule is to ensure that all West Virginia hospices conform to a common set of standards and procedures. All standards and procedures are minimum requirements whereby hospices may be surveyed and evaluated to ensure the health and safety of all patients treated in West Virginia hospices.

§ 64-54-2. Definitions.

2.1. Administrator – A qualified person who possesses the education and experience required by the hospice's governing body. The administrator reports to the governing body and is responsible for the day to day operation of the hospice.

2.2. Department - West Virginia Department of Health and Human Resources.

2.3. Director - The official designated by the Secretary of the West Virginia Department of Health and Human Resources as his or her designee unless otherwise specifically noted. This individual is the Director of the Office of Health Facility Licensure and Certification or his or her designee.

2.4. Emergency Medication Kits - Medication provided in the home that is not routine for the patient and may be required for emergency symptom management.

2.5. Governing Body - The designated persons assuming full legal authority and responsibility for the management of the hospice, the provision of all hospice services, its fiscal operations, and continuous quality assessment and performance improvement.

2.6. Hospice - a coordinated program of home and inpatient care provided under the direction of an identifiable hospice administration which provides palliative and supportive medical and other health services to terminally ill individuals and their families. Hospice uses a medically directed interdisciplinary team. A hospice program of care provides care to meet the physical, psychological, social, spiritual and other special needs which are experienced during the final stages of illness and during dying and bereavement.

2.7. Inpatient Hospice Facility - A satellite location of a hospice that provides inpatient services directly at a facility provided by the Director.

2.8. NFPA- National Fire Protection Association.

2.9. Restraint - Any medication used to control behavior or to restrict the patient's freedom of movement which is not part of the standard treatment for a patient's medical or psychiatric condition or any physical or mechanical device, material, or equipment attached to the patient's body that he or she cannot easily remove and restricts freedom of movement or normal access of the patient to his or her body.

2.10. Satellite Location- A state approved location that provides hospice care and services within a portion of the total geographic area served by the hospice provider. The satellite location is part of the hospice and shares the same name, administration, and services in a manner that renders it unnecessary for the satellite location to independently meet this rule.

§ 64-54-3. State Administrative Procedures.

3.1. General Licensure Provisions

3.1.a. A person, partnership, association, corporation, or any governmental unit or any division, department, board or agency thereof may not operate a hospice, satellite location or inpatient facility in the State of West Virginia without first obtaining a license under this rule.

3.1.b. An original or a renewal license shall not be issued under this rule for a project reviewable under W. Va. Code § 16-2D-1, *et seq.*, unless the State Health Planning and Development Agency has issued a determination, after a final conformance review, that the completed project conforms to the terms of the Certificate of Need decision issued for the project. The hospice shall supply evidence of compliance with the State Health Planning and Development Agency when submitting licensure applications to the Director.

3.1.c. A license is valid only for the premises and persons named and described in the application.

3.1.d. A license is not transferable or assignable.

3.1.e. A license is issued to applicants who are in compliance with the

conditions of this rule, W. Va. Code § 16-51-1, *et seq.* and the Hospice Conditions of Participation promulgated by the Centers for Medicare and Medicaid Services.

3.1.f. A hospice shall surrender its license to the Director:

3.1.f.1. Upon written demand stating the cause for the demand; or

3.1.f.2. In the event the hospice ceases to provide services.

3.1.g. A hospice shall report a proposed change of ownership, including a change in a controlling interest, to the Director a minimum of sixty (60) days prior to the change.

3.1.g.1. A new owner shall immediately apply for a new license.

3.1.g.2. A new owner's application for a license has the effect of a valid license for three (3) months from the date the application is received by the Director.

3.1.h. A license shall state:

3.1.h.1. The specific name of the hospice to which it applies;

3.1.h.2. The date of its issuance; and

3.1.h.3. Its expiration date.

3.1.i. A hospice name change shall be shown on the next license issued.

3.1.j. The license shall be posted in a conspicuous and public place of the hospice.

3.1.k. Any hospice, satellite location or inpatient facility's advertisement shall contain the legal name provided to the Director at the time of application.

3.1.l. A hospice shall apply and receive notification and approval from the Director before a hospice may operate an inpatient facility, satellite location or any other location.

3.2. Initial License

3.2.a. An applicant shall submit a completed application to the Director, on a form prescribed by the Director, not less than thirty (30) days and not more than ninety (90) days prior to the date proposed for commencement of operation for a hospice office, satellite location or an inpatient facility. A non-refundable fee of one hundred dollars ($100) shall be submitted with the application for the initial license.

3.2.b. A hospice shall identify the following as part of the application:

3.2.b.1. The hospice's operating name, the office location, the mailing address and telephone number;

3.2.b.2. The name and title of its administrator or other contact person;

3.2.b.3. A listing of services the hospice intends to offer either directly or by contractual agreement;

3.2.b.4. Written evidence that the building or part of the building in which the hospice office, satellite location or inpatient facility is to be located is in compliance with applicable local zoning, building and fire safety laws and chapters;

3.2.b.5. The mailing address, phone number and location of each satellite location or inpatient facility;

3.2.b.6. A copy of a valid Certificate of Need or a letter of exemption from the West Virginia Healthcare Authority; and

3.2.b.7. The name, address, principal occupation and official position of all persons who have an ownership interest in the hospice or the name, address, principal occupation, and official position of each member of the board of directors, if a corporation owns the hospice.

3.2.c. If, at the initial licensing survey, an agency has more than five (5) violations of any minimum requirements or if any of the violations are determined to be of such a serious nature that they may cause or have the potential to cause harm, the Director shall deny licensing until the hospice is found to be in substantial compliance with this rule.

