



R.61-78, STANDARDS FOR LICENSING HOSPICES

Effective April 22, 2016

(This regulation replaces and supersedes any former regulations)

**Bureau of Health Facilities Licensing
S.C. Department of Health and Environmental Control
2600 Bull Street
Columbia, SC 29201**

DISCLAIMER

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PROMULGATION HISTORY

This Regulation was promulgated pursuant to 1976 S.C. Code Sections 44-71-10 and 44-7-110.

April 22, 2016 - R.61-78, Standards for Licensing Hospices, was amended by Document 4553 in State Register Volume 40 Issue 4 effective April 22, 2016. This amendment supersedes and replaces in entirety all former versions of this Regulation.

R.61-78. STANDARDS FOR LICENSING HOSPICES

Statutory Authority: 1976 Code Sections 44-71-10 and 44-7-110

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SECTION 100 – DEFINITIONS

For the purpose of this regulation, the following definitions shall apply:

A. Administrator. The individual designated by the governing body to be responsible for the day-to-day management of the Hospice and when licensed to provide Inpatient Services, Hospice Facility.

B. Advanced Practice Registered Nurse. An individual who has Official Recognition as such by the South Carolina Board of Nursing.

C. Airborne Infection Isolation (AII). A room designed to maintain Airborne Infection Isolation (AII), formerly called a negative pressure isolation room. An Airborne Infection Isolation (AII) room is a single-occupancy patient-care room used to isolate persons with suspected or confirmed infectious tuberculosis (TB) disease. Environmental factors are controlled in Airborne Infection Isolation (AII) rooms to minimize the transmission of infectious agents that are usually spread from person-to-person by droplet nuclei associated with coughing or aerosolization of contaminated fluids. Airborne Infection Isolation (AII) rooms may provide negative pressure in the room (so that air flows under the door gap into the room), an air flow rate of six to twelve (6 to 12) air changes per hour (ACH), and direct exhaust of air from the room to the outside of the building or recirculation of air through a high efficiency particulate air (HEPA) filter.

D. Architect. An individual currently registered as such by the South Carolina State Board of Architectural Examiners.

E. Attending Physician. The physician who is identified by the patient as having the most significant role in the determination and delivery of medical care to the patient.

F. Authorized Healthcare Provider. An individual authorized by law and currently licensed in South Carolina to provide specific care, treatment, or services to patients such as, advanced practice registered nurse, physician assistant.

G. Consultation. A visit by Department representative(s) to provide information to the licensee in order to facilitate compliance with these regulations.

H. Controlled Substance. A medication or other substance included in Schedule I, II, III, IV, and V of the Federal Controlled Substances Act and the South Carolina Controlled Substances Act.

I. Counseling Services. Counseling includes bereavement counseling, as well as dietary, spiritual, and any other counseling services provided to the individual and family or responsible party.

J. Department. The South Carolina Department of Health and Environmental Control (DHEC).

K. Dietitian. A person who is registered by the Commission on Dietetic Registration and licensed by the South Carolina Department of Labor, Licensing and Regulation.

L. Dietary Counseling. Education and interventions provided to the patient and family regarding appropriate nutritional intake as the patient's condition progresses. Dietary counseling is provided by qualified individuals, which may include a registered nurse, dietitian or nutritionist, when identified in the patient's plan of care.

M. Direct Care Staff Member/Direct Care Volunteer. Individuals who provide care to patients within the parameters of their training and/or as determined by state law or statute.

N. Health Assessment. An evaluation of the health status of a staff member or volunteer by a physician, other authorized healthcare provider, or registered nurse, pursuant to written standing orders and/or protocol approved by a physician's signature. The standing orders or protocol shall be reviewed annually by the physician, with a copy maintained at the Hospice.

O. Hospice Aide. An individual supervised by a registered nurse who renders assistance with personal care to patients needing assistance with activities of daily living, and who meets minimum qualifications and training as set by the Hospice.

P. Hospice. A centrally administered, interdisciplinary healthcare program, which provides a continuum of medically supervised palliative and supportive care for the terminally ill patient and the family or responsible party, including but not limited to home, Outpatient Services and Inpatient Services provided directly or through written agreement.

Q. Hospice Facility. An institution, place, or building in which a licensed Hospice provides room, board, and Inpatient Services on a twenty-four (24) hour basis to individuals requiring Hospice care pursuant to the orders of a physician. Prior to construction or establishment of a new Hospice Facility, or increasing the number of beds in an existing facility, a Hospice Facility shall obtain a Certificate of Need from the Department.

R. Inpatient Services. A continuum of medically supervised palliative and supportive care for the terminally ill patient and the family or responsible party provided by a Hospice for individuals intended to stay one (1) or more nights in an institution, place, or building licensed by the Department to provide room, board, and applicable care on a twenty-four (24) hour basis, such as a Hospice Facility, community residential care facility, nursing home, hospital, or general infirmary.

S. Inspection. A visit by Department representative(s) for the purpose of determining compliance with this regulation.

T. Interdisciplinary Team or Group. A group designated by the Hospice to provide or supervise care, treatment, and services provided by the Hospice. The group must include at least the following individuals: a physician, a registered nurse, a social worker, and a pastoral or other counselor.

U. Investigation. A visit by Department representative(s) to an unlicensed or licensed Hospice or Hospice Facility for the purpose of determining the validity of allegations received by the Department.

V. Legend Drug.

1. Medication required by federal law to be labeled with any of the following statements prior to being dispensed or delivered:

a. "Caution: Federal law prohibits dispensing without prescription";

b. "Rx only" or;

2. Medication required by federal or state law to be dispensed pursuant to a prescription drug order or restricted to use by practitioners only; or

3. Any medication products designated by the South Carolina Board of Pharmacy to be a public health threat; or

4. Any prescribed compounded prescription within the meaning of the Pharmacy Act.

W. License. A certificate issued by the Department providing for the establishment and maintenance of a Hospice and, when specified on the face of the certificate, Hospice Facility in accordance with this regulation.

X. Licensed Nurse. A person licensed by the South Carolina Board of Nursing as a registered nurse or licensed practical nurse or a person licensed as a registered nurse or licensed practical nurse who resides in another state that has been granted multi-state licensing privileges by the South Carolina Board of Nursing. This person may practice nursing in any facility or activity licensed by the Department subject to the provisions and conditions as indicated in the Nurse Licensure Compact Act.