3.2.d. The Director shall issue an initial license only after the Director or his or her designee inspects the hospice or inpatient facility and finds the hospice complies with this rule and W. Va. § 16-5I-1, *et seq.*

3.2.e. An initial license issued is valid for a period of one (1) year from the date of issuance.

3.2.f. The Director may inspect a satellite location prior to the issuance of a license.

3.3. Renewal License

3.3.a. An applicant for a renewal license shall submit a completed application to the Director, on a form prescribed by the Director, not less than sixty (60) days and not more than ninety (90) days prior to the scheduled expiration date of the current license. A non-refundable fee of one hundred dollars ($100) shall be submitted with the license renewal application for a hospice whose yearly caseload exceeds ten (10) or more patients, and fifty dollars ($50) for a hospice whose yearly caseload is fewer than ten (10) patients.

3.3.b. The Director shall issue a renewal license when he or she finds the hospice is determined to be in compliance with this rule and W. Va. 16-5I-1, *et seq.* and the licensee submits a completed application and the correct renewal fee.

3.3.c. A renewal license is valid for a period of one (1) year from the date of issuance.

3.3.d. The Director shall issue a renewal license to each hospice office, satellite location and inpatient facility.

3.4. Inspections

3.4.a. The Director shall inspect all hospices that are subject to the provisions of this rule and W. Va. Code § 16-5I-1, *et seq.* periodically and at least as

often as required by the Centers for Medicare and Medicaid Services in order to determine compliance with the provisions of this rule, W. Va. Code § 16-5I-l, *et seq.* and the Hospice Conditions of Participation promulgated by the Centers for Medicare and Medicaid Services.

3.4.b. The Director shall inspect or investigate a main hospice office, satellite location, inpatient facility or office advertised with the hospice name as he or she considers necessary.

3.4.b.1. The Director shall conduct an unannounced inspection of a hospice, satellite location or inpatient facility. This inspection may include home visits with prior patient consent, interviews with agency staff and family members, reviews of clinical records, environmental and life safety inspections and any other documents necessary for the determination of compliance with this rule.

3.4.c. The Director may enter the premises of any hospice the Director has reason to believe is being operated or maintained as a hospice without a license.

3.4.c 1. If the owner or person in charge of a licensed hospice or of an unlicensed hospice which the Director has reason to believe is being operated as a hospice refuses entry pursuant to this rule, the Director shall petition the Circuit Court of Kanawha County for an inspection warrant.

3.4.c.2. If the Director finds on the basis of the inspection that any person, partnership, association or corporation and any local governmental unit or any division, department, board or agency thereof is operating as a hospice without a license, the hospice shall apply for a license within ten (10) days, in accordance with the provisions of this rule.

3.4.d. A hospice that fails to apply for a license is subject to the penalties established by W. Va. Code § 16-5I, *et seq.*

3.4.e. The Director shall maintain a written report of the inspection on file.

3.4.f. The Director shall send the inspection report to the hospice.

3.4.g. The hospice shall submit to the Director a plan of correction to any violations of this rule or W. Va. Code 16-5I, *et seq.* identified during an inspection of a hospice, satellite location or inpatient facility.

3.5. Complaint Investigation

3.5.a. Any person may register a complaint with the Director alleging violation of applicable laws, rules or requirements by a hospice. The complaint shall state the substance of the complaint, the patient's name if applicable and the hospice involved.

3.5.b. The Director may conduct an unannounced inspection of a hospice, satellite location or inpatient facility to determine the validity of the complaint.

3.5.c. The Director shall notify the complainant in writing that an investigation was conducted.

3.5.d. The Director shall notify

the hospice in writing of the results of the investigation no later than fifteen (15) working days after completing the investigation.

3.5.d.1. If the complaint is substantiated by the investigation as a violation of this rule or W. Va. Code § 16-5I-1, *et seq.* the Director shall require the hospice to develop a plan of correction or may take other action authorized by state law or this rule.

3.6. Plans of Correction

3.6.a. A hospice, satellite location or inpatient facility found to have deficiencies based on an inspection or complaint investigation shall develop a plan of correction and submit it to the Director within ten (10) calendar days of receipt of the inspection report.

3.6.b. A plan of correction shall specify a reasonable time within which a hospice shall correct each deficiency cited in the report and in any case shall be no more than sixty (60) days after the date of the inspection.

3.6.c. The Director may approve or reject a plan of correction submitted by a hospice. The Director shall notify the hospice within fifteen (15) working days whether a plan of correction has been approved or rejected. If the Director rejects the plan, he or she shall state the reasons for the action. When the Director rejects a plan of correction, the Director may give the hospice up to ten (10) calendar days for submission of a revised plan.

3.6.d. Upon failure of a hospice to submit an approved plan of correction or to correct any deficiency within the time specified in the approved plan of correction, the Director may initiate action in accordance with W. Va. Code § 16-5I-1, *et seq.*

3.7. Availability of Reports

3.7.a. The Director shall make a copy of the inspection report available upon written request. A reasonable fee may be charged to cover the cost of research and copying.

3.7.b. The Director shall treat the inspection report as public information from the time a written plan of correction is received and accepted by the Director.

3.7.c. The hospice shall submit plan of correction to the Director within twenty (20) calendar days or the report will be made available to the public.

3.7.d. Nothing contained in this section shall be construed to require or permit the public disclosure of confidential medical, social, personal or financial records of any patients.

§ 64-54-4. Organization and Management.