Y. Licensee. The individual, corporation, or public entity with whom rests the ultimate responsibility for maintaining statutory and regulatory standards for the licensed Hospice and, if applicable in accordance with the license issued, Hospice Facility.

Z. Life-limiting Condition. A condition with no reasonable hope for a cure and will certainly prevent a child from surviving to adulthood.

AA. Medication. A substance that has therapeutic effects, including, but not limited to, legend drugs, nonlegend and herbal products, vitamins, and nutritional supplements.

BB. Minor. A person seventeen (17) years of age or younger who has not been emancipated in accordance with state law.

CC. Nonlegend Medication. A medication which may be sold without a prescription and which is labeled for use by the consumer in accordance with the requirements of the laws of this state and the federal government.

DD. Occupational Therapist. A person currently licensed as such by the South Carolina Board of Occupational Therapy Examiners.

EE. Outpatient Services. A continuum of medically supervised palliative and supportive care for the terminally ill patient and the family or responsible party provided by a Hospice and intended for individuals not staying one or more nights in an institution, place, or building licensed by the Department to provide room, board, and applicable care on a twenty-four (24) hour basis, such as a Hospice Facility, community residential care facility, nursing home, hospital, or general infirmary.

FF. Palliative Care. Treatment that enhances comfort and improves the quality of an individual's life during the last phase of life.

GG. Patient. A person who receives care, treatment, or services from a Hospice licensed by the Department.

HH. Pharmacist. An individual currently registered as such by the South Carolina Board of Pharmacy.

II. Physical Assessment. An assessment of a patient by a physician or other authorized healthcare provider that addresses those issues identified in Section 1200 of this regulation.

JJ. Physical Therapist. An individual currently registered as such by the South Carolina Board of Physical Therapy Examiners.

KK. Physician. An individual currently licensed by his or her state medical licensing board to practice medicine within that state.

LL. Physician Assistant. An individual currently licensed as such by the South Carolina Board of Medical Examiners.

MM. Plan of Care. A documented regimen of care, treatment, and services prepared by the Hospice for each patient based on assessment data and implemented for the benefit of the patient.

NN. Quality Improvement Program. The process used by the Hospice to examine its methods and practices of providing care, identifying the opportunities to improve its performance, and taking actions that result in higher quality of care for the Hospice's patients.

OO. Repeat Violation. The recurrence of a violation cited under the same section of the regulation within a thirty-six (36) month period. The time period determinant of repeat violation status is not interrupted by licensee changes.

PP. Respite Care. Short-term care provided to an individual to relieve the family members, responsible party, or other persons caring for the individual.

QQ. Responsible Party. A person who is authorized by law to make decisions on behalf of a patient, including, but not limited to, a court-appointed guardian or conservator, or person with a health care or other durable power of attorney.

RR. Restraint. Any means by which movement of a patient is inhibited, including physical, mechanical, and/or chemical. In addition, devices shall be considered a restraint if a patient is unable to easily release from the device.

SS. Revocation of License. An action by the Department to cancel or annul a license by recalling, withdrawing, or rescinding its authority to operate.

TT. Social Worker. An individual who is licensed by the South Carolina Board of Social Worker Examiners.

UU. Speech Therapist. An individual currently licensed as such by the South Carolina Board of Speech-Language Pathology and Audiology.

VV. Staff Member. A person who is a compensated employee of the Hospice on either a full or part-time basis.

WW. Suspension of License. An action by the Department requiring a Hospice to cease operations for a period of time or to require a Hospice to cease admitting patients until such time as the Department rescinds that restriction.

XX. Terminally Ill. A medical prognosis that, if the disease runs its usual course, limits an individual's life expectancy to twenty-four (24) months or less; or, if the individual is twenty-one (21) years of age or less includes a Life-limiting Condition.

YY. Volunteer. An individual who performs tasks at the Hospice at the direction of the administrator or his or her designee without compensation.

SECTION 200 - LICENSE REQUIREMENTS

201. Scope of Licensure

A. No person, private or public organization, political subdivision, or governmental agency may establish, conduct, or maintain a Hospice or Hospice Facility, or represent itself as a Hospice or Hospice Facility without first obtaining a license from the Department.

B. A license is effective for the twelve (12) month period following the date of issue and must prescribe by county the geographic area authorized to be served.

C. For a Hospice Facility, the license certificate shall specify the facility's address and number of beds authorized by a Certificate of Need issued by the Department.

D. Notwithstanding common ownership of multiple facilities, Hospice Facility buildings not located on the same adjoining or contiguous property requires an additional license per location. Roads or local streets, except limited access, such as interstate highways, shall not be considered as dividing otherwise adjoining or contiguous property.

E. A Hospice Facility shall include a posted license in a conspicuous place in a public area within the Hospice Facility. For multiple buildings on the same or adjoining grounds, the licensee shall post a copy of the license in a conspicuous place in a public area in each building.

F. A person, private or public organization, political subdivision, or governmental agency conducting or maintaining a Hospice or Hospice Facility without a Department-issued license shall cease operation immediately and ensure the safety, health, and well-being of the patients. (I)

202. License Application

Applicants for a license shall submit to the Department a completed application on a form prescribed and furnished by the Department prior to initial licensing and periodically thereafter at intervals determined by the Department. The application includes both the applicant's oath assuring that the contents of the application are accurate and true, and that the applicant will comply with this regulation. The application shall indicate and be signed by the owner(s) if an individual or partnership; in the case of a corporation by two (2) of its officers; or in the case of a governmental unit, by the head of the governmental department having jurisdiction. The application shall set forth the full name and address of the Hospice headquarters, and the county or counties of service. For a Hospice Facility, the application shall also set forth the Hospice Facility address and number of beds to be licensed. The Department may issue a single license certificate to an applicant to function as both a Hospice and Hospice Facility license. The Department may require additional

information, including affirmative evidence of the applicant's ability to comply with these regulations. Corporations or partnerships shall be registered with the South Carolina Office of the Secretary of State.

203. Compliance

An initial license shall not be issued to an applicant not previously or continuously licensed by the Department until the applicant demonstrates to the Department substantial compliance with the applicable licensing standards. A copy of the licensing standards shall be accessible to all Hospices and Hospice Facility staff. In the event a licensee, who already has a Hospice or any facility licensed by the Department, makes application for licensure for an additional Hospice or other facility, the currently licensed Hospice or other facility shall be in substantial compliance. Prior to construction or establishment of a new Hospice Facility, or increasing the number of beds in an existing facility, a Hospice Facility shall obtain a Certificate of Need from the Department.

204. Issuance of License

A. Current or previous violations of the South Carolina Code and/or Department regulations may jeopardize the issuance of a license for a Hospice, Hospice Facility, and/or any other facility licensed by the Department.

B. A license is not assignable or transferable and is subject to suspension or revocation at any time by the Department for the licensee's failure to comply with the laws and regulations of this state.

C. The issuance of a license does not guarantee adequacy of individual care, treatment, or services, personal safety, fire safety, or the well-being of any Hospice patient or Hospice Facility occupant.

D. The entirety of this regulation only applies to Hospices operating within the State of South Carolina.

205. Licensing Fees

A. Method of Payment. Licensing fees shall be made payable by check, credit card, or money order to the Department.

B. Fee Amount. Fees include an initial and renewal license fee of one hundred dollars (\$100.00) plus fifty dollars (\$50.00) for each county in which services are provided. For a Hospice Facility, fees include an additional ten dollars (\$10.00) per bed or seventy-five dollars (\$75.00), whichever is greater.

C. Additional Counties or Beds. Fees for additional licensed beds or counties shall not be prorated based upon the remaining months of the licensure year.

D. Applicants shall pay the initial fee with submission of the license application. Licensees shall pay renewal fees with submission of the renewal application. If an application is denied, the fee shall be refunded.

206. Late Fee

Failure to submit a renewal application or fee before the license expiration date shall result in a late fee(s) of twenty-five percent (25%) of the licensing fee amount, but not less than seventy-five dollars (\$75.00), in addition to the licensing fee. Continual failure to submit completed and accurate renewal applications and/or fees by the time-period specified by the Department may result in an enforcement action.

207. License Renewal

To renew a license, an applicant shall file an application with the Department and pay a license fee. Additionally, the licensee must not be under consideration for an enforcement action by the Department or undergoing enforcement actions by the Department. If the license renewal is delayed due to enforcement actions, the renewal license will be issued only when the matter has been resolved satisfactorily by the Department or when the adjudicatory process is completed, whichever is applicable.

208. Change of License

A. A licensee shall request issuance of an amended license by application to the Department prior to any of the following circumstances:

1. Change of ownership; or
2. Change of licensed bed capacity (if applicable);

B. Change of location from one geographic site to another shall be by letter or application.

C. Changes in Hospice name or address as notified by the post office may be accomplished by application or by letter from the licensee.

209. Hospice Name

No proposed Hospice or Hospice Facility shall be named, nor may any existing Hospice or Hospice Facility have its name changed to, the same or similar name as any other Hospice or Hospice Facility licensed in the State. If a Hospice is part of a franchise with multiple locations, the Hospice must include the geographic area in which it is located as part of its name. (II)

210. Licensed Area

A Hospice shall only serve those counties identified on the face of the license, and all services must be made available throughout the entire licensed county or counties identified. Failure to provide the full scope of services in all areas indicated on the license may be cause for revocation of the Hospice's license in those counties or other sanction. (II)

211. Licensed Bed Capacity

A Hospice Facility shall not exceed the bed capacity identified on the face of the license. A licensee shall obtain authorization from the Department before establishing new care, treatment, or services or occupying additional beds or renovated space. Beds for use by staff members and/or volunteers shall not be included in the licensed bed capacity number provided such beds and locations are identified and used exclusively by staff members and/or volunteers. (I)

EXCEPTION: Designated guest rooms, which shall not be counted as part of the licensed bed capacity, may be utilized for housing of family members or responsible party.

212. Persons Received in Excess of Licensed Bed Capacity

A Hospice Facility shall not receive persons in excess of the licensed bed capacity except in cases of justified emergencies. (I)

EXCEPTION: In the event the Hospice Facility temporarily provides shelter for evacuees who have been displaced due to a disaster, then for the duration of that emergency, provided the health, safety, and well-being of all patients are not compromised, it is permissible to temporarily exceed the licensed capacity for the Hospice Facility in order to accommodate these individuals.

213. Exceptions to Licensing Standards

The Department has the authority to make exceptions to these standards where it is determined that the health, safety, and well-being of the patients are not compromised, and provided the standard is not specifically required by statute.

SECTION 300 – ENFORCEMENT OF REGULATIONS

301. General

The Department shall utilize inspections, investigations, consultations, and other pertinent documentation regarding a proposed or licensed Hospice or Hospice Facility in order to enforce this regulation.

302. Inspections and Investigations

A. Inspections shall be conducted prior to initial licensing of a Hospice or Hospice Facility. The Department, at its own determination, may also conduct subsequent inspections.

B. All Hospices, whether providing Inpatient or Outpatient Services, and Hospice Facilities are subject to inspection or investigation at any time without prior notice by individuals authorized by the South Carolina Code of Laws.

C. Individuals authorized by the Department shall be granted access to all properties and areas, objects, and records. If photocopies are made for the Department inspector, they shall be used only for purposes of enforcement of regulations and confidentiality shall be maintained except to verify individuals in enforcement action proceedings. Physical area of inspections shall be determined by the extent to which there is potential impact or effect upon patients as determined by the inspector. (I)

D. A Hospice or Hospice Facility found noncompliant with the standards of this regulation shall submit an acceptable written plan of correction to the Department that shall be signed by the administrator and returned by the date specified by the Department. The written plan of correction shall describe: (II)

1. The actions taken to correct each cited deficiency;
2. The actions taken to prevent recurrences (actual and similar);

3. The actual or expected completion dates of those actions.

E. The Department may charge a fee for plan reviews, construction inspections, and licensing inspections.

SECTION 400 - ENFORCEMENT ACTIONS

401. General

When the Department determines that a Hospice or Hospice Facility is in violation of any statutory provision, rule, or regulation relating to the operation or maintenance of such Hospice or Hospice Facility, the Department, upon proper notice to the licensee, may impose a monetary penalty, and deny, suspend, or revoke its license.