4.1. A hospice shall have a governing body that determines, implements and monitors policies governing the hospice's total operation in accordance with established bylaws.

4.1.a. If a hospice is operated by a hospital, nursing home or other type of organization, there shall be an identifiable separate administration which serves the

function of the governing body for a hospice program, although a separate ownership or board of directors is not required.

4.1.b. The governing body shall meet at least annually to review the hospice's total operation including at a minimum:

4.1.b.1. Policy review;

4.1.b.2. Provision and coordination of inpatient care and in home care;

4.1.b.3. The quality assessment and performance improvement committee's reports and actions; and

4.1.b.4. Any other reviews necessary to determine adequate care, treatment, health, safety, welfare and comfort of hospice patients .

4.1.c. Annual reviews shall be documented by signed meeting minutes kept at the hospice.

4.2. The governing body shall designate a person who is responsible for the day to day operation of the hospice.

4.2.a. The person designated shall be qualified by education or training as specified in a job description developed by the governing body.

4.2.b. The person designated shall be responsible for the overall supervision of all staff working on behalf of the hospice.

4.2.c. The person designated shall be responsible for the overall development of staff qualifications and shall develop and approve job descriptions for each job classification.

4.2.d. Each job description shall designate by job title who is responsible for supervision for all licensed and unlicensed staff providing services to the hospice.

4.3. The governing body shall develop and maintain a current organizational chart which clearly delineates the lines of authority and supervision of all staff.

4.4. The hospice shall develop and implement written policies and procedures consistent with this rule.

4.4.a. Policies and procedures shall accurately reflect a description of the hospice's goals, methods by which these goals are sought, and mechanisms by which the hospice care services are delivered.

4.4.b. The interdisciplinary team shall review the clinical policies and procedures annually and shall document the review by a dated signature.

4.4.c. The interdisciplinary team shall revise the clinical policies and procedures as needed.

4.5. The hospice shall maintain clinical records and business records pertaining to the patient according to hospice policy.

4.5.a. The hospice shall establish policies and procedures specifying who may use the records, under what conditions the records may be removed from the hospice and under what conditions the

information from the records may be released.

4.5.b. A hospice that discontinues operation shall inform the Director, in writing, where the clinical and business records are stored and how the records may be accessed.

4.5.c. The hospice shall take measures to ensure the safety of the clinical and business records.

4.5.d. The patient or his or her legal representative has the right to examine the patient's clinical record at reasonable times and shall, upon written request, be provided with a copy or a summary of the clinical record within a reasonable time. A hospice shall comply with other provisions of W. Va. Code § 16-29-1 *et seq.*

4.6. The patient or his or her legal representative may voice complaints regarding the care or lack of care and services provided by the hospice.

4.6.a. The person designated by the governing body for the day to day operation of the hospice shall be responsible for the complaint process.

4.6.b. The hospice shall designate a person or persons who shall be responsible for reviewing and investigating allegations.

4.6.c. The hospice shall communicate the results of the investigation to the patient or his or her legal representative as soon as possible but no later than 30 days after the receipt of the complaint.

4.6.d. The hospice shall maintain documentation of the investigation until the next re-certification survey.

4.7. The hospice shall have a legally binding contract for any services provided by contract at the hospice.

4.7.a. The contract shall state the services to be provided.

4.7.b. The contract shall state how the hospice will be responsible for the supervision of services.

§ 64-54-5. Provision of care.

5.1. A hospice shall provide services seven days a week, twenty-four hours a day to meet the needs of the patient.

5.2. A hospice shall provide the services described in subsections 5.6. and 5.7. of this rule to the extent necessary to meet the needs of patients that are reasonable and necessary for the palliation and management of the terminal illness.

5.3. The hospice shall make services available at the patient's place of residence.

5.3.a. Services provided to patients residing at skilled nursing facilities, nursing facilities, intermediate care facilities for the mentally retarded or any other facilities, shall meet all the same requirements as any other patient of the hospice and the hospice shall have an agreement for services.

5.3.a.1. The hospice shall retain professional management of hospice care.

5.3.a.2. The hospice shall ensure continuity of care.

5.3.a.3. The hospice shall ensure care is provided in accordance with the plan of care.

5.3.a.4. The hospice shall develop a way to monitor and supervise hospice services in these facilities.

5.4. Services shall be provided in a manner consistent with accepted standards of practice.

5.5. Services shall be provided under the supervision of a hospice Interdisciplinary Team.

5.6. The hospice shall provide the following services at a minimum:

5.6.a. Physician services which shall meet the medical needs of the patients for the palliation and management of the terminal illness. The medical director and hospice physicians shall be licensed according to the West Virginia Board of Medicine or the West Virginia Board of Osteopathy and are subject to the rules of the Board. Nurse practitioner's, when serving as the patient's attending physician, shall be licensed according to the West Virginia Board of Examiners for Registered Professional Nurses and are subject to the rules of the Board;

5.6.b. Nursing services which shall meet the nursing needs of all patients for the palliation and management of the terminal illness. Each patient shall be under the care of a Registered Nurse, who is licensed by the West Virginia Board of Examiners for Registered Professional Nurses. Licensed Practical Nurses shall be licensed by the West Virginia State Board of Examiners for Licensed Practical Nurses;

5.6.c. Medical social services which shall meet the needs of the patients for the palliation and management of the terminal illness. The medical social worker shall have at least a Bachelor's degree from an accredited Social Work study and be licensed in accordance with the West Virginia Board of Social Work Examiners;

5.6.d. Spiritual care which shall meet the spiritual needs of the patients. Spiritual care shall be provided under the direction of a person who has received education or training in providing spiritual care;

5.6.e. Bereavement services which are provided up to one year after a patient has died. Bereavement services shall be provided under the direction of a person who has received education or training in bereavement counseling;

5.6.f. Interdisciplinary team services which includes a Physician, Registered Nurse, Social Worker, Counselor and any other services required to meet the needs of the patient for the palliation and management of the terminal illness; and

5.6.g. Nutritional counseling which shall meet the needs of the patients.