402. Violation Classifications

Violations of standards in this regulation are classified as follows:

A. Class I violations of standards are those that the Department determines to present an imminent danger to the health, safety, or well-being of Hospice patients or any person in a Hospice Facility or a substantial probability that death or serious physical harm could result therefrom. A physical condition or one or more practices, means, methods or operations in use in a Hospice and/or Hospice Facility may constitute such a violation. The condition or practice constituting a Class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the Department, is required for correction. Each day such violation exists after expiration of this time may be considered a subsequent violation.

B. Class II violations are those, other than Class I violations, that the Department determines to have a negative impact on the health, safety or well-being of Hospice patients or any person in a Hospice Facility. The citation of a Class II violation shall specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time may be considered a subsequent violation.

C. Class III violations are those that are not classified as Class I or II in these regulations or those that are against the best practices as interpreted by the Department. The citation of a Class III violation shall specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time may be considered a subsequent violation.

D. Class I and II violations are indicated by notation after each applicable section as “(I)” or “(II).” Sections not annotated in that manner denote Class III violations. A classification at the beginning of a section/subsection applies to all subsections following, unless otherwise indicated.

E. In arriving at a decision to take enforcement actions, the Department will consider the following factors: specific conditions and their impact or potential impact on health, safety or well-being of patients; efforts by the Hospice and/or Hospice Facility to correct cited violations; behavior of the licensee that reflects negatively on the licensee’s character, such as illegal or illicit activities; overall conditions; history of compliance; any other pertinent conditions that may be applicable to current statutes and regulations including participating in, or offering, or implying an offer to participate in the practice generally known as rebates, kickbacks, or fee-splitting arrangements.

F. When a decision is made to impose monetary penalties, the Department may utilize the following schedule as a guide to determine the dollar amount:

Frequency of violation of standard within a thirty-six (36) month period:

MONETARY PENALTY RANGES

FREQUENCY	CLASS I	CLASS II	CLASS III
1st	\$ 500 - 1500	\$ 300 - 800	\$ 100 - 300
2nd	1000 - 3000	500 -1500	300 - 800
3rd	2000 - 5000	1000 - 3000	500 - 1500
4th	5000	2000 - 5000	1000 - 3000
5th	5000	5000	2000 - 5000
6th	5000	5000	5000

SECTION 500 - POLICIES AND PROCEDURES (II)

A. Policies and procedures addressing each section of this regulation regarding patient care, rights, and the operation of the Hospice shall be developed and implemented and revised as required in order to accurately reflect actual Hospice operation. The policies and procedures shall address the provision of any special care offered by the Hospice. Information shall include the means by which the Hospice will meet the specialized needs of the affected patients, such as those with Alzheimer’s disease and/or related dementia, and those who are physically and/or developmentally disabled, in accordance with any laws which pertain to that service offered, such as the Alzheimer’s Special Care Disclosure Act. The Hospice shall establish a time period for review of all policies and procedures. These policies and procedures shall be accessible at all times and a hard copy shall be available or be readily accessible electronically.

B. By its application, the licensee agrees to comply with all standards in this regulation. The policies and procedures shall describe the means by which the Hospice shall assure that the standards described in this regulation are met.

SECTION 600 - STAFF AND TRAINING

601. General (II)

A. Appropriate staff in numbers and training shall be provided to meet the needs and condition of the patients. Training and qualifications for the tasks each performs shall be in compliance with all professional standards and applicable federal and state laws.

B. Before being employed or contracted as a staff member or direct care volunteer by a Hospice, a person shall undergo a criminal background check pursuant to South Carolina Code Section 44-7-2910. Direct care staff members and direct care volunteers of the Hospice shall not have a prior conviction or have pled no contest (nolo contendere) for child or adult abuse, neglect, exploitation, or mistreatment. The Hospice shall coordinate with applicable registries should licensed or certified individuals be considered as employees of the Hospice. For those staff members and volunteers who are licensed or certified, a copy of the license or certificate shall be available for review. (I)

C. The Hospice shall maintain accurate current information regarding all staff members and volunteers of the Hospice, including at least address, phone number, health and personal, work, and

training background. The Hospice shall assign duties and responsibilities to all staff members and volunteers in writing and in accordance with the individual's capability.

602. Administrator (II)

The Hospice shall designate an individual to serve as administrator. The administrator shall have the authority and responsibility for the functions and activities of the Hospice, be an employee of the Hospice, and be available within a reasonable time and distance. Administrators hired subsequent to the promulgation of this regulation shall hold at least a baccalaureate or associate degree and have a minimum of three (3) years of experience in a health-related field within the past five (5) years. A qualified staff member shall be designated, in writing, to act in the absence of the administrator.

603. Medical Director (II)

The Hospice shall designate a physician who assumes overall responsibility for the medical component of the Hospice. This individual may also serve as administrator.

604. Staffing (I)

A. A physician shall supervise the care and treatment of the patient while receiving Hospice treatment, care, and/or services.

B. Nursing care services shall be supervised by a staff registered nurse.

C. Minimum staffing for a Hospice Facility shall consist of one (1) registered nurse (RN) and one (1) additional direct care staff member on duty at all times. Staffing for Outpatient Services shall consist of a sufficient number of direct care staff on duty at all times to provide care to meet the needs of the patient population for all areas where direct care is provided. A Hospice Facility shall adhere to the following minimum staffing ratio:

1. Facilities with zero to ten (0 to 10) patients:

- a. Two (2) staff members for shift one* (1);
- b. Two (2) staff members for shift two* (2);
- c. Two (2) staff members for shift three (3);

2. Facilities with eleven to twenty (11 to 20) patients:

- a. Three (3) staff members for shift one* (1);
- b. Two (2) staff members for shift two* (2);
- c. Two (2) staff members for shift three (3);

3. Facilities with twenty-one to thirty (21 to 30) patients:

- a. Four (4) staff members for shift one* (1);

- b. Three (3) staff members for shift two* (2);
- c. Three (3) staff members for shift three (3).

If staffing is scheduled in two 12-hour shifts, the minimum staffing ratios marked with an (*) above will be followed for the day and night shifts respectively.

D. For care provided in a Hospice Facility with more than thirty (30) patients, the Hospice Facility shall include additional staff at a ratio of 1:10.

E. Additional staff members shall be provided if it is determined by the Department that the minimum staff requirements are inadequate to provide appropriate care, treatment, and services and supervision to the patients of a Hospice.