5.7. The hospice shall provide additional services as needed for the support and care of hospice patients.

5.7.a. Therapy services shall be provided under the supervision of a Physical Therapist, Occupational Therapist or

Speech Pathologist Therapist as needed for the palliation and management of the terminal illness.

5.7.a.1. The Physical Therapist or Physical Therapist Assistant shall be licensed and supervised in accordance with the West Virginia Board of Physical Therapy.

5.7.a.2. The Occupational Therapist or Certified Occupational Therapy Assistant shall be licensed and supervised in accordance with the West Virginia Board of Occupational Therapy.

5.7.a.3. The Speech - Language Pathologist shall be licensed in accordance with the West Virginia Board of Examiners Speech-Language Pathology and Audiology.

5.7.b. The hospice shall provide Home Health Aides and homemaker services to meet the personal care needs of the patient.

5.7.b.1. The Home Health Aide shall be competency evaluated for all duties he or she performs.

5.7.b.2. The Home Health Aide shall be under the supervision of a Registered Nurse. A Registered Nurse shall make an onsite visit to the patient's place of residence no less than every 14 (fourteen) days to assess the home health aide's services. The home health aide does not need to be present during this visit. A Registered Nurse shall make an onsite visit to the patient's place of residence in order to observe and assess each aide while he or she is performing care no less than every 28 (twenty eight) days.

5.7.b.3. The Homemaker shall be under the supervision of the Registered Nurse and shall be supervised directly at the patient's residence by the Registered Nurse every 30 (thirty) days.

5.7.c. The hospice shall provide nutritional services to meet the dietary needs of the patient. These services shall be under the direction of a person who is qualified by training or education.

5.7.d. The hospice shall provide pharmaceutical services to meet the patients' needs for palliative care and symptom management. The Pharmacist shall be licensed in the state in which he or she practices.

5.7.e. The hospice shall provide volunteer services to meet the patient's needs. The services shall be provided under the direction of a person qualified by training or education.

5.7.f. The hospice shall provide Respite and Inpatient care for patient symptom management or caregiver relief. The care shall be provided in a facility acceptable to the Centers for Medicare and Medicaid Services for this purpose.

5.7.g. The hospice shall provide continuous care nursing on a twenty-four hour basis for palliative care and symptom management at the patient's residence during periods of crisis.

5.7.h. The hospice shall provide medical supplies including drugs and biologicals, as needed for the patient's

palliation and symptom management.

5.8. A hospice program shall provide or arrange a competency evaluation, employee training and continuing education program.

5.8.a. The hospice shall ensure all licensed and unlicensed staff are competent to perform the duties assigned to them.

5.8.b. The orientation and continuing education program for all patient care staff shall contain at a minimum:

5.8.b.1. Orientation and training for new employees to acquaint them with the philosophy, organization, services, practices and goals of the hospice program;

5.8.b.2. The psychological aspects of terminal disease and the hospice's goal in providing palliative care and supportive services;

5.8.b.3. Family dynamics and psychosocial issues surrounding terminal disease, death and bereavement;

5.8.b.4. Communication and documentation skills;

5.8.b.5. Policies and services of the hospice;

5.8.b.6. The role of the plan of care in determining the services to be provided;

5.8.b.7. Ethics, confidentiality of patient information, patient and family rights and grievance procedures; and

5.8.b.8. Additional initial and continued training needed specific to the duties, responsibilities and the competency of the employee.

5.9. A hospice shall admit a patient only on the recommendation of the medical director or physician designee in consultation with the patient's attending physician.

5.10. The hospice shall not deny acceptance of a patient to the hospice service based on race, color, national origin, age, sex, religion or ethnicity.

5.11. The hospice shall inform a patient or his or her legal representative in writing at the time of admission and again per hospice policy with any changes to the following:

5.11.a The responsibilities of a hospice in regards to the care of the patient, including services to be provided by the hospice and the patient's and caregiver's role in the care;

5.11.b. The materials and equipment available to the patient and family;

5.11.c. Any existing pre-payment, refund or sliding scale fee policy;

5.11.d. A statement of the patient's and family's financial responsibility if any;

5.11.e. The phone number of the Office of Health Facility Licensure and Certification with instructions on how to make a complaint; and

5.11.f. The drugs and biologicals for which the patient and the hospice would be responsible.

5.12. Once a patient has been accepted for care, care shall not be reduced due to the patient's inability to pay for the care unless the following requirements are met:

5.12.a. A list of services is provided to the patient or his or her legal representative detailing what the patient is responsible for with the dollar amount of those services; and

5.12.b. A review of the patient's finances and referrals to outside agencies shall determine no further financial assistance is available and the patient or his or her legal representative refused continued services based on this assessment.

5.13. A hospice may discharge a patient if:

5.13.a. The patient moves out of the hospice service area or transfers to another hospice;

5.13.b. It determines the patient no longer meets the terminally ill diagnosis; or

5.13.c. Its policy determines justifiable reason for the discharge.