605. Inservice Training (I)

A. The following training shall be provided by appropriate resources, such as, licensed or registered persons, video tapes, books, etc., to all staff members and direct care volunteers in the context of their job duties and responsibilities prior to patient contact and at a frequency determined by the Hospice, but at least annually:

1. Management and/or care of persons with contagious and/or communicable disease, for example, hepatitis, tuberculosis, HIV infection;
2. Care of persons specific to the physical and/or mental condition being cared for by the Hospice, such as, cancer, AIDS, dementia, or cognitive disability;
3. Use of restraints to include but not be limited to the provisions of Section 1804 (for designated staff members only);
4. OSHA standards regarding bloodborne pathogens;
5. Cardiopulmonary resuscitation (CPR) for designated staff members to ensure that there is a certified staff member available to patients who wish to receive CPR;
6. Confidentiality of patient information and records and the protection of patient rights;
7. Fire response training within twenty-four (24) hours of their first day on duty in the Hospice Facility (See Section 2303);
8. Emergency procedures and disaster preparedness within twenty-four (24) hours of their first day on duty in the Hospice Facility (See Section 1800).

B. Job Orientation. All new staff members and volunteers shall be oriented to acquaint them with the organization and environment, specific duties and responsibilities of staff members and volunteers, and patients' needs.

606. Health Status (II)

A. All staff and volunteers who have contact with patients shall have a health assessment within one (1) year prior to patient contact.

B. All staff and direct care volunteers shall undergo a tuberculin skin test pursuant to Section 1300.

607. Staff Living Quarters

Other than patients, only staff members, volunteers, or owners of the Hospice and members of the owner's immediate family may reside in a Hospice Facility. Patient rooms shall not be utilized by staff members or volunteers nor shall bedrooms of staff members or volunteers be utilized by patients.

SECTION 700 -REPORTING

701. Accidents and/or Incidents (II)

A. The Hospice Facility shall report each accident and/or incident resulting in unexpected death or serious injury to the next of kin or responsible party for each affected individual at the earliest practicable hour, not exceeding twenty-four (24) hours. The licensee shall notify the Department immediately, not to exceed twenty-four (24) hours, via telephone, email, or facsimile. The licensee shall submit a report of the licensee's investigation of the accident and/or incident to the Department within five (5) calendar days. Accidents and/or incidents requiring reporting include, but are not limited to,:

1. Abuse, Neglect, or Exploitation (Confirmed);
2. Abuse, Neglect, or Exploitation (Suspected);
3. Criminal event against patient;
4. Fire; and
5. Use of physical restraints.

B. Reports submitted to the Department shall contain only: Hospice Facility name, license number, type of accident and/or incident, date of accident and/or incident occurred and location, number of patients directly injured or affected, patient medical record identification number, patient age and sex, number of staff directly injured or affected, number of visitors directly injured or affected, witness(es) name(s), identified cause of accident and/or incident, internal investigation results if cause unknown, a brief description of the accident and/or incident including location where occurred, and treatment of injuries. The report retained by the facility, in addition to the minimum reported to the Department, shall contain: names of patient(s), staff, and/or visitor(s), the injuries and treatment associated with each patient, staff, and/or visitor. Records of all accidents and incidents shall be retained by the Hospice Facility for ten (10) years after the patient stops receiving services.

702. Patient Death

The Hospice shall have a written plan to be followed at the time of patient death. The plan must provide for:

- A. Collection of data needed for the death certificate, as required by state law;

- B. Recording time of death;
- C. Assessment of death;
- D. Notification of attending physician responsible for signing death certificate;
- E. Notification of next-of-kin or responsible party;
- F. Authorization and release of body to funeral home; and
- G. Notification to the Department of any death resulting from an injury, accident, or other possible unnatural causes.

703. Fire and Disasters (II)

A. The Department shall be notified immediately via telephone, email, or fax regarding any fire in a Hospice Facility followed by a complete written report, to include fire department reports, if any, to be submitted within a time-period determined by the licensee, but not to exceed seventy-two (72) hours from the occurrence of the fire.

B. Any natural disaster or fire that jeopardizes the safety of any persons in the Hospice Facility shall be reported to the Department via telephone, email, or fax immediately, with a complete written report which includes the fire report from the local fire department, if appropriate, submitted within a time-period as determined by the licensee, but not to exceed seventy-two (72) hours.

704. Communicable Diseases and Animal Bites (I)

A Hospice providing Inpatient Services shall notify the appropriate county health department of all cases of diseases and animal bites required to be reported in accordance with Regulation 61-20, Communicable Diseases.

705. Administrator Change

The Department shall be notified in writing by the licensee within ten (10) days of any change in administrator. The notice shall include at least the name of the newly-appointed individual and effective date of the appointment.

706. Joint Annual Report

Hospices shall complete and return a "Joint Annual Report" to the Revenue and Fiscal Affairs Office (RFA) within the time period specified by the Department or RFA.

707. Accounting of Controlled Substances (II)

Any licensee registered with the Department's Bureau of Drug Control and the United States Drug Enforcement Agency shall report any theft or loss of controlled substances to local law enforcement and to the Department's Bureau of Drug Control upon discovery of the loss or theft.

708. Emergency Placements

In instances where evacuees have been relocated to a Hospice Facility, the Department shall be notified not later than the following workday of the names of the individuals received.

709. Hospice Closure

Prior to the permanent or temporary closure of a Hospice, the Hospice shall notify the Department in writing of the intent to close, the effective closure date, and, for a Hospice Facility, the place the patients have been relocated. On the date of permanent closure, the license shall be returned to the Department. For temporary Hospice closures, the Hospice shall notify the Department in writing in advance of re-opening.

710. Zero Census

In instances when there have been no patients in a Hospice Facility for any reason for a period of ninety (90) days or more, the facility shall notify the Department in writing that there have been no admissions, no later than the one hundredth (100th) day following the date of departure of the last active patient. At the time of that notification, the Department shall consider, upon appropriate review of the situation, the necessity of inspecting the facility prior to any new and/or re-admissions to the facility. The licensee is still required to complete application and pay the licensing fee to keep the license active, even though the facility is at zero census or temporarily closed. If the Hospice Facility has no patients for a period longer than one (1) year, and there is a desire to admit a patient, the facility shall re-apply to the Department for licensure and shall be subject to all licensing requirements at the time of that application, including construction-related requirements for a new Hospice Facility.

SECTION 800 - PATIENT RECORDS

801. General

A Hospice shall maintain and store a record for each Hospice patient in a manner that ensures confidentiality, security, and integrity of the information.

802. Content (II)

A. The Hospice shall initiate and maintain an organized record for each patient. The record shall contain sufficient documented information to identify the patient and verify appropriate care rendered. All entries shall be written legibly in ink or typed, signed, and dated.

B. Specific entries and/or documentation shall include at a minimum:

1. Consultations by physicians or other authorized healthcare providers;
2. Orders for all medication, care, treatment, services, and procedures from physicians or other authorized healthcare providers shall be completed prior to, or at the time of admission, and updated when revised. Verbal orders received shall include the date of receipt of the order, description of the order, and identification of the individual receiving the order;
3. Care, treatment, and services provided;
4. Medications administered and procedures followed if an error is made, to include adverse reactions;

5. The Hospice Facility shall document medication administration by including medication name, dosage, mode of administration, date, time, and the signature of the individual administering or supervising the taking of the medication. Initials are acceptable when they can be identified readily by signatures;

6. Notes of observation;

7. Time and circumstances of death or of discharge or transfer, including condition at discharge or transfer.

803. Individualized Assessment

An individualized assessment of physical, emotional, and spiritual needs shall be conducted within forty-eight (48) hours of admission for each patient.

804. Plan of Care (II)

A plan of care ("POC") (See 100.MM) shall be developed by the interdisciplinary team within five (5) days of admission, approved by a physician, and updated as needed, and shall include the care, treatment, and services relative to the needs of the patient and maintained in the patient record.

805. Record Maintenance

A. The licensee shall adequately produce, protect, and store patient records.

B. When a patient is transferred from a Hospice to another Hospice or other type of facility, copies of appropriate supporting documentation to include at a minimum, a copy of the POC and medication record shall be forwarded, in a manner preserving confidentiality, to the receiving Hospice or other type of facility (for use by the licensed Hospice operating in the facility) at the time of transfer. (II)

C. The patient record is confidential and may be made available only to authorized individuals. Active patient records, with the exception of records utilized by providers during home visits, shall be available at all times and shall be accessible by the staff member in charge and by other authorized individuals such as representatives of the Department. (II)

D. Records generated by organizations or individuals with whom the Hospice contracts for care, treatment, or services shall be maintained by the Hospice that has admitted the patient.

E. The Hospice shall determine the medium in which information is stored.

F. Hospices employing electronic signatures or computer-generated signature codes shall ensure authentication and security.

G. Upon discharge of a patient, the patient record shall be completed and filed in an inactive or closed file within a time period as determined by the Hospice, but no later than thirty (30) days after discharge. Closed patient records shall be stored by the licensee and retained for six (6) years following the discharge of the patient. Such records shall be made available to the Department upon request.

H. Upon discharge of the Hospice patient's family from bereavement services, the bereavement information shall be filed in an inactive or closed file within a time-period as determined by the Hospice. Closed bereavement information shall be stored by the licensee and retained in accordance with patient record retention.

I. The Hospice shall store medical records in an environment which will prevent unauthorized access and deterioration. The records shall be treated as confidential and shall not be disposed of before six (6) years. Records may be destroyed after six (6) years provided that:

1. Records of minors must be retained until after the expiration of the period of election following achievement of majority as prescribed by statute; and

2. The Hospice retains a register, either electronic or paper based.

J. Licensees that store records in a format other than paper, such as, but not limited to, microfilm, before six (6) years have expired must include the entire record.

K. In the event of change of ownership, all medical records shall be transferred to the new owners.

L. Prior to the closing of a Hospice for any reason, the licensee shall arrange for preservation of records to ensure compliance with these regulations. The licensee shall notify the Department, in writing, describing these arrangements within ten (10) days of closure.

M. The Department shall have access to all Hospice records during an inspection or investigation.

N. Records of patients are the property of the Hospice and shall not be removed from the designated patient record storage area, to include on-site, off-site, or contracted storage, without court order, except when care is delivered in the home or the Hospice Facility.

EXCEPTION: When a patient is transferred from one Hospice Facility to another Hospice Facility within the same provider network (same licensed Hospice), the original record may follow the patient; the sending Hospice shall maintain documentation of the patient's transfer or discharge date and identification information. In the event of change of ownership, all active patient records or copies of active patient records shall be transferred to the new owner(s).

SECTION 900 - ADMISSION AND RETENTION

A. Individuals seeking admission shall be identified as appropriate for the level of care, treatment, services, or assistance offered. The Hospice shall establish admission criteria that are consistently applied and comply with local, state, and federal laws and regulations.

B. The Hospice shall admit and retain only those persons whose needs can be met by the accommodations and services provided. (I)

C. Admissions and retention of patients shall be deemed appropriate based on the following considerations:

1. The person is under the care of a physician, and is certified by the physician to be terminally ill and is appropriate for services the Hospice is licensed to provide.

2. The person and/or his or her responsible party agree to accept Hospice services.
3. The person and family have a demonstrated need for physical, emotional, or spiritual care that can be adequately provided by the Hospice, as defined in Section 100.P.
4. The person is not likely to endanger himself or herself or others as determined by a physician or other authorized healthcare provider. (I)

SECTION 1000 - PATIENT CARE, TREATMENT, AND SERVICES (I)

A. Services relative to the needs of the patient and family are provided as identified in the POC, to include emergency treatment as appropriate. These services shall be coordinated across the continuum of care and modified as warranted based on any changing needs of the patient and family with changes reflected in the POC. In instances of emergency due to disaster, shall have a disaster plan to address the needs of the patients, which includes the continued care, treatment, and services provided by the Hospice to the patients in accordance with Section 1800.

B. Inpatient Services Disaster Plan. In instances of emergency due to disaster, a Hospice Facility shall have a disaster plan to address the needs of the patients, which includes the continued care, treatment, and services provided by the Hospice to the patients in accordance with Section 1800.

C. Outpatient Services Disaster Plan. In instances of emergency due to disaster, a Hospice licensed to provide Outpatient Services shall assist its patients in the planning and development of an appropriate individual emergency and disaster evacuation plan that addresses the needs of the patient, including coordination of transportation assistance and in the continuation of care, treatment, and services in the event of emergency evacuation from their place of residence or when the nature of the disaster precludes the Hospice from continuing such care, treatment, and services.