5.14. A hospice shall assist a patient in obtaining necessary follow up care before discharging or transferring the patient and shall give the patient at least a 48 hour notice of the pending discharge from hospice services. This notice may be less than 48 hours in the event of a patient discharge for staff safety reasons.

5.15. A hospice shall complete a discharge summary to provide important clinical information to health care professionals assuming the care of the patient.

5.15.a. The hospice shall provide a discharge summary along with pertinent hospice documentation to the patient's attending physician.

5.15.b. The hospice shall provide the discharge summary along with pertinent hospice documentation to the agency or facility assuming the patient's care.

5.16. A hospice shall supply an itemized statement detailing services provided and charges assessed at no additional cost upon request from the patient or his or her legal representative.

§ 64-54-6. Coordination of care.

6.1. At the time an individual is accepted for care, or no later than the second calendar day, a hospice shall obtain documentation from the attending physician and the physician member of the hospice interdisciplinary team or medical director stating the client is terminally ill.

6.1.a. The physician shall certify the patient to be terminally ill indicating a life expectancy of six (6) months or less or another length of time as determined by the Centers for Medicare and Medicaid Services and designated in federal hospice regulations.

6.1.b. A verbal certification

shall be obtained and signed by both physicians if the written certification is not obtained by both physicians within two (2) calendar days following the initiation of hospice care.

6.1.c. The certification may be completed up to two (2) weeks before hospice care is elected.

6.2. The physician member of the hospice interdisciplinary team or medical director shall document re-certification of the terminal illness at the end of the first ninety (90) days of care and again at the end of the second ninety (90) days of care if the patient remains under the care of the hospice.

6.3. A patient remaining under the care of a hospice for a period of time in excess of six (6) months shall be re-evaluated every sixty (60) days by the physician member of the interdisciplinary team or medical director with respect to the prognosis for life expectancy. A patient shall be considered for transfer to other types of health care providers in the event of an improvement in his or her medical condition.

6.3.a. The documentation shall be included in the clinical record and shall be signed by the hospice physician within fourteen (14) days of the re-evaluation assessment.

6.4. A registered nurse shall make an initial assessment evaluation visit to the patient's residence in a time frame consistent with Medicare hospice guidelines after a hospice receives a physician's order for care, unless ordered otherwise by the physician, to determine the patient's immediate care and support needs.

6.5. The medical social worker shall make an initial home visit to assess the patients' needs in a time frame consistent with Medicare hospice guidelines after the initial visit by the registered nurse.

6.6. The initial spiritual assessment and documentation of volunteer services shall be conducted after the initial visit in a time frame consistent with Medicare hospice guidelines.

6.7. All other assessments shall be conducted in a time frame consistent with Medicare hospice guidelines.

6.8. The interdisciplinary team, in consultation with the patient's attending physician, shall complete a comprehensive assessment in a time frame consistent with Medicare hospice guidelines.

6.8.a. The comprehensive assessment shall include an assessment of the patient's physical, psychosocial, emotional and spiritual needs and a family bereavement assessment.

6.9. The interdisciplinary team shall develop an interdisciplinary plan of care within seven (7) days of the patient's acceptance into the hospice program.

6.9.a. The plan of care shall contain at a minimum the following:

6.9.a.1. A diagnosis and prognosis;

6.9.a.2. Orders for each service that includes the scope and frequency of visits needed to meet the patient's needs;

6.9.a.3. Orders for medications and treatments;

6.9.a.4. Orders for medical tests; and

6.9.a.5. Any other information needed to meet the needs of the patient for palliation and management of the patient's terminal illness.

6.9.b. The interdisciplinary team shall update the plan of care as frequently as the patients condition requires:

6.9.b.1. But no less than every fourteen (14) days; and

6.9.b.2. At the time of each re-certification.

6.9.c. All personnel representing the scope of services being provided to the patient shall participate in the plan of care.

6.9.d. The patient and his or her family shall be included in the establishment and review of the plan of care.

6.10. When the patient requires an inpatient stay for services related to the hospice diagnosis, the hospice shall provide, at a minimum, the written interdisciplinary team plan of care to the facility within twenty-four (24) hours of the patient's transfer.

6.10.a. An inpatient stay for acute symptom management shall:

6.10.a.1. Be provided in a facility acceptable to the Centers for Medicare and Medicaid Services for this purpose, and;

6.10.a.2. Include the hospice ensuring a Registered Nurse is directly available for care of the patient at all times.

6.10.b. Respite care for caregiver relief shall:

6.10.b.1. Be provided in a facility acceptable to the Centers for Medicare and Medicaid Services for this purpose.

6.10.c. Upon transfer to an inpatient facility the hospice nurse shall make a visit to the facility to provide instructions and ensure the patient's continuity of care.

6.10.c.1. If the visit to the facility can not be completed on admission, then the hospice shall contact the facility with a verbal report to the nursing staff and follow up with a visit within forty-eight (48) hours of the transfer.

6.10.d. The plan of care shall be updated to reflect the change in the patient's status.

6.10.e. The hospice shall continue to make visits as noted in the plan of care to the patient during the inpatient stay to ensure the continuity of care.

§ 64-54-7. Infection Control

7.1. A hospice shall maintain an effective infection control program that protects the patients, their families and hospice personnel by preventing and controlling infections and communicable

diseases.

7.2. The program shall include the implementation of a nationally recognized system of infection control guidelines.

7.3. A hospice shall designate a person or persons responsible for the education and training of all staff in regards to infection control.

§ 64-54-8. Quality Assessment and Performance Improvement

8.1. A hospice shall establish a quality assessment and performance improvement program that ensures quality of care is provided to all patients. The program shall monitor, identify and take corrective actions to identified problems.

8.2. The hospice shall designate a person or persons responsible for the quality assessment and performance improvement program.

8.3. The designated person or persons of the quality assessment and performance improvement program shall have a written plan for the annual review and evaluation of all hospice care and services.

8.4. The annual review and evaluation shall include a representative of each hospice service offered.

8.5. The annual review shall be sent to the governing body for review.

§ 64-54-9. Volunteer Services

9.1 A hospice shall use volunteers in the provision of care and services under the direction of the interdisciplinary team.

9.2. The hospice shall designate a person or persons responsible for the training, education and supervision of volunteers.

9.3. A hospice shall develop written policies and procedures for volunteers providing care and services.

9.4. A hospice shall document the training of volunteers. The training shall contain at a minium:

9.4.a. Volunteer duties and responsibilities;

9.4.b. The person or persons to whom the volunteer reports;

9.4.c. The person or persons to contact if the volunteer needs assistance and instructions regarding the performance of his or her duties and responsibilities;

9.4.d. Confidentiality and protection of the patient's and family's rights;

9.4.e. Procedures to be followed in an emergency;

9.4.f. Job responsibilities specific to the individual's responsibilities;

9.4.g. Instructions on documentation of volunteer hours and documentation of patient contacts; and

9.4.h. Training regarding procedures to follow at the time of a patient death;

9.5. A hospice shall ensure volunteers

document patient encounters which are included in the clinical record.

9.6. A hospice shall provide and document a continuing education program for volunteers.

§ 64-54-10. Counseling Services

10.1. A hospice shall designate a person or persons responsible for the delivery and supervision of nutritional counseling, spiritual counseling and bereavement services.

10.2. The hospice program shall provide for the delivery of nutritional counseling, spiritual counseling and bereavement services that reflect the patient's and family's needs and desires and is delivered based on the plan of care.

10.3. 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.

10.3.a. The hospice shall maintain documentation of a patient's or family's request for clergy and the delivery of the services.

10.4. Bereavement services shall be provided by a qualified person or persons for a minimum of twelve (12) months after the patient's death, as requested. Refusal of bereavement services by the family must be documented.

10.4.a. A bereavement assessment of survivor risk factors shall be completed after a patient's admission to hospice and updated at the patient's death.

10.4.b. The bereavement care plan shall be established for those survivors requesting bereavement care within six (6) weeks after a patient's death.

10.4.c. The bereavement care plan shall contain information about who shall receive bereavement services, how often services are to be provided and what services will be offered.

10.4.c.1. Bereavement services may also extend to residents and employees of a skilled nursing facility, nursing facility, intermediate care facility for the mentally retarded or other facility identified in the bereavement plan of care.

10.4.d. The bereavement care plan shall be updated as needed.

10.4.e. If the hospice discharges survivors from bereavement services before the twelve (12) months expire, the hospice shall justify and document the discharge.

10.5. Nutritional counseling shall be performed by a qualified individual to address and assure the dietary needs of the patient are met.

§ 64-54-11. Pharmaceutical Services

11.1. All drugs and biologicals shall be administered in accordance with standards of practice by:

11.1.a. Appropriately licensed employees of a hospice; or

11.1.b. The patient and his or her family who have been properly educated

on administration of the medications by a licensed employee of the hospice.

11.2. The hospice shall formulate written policies and procedures relative to medications and biologicals in accordance with accepted standards of practice.

11.3. The hospice shall formulate written policies and procedures for the control and accountability of all drugs and biologicals to prevent their unauthorized use or distribution.

11.4. The hospice shall formulate written policies and procedures for the use of emergency medication kits left in the patient's home for emergency use.

11.5. If the hospice uses emergency kits in the patient's home then the following minium requirements shall be met:

11.5.a. A licensed physician shall order all medications included in the medication kit;

11.5.b. The emergency medication kit shall include a list of the medications with information on each drug included in the emergency medication kit;

11.5.c. The emergency medication kit shall contain only medications needed for palliative care;

11.5.d. A licensed nurse shall assess the emergency medication kit at least weekly, or at the next scheduled visit if not weekly, to ensure unauthorized use has not occurred; and

11.5.e. Documentation of all information regarding the emergency kit shall be kept in the patient's clinical record.

§ 64-54-12. Inpatient Facility Services

12.1. General Requirements.

12.1.a. If a hospice administers an inpatient facility for acute symptom management, respite care or residential care, the provisions of this section apply.

12.1.b. An inpatient facility shall have a full time administrator. The administrator shall designate an individual who shall act in his or her absence as needed.

12.1.c. An inpatient facility shall have a full or part time physician to meet the needs of the patient.

12.1.c.1. A physician, who can be the medical director for the hospice, or designee shall be available on call at all times.

12.1.d. An inpatient facility shall make reasonable efforts to safeguard personal property and promptly investigate complaints of any loss. At the time of admission, the inpatient facility shall prepare a record of all clothing, personal possessions and money brought by the patient to the inpatient facility. The inpatient facility shall update the record as additional personal property is brought to the inpatient facility.

12.1.e. If an inpatient facility keeps patient funds, the funds shall be kept in an account separate from the inpatient facility funds. Patient funds shall not be used by the inpatient facility.

12.1.f. An inpatient facility shall have a policy to admit only patients who:

12.1.f.1. Have been diagnosed as terminally ill; and

12.1.f.2. Have personally or through a legal representative, in writing, given informed consent to receive hospice care.