D. Nursing and other interdisciplinary services, including medications administered, shall be provided in a safe, effective manner and in accordance with local, state, and federal laws and regulation and with established professional practices. Services provided shall be supervised by appropriate qualified professionals and be available twenty-four (24) hours a day, seven (7) days a week.

E. A Hospice Facility shall provide or furnish the following:

1. All required care, treatment, and services in a manner that does not require patients to ambulate nor does it impede patients from ambulating from one site to another due to the presence of physical barriers;

2. Methods for ensuring visual and auditory privacy between patient and staff, volunteers, and/or visitors; and

3. Equipment such as bedpans, urinals, and hot water bottles as necessary to meet patient needs. Permanent positioning of a portable commode at bedside shall only be permitted if the room is private, the commode is maintained in a sanitary condition, and the room is of sufficient size to accommodate the commode. (II)

F. A Hospice shall directly and routinely provide the following:

1. Medical Director;

2. Nursing care by or under the supervision of an RN;
3. Social work;
4. Counseling Services, to include dietary, bereavement, and spiritual counseling;
5. Volunteer Services; and
6. Supervision of hospice aides.

G. The following shall be provided as specified in the patient's POC, either directly by the Hospice or arranged for through legally-binding arrangements made by the Hospice:

1. Spiritual care;
2. Hospice aide;
3. Physical therapy, occupational therapy, speech therapy;
4. Medical supplies;
5. Prescription medications;
6. Durable medical equipment;
7. Short-term respite care;
8. Short-term inpatient care for pain control and/or symptom management; and
9. Continuous care.

H. Additional services shall be provided, either directly or by contractual arrangement, when specified in the POC.

I. When appropriate to meet the needs of the patient and as ordered by the attending physician, the Hospice shall initiate the referral to an appropriate facility.

SECTION 1100 - RIGHTS AND ASSURANCES (II)

A. The Hospice shall comply with all relevant federal, state, and local laws and regulations related to patient care and protections, such as, Title VI, Section 601 of the Civil Rights Act of 1964, Americans with Disabilities Act (ADA), and ensure that there is no discrimination with regard to source of payment, recruitment of potential patients, location of patients, or provision of care, treatment, and services to patients. Care shall not be discontinued or diminished due to the inability to pay for the care until provisions can be made for transfer of the patient.

B. The following rights shall be guaranteed to the patient, and, at a minimum, the Hospice shall provide the patient a written and oral explanation of these rights:

1. Hospice Services.

- a. To be informed of care to be provided and the opportunity to participate in care and treatment and to be informed about, and updated on changes in condition;
- b. To refuse to participate in experimental research;
- c. To choose a physician or other authorized healthcare provider;
- d. Confidentiality of patient records;
- e. Respect and security for the patient's property and in a Hospice Facility for the patient to keep personal possessions as space permits, unless it interferes with the rights and safety of other patients;
- f. Advance directive options;
- g. Freedom from abuse (physical or mental), neglect, and exploitation;
- h. Freedom from physical restraint through the use of medications unless they are prescribed by a doctor;
- i. Respect and dignity in receiving care, including privacy in receiving treatment or personal care.

2. Hospice Facility Services.

- a. To choose meals and food as desired.
- b. Immediate access to family members, other relatives, or responsible party without restriction or unreasonable delay.
- c. Privacy in visits, including the right to associate and communicate privately with people of the patient's choice, including spousal visits of a conjugal nature.
- d. Receive visitors at any reasonable hour, including small children.
- e. Privacy when sending or receiving mail. The Hospice shall not open and read mail without patient permission either when received or prior to being mailed.
- f. To share a patient room, unless contraindicated by their attending physician.
- g. To receive a refund based on the actual number of days a patient is physically in the Hospice Facility (along with bed-hold days). The patient or responsible party shall be informed of the refund policy in writing at the time of admission and shall be notified in writing anytime the policy is changed.

C. The Hospice shall inform the patient or responsible party in writing of the grievance procedure should the patient consider one or more of his or her rights violated. The Hospice shall include the address and phone number of the Department in the grievance procedure.

D. The patient rights, the grievance procedure and other notices as required by law shall be prominently displayed in public areas of the Hospice Facility.

E. Patients being transferred or discharged for medical reasons or for the welfare of the patients or the welfare of other staff or patients must be given written notice of not less than ten (10) days prior to transfer or discharge. When the health, safety, or well-being of the patient or other patients in the facility would be endangered by the ten (10) day notice requirement, the time for giving notice shall be that which is practicable under the circumstances. A patient being transferred or discharged due to a change in his or her condition and who no longer qualifies for hospice care shall be given written notice of not less than forty-eight (48) hours.

F. The Hospice shall not retaliate against a patient who exercises his or her right to complain about a violation of his or her rights, such as, increasing charges, decreasing the services received; taking away any privileges; use of abuse, threatening language, or trying to force a patient to discontinue Hospice care or leave a Hospice Facility.

SECTION 1200 - PATIENT PHYSICAL ASSESSMENT (I)

A. A medical history and physical assessment shall be completed for patients within thirty (30) days prior to or no later than forty-eight (48) hours after admission. The physical assessment shall address the appropriateness of admission, medications required and self-administration status, and identification of special conditions and/or care required, for example, communicable disease, such as tuberculosis, Alzheimer's disease and/or related dementia, pain management, imminent death.

B. The physical assessment shall be performed only by a physician or other authorized healthcare provider.

C. If a patient or potential patient has a communicable disease, the Hospice shall seek advice from a physician or other authorized healthcare provider in order to:

1. Ensure the Hospice has the capability to provide adequate care and prevent the spread of that condition and that the staff members and/or volunteers are adequately trained;
2. Transfer the patient to an appropriate facility, if necessary.

D. A discharge summary from an inpatient health care facility, which includes a physical assessment, may be acceptable as the admission physical assessment, provided the summary includes the requirements of Sections 1200.A and 1200.B above.

E. If a patient transfers from a facility licensed by the Department to a Hospice, an additional admission physical assessment shall not be required, provided the transferring facility conducted a physical assessment on the patient not earlier than twelve (12) months prior to the admission of the patient to the Hospice and the physical assessment meets requirements specified in Sections 1200.A and 1200.B above unless the Hospice receiving the patient has an indication that his or her health status has changed significantly. The receiving Hospice shall acquire a copy of the admission physical assessment and the results of the tuberculosis symptoms screening questionnaire from the facility transferring the patient (See Section 1304 regarding Tuberculosis Screening).