12.1.g. Inpatient facility admissions in excess of the licensed bed capacity are prohibited except when the Director approves an emergency admission.

12.1.h. If a patient is transferred from in-home hospice care to the inpatient facility then the following shall occur:

12.1.h.1. The home hospice staff shall contact the inpatient facility with a report including the services to be provided;

12.1.h.2. The home hospice care shall provide a copy of the interdisciplinary team care plan within twenty-four (24) hours to the inpatient facility;

12.1.h.3. The home hospice care shall provide significant information to the inpatient facility to ensure continuity of care.

12.2. Nursing requirements.

12.2.a. An inpatient facility shall provide nursing care and services by or under the direct supervision of a Registered Nurse at all times.

12.2.b. An inpatient facility shall have a Registered Nurse on site at all times.

12.2.c. Nursing care and services shall be provided in accordance with the plan of care developed by the interdisciplinary team and as ordered by the physician.

12.2.d. Nursing care, staffing and services shall meet the needs of the patients.

12.2.e. A Registered Nurse shall assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available.

12.2.f. Nursing care and services shall be provided in accordance with recognized standards of practice.

12.3. Pharmaceutical Services

12.3.a. The pharmaceutical services shall be under the direction of a licensed pharmacist.

12.3.b. There shall be a medicine room or drug preparation area of sufficient size for the orderly storage of drugs, both liquid and solid dosage forms, and for the preparation of medications for patient administration within the unit. In the event that a drug cart is used for storage and administration of drugs, the room shall be of sufficient size for storage of the cart without crowding.

12.3.c. An inpatient facility

shall develop policies to identify, monitor and track medication errors and adverse drug reactions. The results shall be reported to the quality assurance program.

12.4. Laboratory and Radiological Services.

12.4.a. An inpatient facility shall maintain or have available, whether directly or through a written agreement, adequate laboratory and radiological services available to meet the needs of the patients.

12.5. Food and Dietetic Services.

12.5.a. An inpatient facility shall comply with W. Va. Code § 64-17-1, *et seq.*

12.5.b. An inpatient facility shall designate a person, either directly or by contractual agreement, to serve as the food and dietetic services manager with responsibility for the daily management of the dietary services.

12.5.c. An inpatient facility that does not provide the services of a certified dietary manager shall, at a minimum, train all employees through the county health departments' food managers training course or a comparable course.

12.5.d. An inpatient facility shall designate a qualified dietitian, either directly or through a contractual agreement, who is responsible for the development and implementation of a nutrition care program to meet the needs of the patients. This dietician shall be available as needed to assist in nutritional assessment, menu planning, educating staff and evaluating safe food production.

12.5.e. Menus shall meet the needs of the patients. Special diets shall be prepared and served as ordered.

12.5.f. A current therapeutic diet manual approved by the dietitian and medical director shall be readily available to all medical, nursing and food service personnel.

12.5.g. Families shall be allowed to store home cooked food for a patient. This storage shall be readily available. Food brought from home shall not be co-mingled with the food prepared by the hospice for other patients.

12.6. Restraints

12.6.a. A patient has the right to be free from a restraint of any form imposed as a mean of coercion, discipline, convenience or retaliation by staff.

12.6.b. The use of a restraint shall be:

12.6.b.1. Selected only when less restrictive measures are found ineffective to protect the patient or other persons from harm;

12.6.b.2. Only used as ordered by the hospice physician or attending physician;

12.6.b.3. Implemented in the least restrictive manner possible not to interfere with the palliative care being provided;

12.6.b.4. In accordance with safe and appropriate restraining practices; and

12.6.b.5. Ended at the earliest possible time.

12.6.c. The hospice shall have policies and procedures for the use of restraints.

12.6.d. All staff shall receive training in proper and safe restraining techniques and training in de-escalation of behaviors at least annually.

12.6.e. The patient shall be monitored and evaluated to ensure the safety of the patient.

§ 64-54-13. Inpatient Physical Facilities, Equipment, and Related Items.

13.1. The provisions of this section apply to all hospice inpatient facilities. An inpatient facility licensed prior to the effective date of this rule shall be maintained in accordance with applicable standards of practice as referenced in "Sections 8 and 13" in the 2001 edition of The Guidelines for Design and Construction of Hospital and Health Care Facilities as recognized by the American Institute of Architects Academy of Architecture for Health.

13.2. The following documents shall be adopted as construction, equipment, physical facility, and related procedural standards for all inpatient facilities, new construction and any additions, alterations, renovations, or conversions of existing buildings:

13.2.a. "Section 4.2: of the 2006 edition of The Guidelines for Design and Construction of Hospital and Health Care Facilities as recognized by the American Institute of Architects Academy of Architecture for Health with assistance from the United States Department of Health and Human Resources shall be used as planning standards;

13.2.b. The State Building Code, which is the 2003 Edition of the International Building Code as adopted by the State Fire Commission, State Building Code, 87CSR4;

13.2.c. Provisions applicable to nursing homes, electrical standards, medical gas standards and patient care equipment standards and health care emergency management standards as defined in the applicable subsections in the 2005 Edition of NFPA 99, Standard for Health Care Facilities;

13.2.d. The guidelines set forth in the Americans With Disabilities Act, 28 CFR Part 36; and

13.2.e. The current State Fire Code as adopted by the State Fire Commission, State Fire Code, 87CSR1.

13.3. An inpatient facility shall comply with applicable rules of the West Virginia State Fire Commission.

13.4. An inpatient facility shall ensure that patient rooms are designed and equipped for nursing care, as well as the dignity, comfort, and privacy of patients.

13.4.a. Maximum room

occupancy is one (1) patient unless justified by the hospice. In no case shall a patient room exceed two (2) occupants.

13.4.b. All patient rooms shall provide a minimum of one hundred and twenty (120) square feet of clear floor space per patient excluding toilet room space. Each patient room shall have a private toilet and bathing space.

13.4.c. A minimum of fifty (50) percent of the patient rooms shall meet the guidelines set forth in the Americans With Disabilities Act, 28 CFR Part 36.

13.5. The interior and exterior of the inpatient facility shall be maintained to provide a clean, safe, sanitary environment free of hazards for patients, staff, and visitors.

13.6. An inpatient facility shall have an emergency operations plan in effect for managing the consequences of power failures, natural disasters, and other emergencies that would affect a hospice's ability to provide care or interrupt normal operations.

13.6.a. All staff shall be familiar with the written emergency operations plan developed in accordance with the standards identified in NFPA 99.

13.6.b. New employees shall be trained in emergency operations upon hire and annually thereafter in accordance with the requirements identified in NFPA 99.

13.6.c. The administrator shall review the emergency operations plan on an annual basis, which shall be verified by his or her signature and the date.

13.6.d. There shall be at least one (1) rehearsal of the emergency operations plan on a semiannual basis.

13.7. An inpatient facility shall develop procedures for managing the control, reliability, and quality of the physical facility. This shall include the light, temperature, humidity, ventilation and air exchanges, and air quality throughout the hospice.

13.8. An inpatient facility shall have adequate drainage, electricity, telephone, sanitation, water, and other necessary facilities available on or near the site.

13.9. An inpatient facility shall meet local building codes and zoning restrictions. Where local codes or regulations permit lower standards than required by this rule, the standards contained in this rule take precedence.

13.10. Site conditions shall comply with the relevant sections of the 2006 Edition of The Guidelines for Design and Construction of Hospital and Healthcare Facilities as recognized by the American Institute of Architects Academy of Architecture for Health.

13.11. An inpatient facility shall request, in writing, an inspection of a proposed inpatient facility site and obtain approval for construction from the Director before beginning construction.

13.12. For new construction, renovations and alterations, an inpatient facility shall submit to the Director for review and approval, complete construction drawings and specifications for the inpatient facility construction project which alters a floor plan,

impacts life safety or requires approval under W. Va. Code § 16-2D-1, *et seq.* prior to beginning work on the project. An architect or engineer registered to practice in West Virginia shall prepare and sign and seal the drawings and specifications including architectural, life safety, structural, mechanical, and electrical drawings and specifications.

13.12.a. Each new inpatient facility constructed after the effective date of this rule shall provide a private room for family members to place telephone calls.

13.12.b. Prior to starting any renovations, an inpatient facility shall complete an infection control and safety risk assessment and shall develop a plan to control exposure of patients, employees and the public. This plan shall be implemented prior to and during construction phases.

§ 64-54-14. Penalties.

14.1. Director's Authority

14.1.a. The Director may suspend or revoke a hospice license according to the provisions of W. Va. Code § 16-5I-1, *et seq.* if he or she finds upon inspection that there has been a substantial failure to comply with the provisions of this rule or with the laws of this state or with any other order or final decision.

14.1.b. The Director shall refuse to grant a license if he or she finds that the applicant has failed to be in substantial compliance with the provisions of this rule or the laws of this state or with any other order or final decision.

14.1.c. When the Director takes action pursuant to the suspension or revocation of a license issued under this rule, he or she shall comply with the requirements and procedures set forth in W. Va. Code § 16-5I-1, *et seq.*

14.2. The Secretary shall assess a civil money penalty not to exceed fifty dollars ($50) for each violation of operation of a hospice without first obtaining a license or violation of any provisions of the Code or any rule lawfully promulgated under the Code.

14.2.a. Each day of operation of a hospice without first obtaining a license or violation of any provisions of the Code or any rule lawfully promulgated under the Code constitutes a separate violation.

14.3. The Director may institute an action to restrain or prevent establishment or operation of any hospice, because of violation of any provision of the code or rules, in the circuit court of the county where the hospice is located or the Circuit Court of Kanawha County.

§ 64-54-15. Administrative Due Process.

15.1. Before revoking or suspending a hospice license, the Director shall serve the licensee with written notice of the grounds of the complaint, and the procedure for challenging the allegation.

15.1.a. The notice shall be sent by certified mail to the licensee at the address where the hospice is located.

15.2. All formal hearings shall be governed by W. Va. Code § 29A-5-1, *et seq.* and "Rules of Procedure for Contested Case

Hearings and Declaratory Rulings" 64CSR1, *et seq.*, (1981), and "Rules for Hearings Under the Administrative Procedures Act" 69CSR1, *et seq.*, (1990). These rules of procedure are incorporated in this rule by reference.

15.3. If the license is revoked as a result of these proceedings, the Director may consider a new application for a license if the conditions upon which the revocation is based have been corrected and adequate proof of the correction is furnished.

15.3.a. The Director shall issue a new license upon inspection of the hospice if all provisions of the article and rules promulgated have been satisfied.

15.4. Any applicant or licensee aggrieved by the decision of the Secretary may, within thirty (30) days after receiving the final administrative order, appeal to the Circuit Court of Kanawha County for judicial review of that decision as promulgated in W. Va. Code 29A-5-4.

15.5. The court may affirm, modify or reverse the decision of the Secretary and either party may appeal the court's decision to the Supreme Court of Appeals of West Virginia as promulgated in W. Va. Code 29A-5-4.