SECTION 1300 - INFECTION CONTROL

1301. Staff Practices (I)

Staff and volunteer practices shall promote conditions that prevent the spread of infectious, contagious, or communicable diseases and provide for the proper disposal of toxic and hazardous substances. These preventive measures and practices shall be in compliance with applicable guidelines of the *Bloodborne Pathogens Standard of the Occupational Safety and Health Act (OSHA) of 1970*; the Centers for Disease Control and Prevention (CDC); Regulation 61-105, Infectious Waste Management, and other applicable federal, state, and local laws and regulations.

1302. Tuberculosis Risk Assessment (I)

A. All Hospice Facilities shall conduct an annual tuberculosis risk assessment in accordance with CDC guidelines (see *CDC Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Healthcare Facilities*) to determine the appropriateness and frequency of tuberculosis screening and other tuberculosis related measures to be taken.

B. The risk classification (low risk, medium risk) shall be used as part of the risk assessment to determine the need for an ongoing TB screening program for staff and volunteers and patients and the frequency of screening. A risk classification shall be determined for the entire Hospice Facility. In certain settings, such as healthcare organizations that encompass multiple sites or types of services, specific areas defined by geography, functional units, patient population, job type, or location within the setting may have separate risk classifications.

1303. Staff and Volunteer Tuberculosis Screening (I)

A. Tuberculosis Status. Prior to date of hire or initial patient contact, the tuberculosis status of direct care staff and volunteers shall be determined in the following manner in accordance with the applicable risk classification:

B. Low Risk:

1. Baseline two-step Tuberculin Skin Test (TST) or a single Blood Assay for *Mycobacterium tuberculosis* (BAMT): All staff and volunteers (within three (3) months prior to contact with patients) unless there is a documented TST or BAMT result during the previous twelve (12) months. If a newly employed staff member or volunteer has had a documented negative TST or BAMT result within the previous twelve (12) months, a single TST (or single BAMT) can be administered to serve as the baseline.

2. Periodic TST or BAMT is not required.

3. Post-exposure TST or BAMT for staff upon unprotected exposure to *M. tuberculosis*:

a. Perform a contact investigation when unprotected exposure is identified.

b. Administer one (1) TST or BAMT as soon as possible to all staff and volunteers who have had unprotected exposure to an infectious TB case or suspect. If the TST or BAMT result is negative, administer another TST or BAMT eight to ten (8 to 10) weeks after that exposure to *M. tuberculosis* ended.

C. Medium Risk:

1. Baseline two-step TST or a single BAMT: All staff and volunteers (within three (3) months prior to contact with patients) unless there is a documented TST or BAMT result during the previous twelve (12) months. If a newly employed staff member or volunteer has had a documented negative TST or BAMT result within the previous twelve (12) months, a single TST (or single BAMT) can be administered to serve as the baseline.

2. Periodic testing (with TST or BAMT):

a. All staff and volunteers who have risk of TB exposure and who have previously documented negative results shall have annual periodic testing.

b. Staff and volunteers with documented TB infection (positive TST or BAMT) shall receive a symptom screen annually instead of participating in periodic testing. This symptom screen shall be accomplished by educating the staff and volunteers about symptoms of TB disease (including the staff and/or direct care volunteers responses), documenting the questioning of the staff and volunteers about the presence of symptoms of TB disease, and instructing the staff and volunteers to report any such symptoms immediately to the administrator. Treatment for latent TB infection (LTBI) shall be considered in accordance with CDC and Department guidelines and, if recommended, treatment completion shall be encouraged.

3. Post-exposure TST or BAMT for staff and volunteers upon unprotected exposure to *M. tuberculosis*: Perform a contact investigation when unprotected exposure is identified. Administer one (1) TST or BAMT as soon as possible to all staff and volunteers who have had unprotected exposure to an infectious TB case or suspect. If the TST or BAMT result is negative, administer another TST or BAMT eight to ten (8 to 10) weeks after that exposure to *M. tuberculosis* ended.

D. Baseline Positive or Newly Positive Test Result:

1. Staff and volunteers with a baseline positive or newly positive test result for *M. tuberculosis* infection (TST or BAMT) or documentation of treatment for latent TB infection (LTBI) or TB disease or signs or symptoms of tuberculosis, such as cough, weight loss, night sweats, fever, shall have a chest radiograph performed immediately to exclude TB disease (or evaluate an interpretable copy taken within the previous three (3) months). These staff members or volunteers shall be evaluated for the need for treatment of TB disease or latent TB infection (LTBI) and encouraged to follow the recommendations made by a physician with TB expertise (such as the Department's TB Control program).

2. Staff and volunteers known or suspected to have TB disease shall be excluded from work, required to undergo evaluation by a physician or legally authorized healthcare provider, and permitted to return to work only with approval by the Department TB Control program. Repeat chest radiographs are not required unless symptoms or signs of TB disease develop or unless recommended by a physician or legally authorized healthcare provider.

1304. Tuberculosis Screening (I)

A. Tuberculosis Status. The tuberculosis status of a patient in a Hospice Facility shall be determined upon admission by completion of a tuberculosis symptoms screening questionnaire.

B. Known or Suspected Tuberculosis. Patients known or suspected to have TB disease shall be transferred from the Hospice Facility if the Hospice Facility does not have an Airborne Infection Isolation (AII) room (See Section 100.C), required to undergo evaluation by a physician or legally

authorized healthcare provider, and permitted to return to the Hospice Facility only with approval by the Department's TB Control program.

1305. Infectious Waste (I)

Accumulated waste, including all contaminated sharps, dressings, and/or similar infectious waste, shall be disposed of in a manner compliant with *OSHA Bloodborne Pathogens Standard* and R.61-105.

SECTION 1400 - AGREEMENTS FOR SERVICES (II)

When a Hospice engages a source other than the Hospice to provide services normally provided by the Hospice, such as staffing, training, food service, professional consulting, maintenance, transportation, there shall be a written agreement with the source that describes how and when the services are to be provided, the exact services to be provided, and a statement that these services are to be provided by qualified individuals. The source shall comply with this regulation in regard to patient care, treatment, services, and rights.

SECTION 1500 - QUALITY IMPROVEMENT PROGRAM (II)

A. There shall be a written, implemented quality improvement program that provides effective self-assessment and implementation of changes designed to improve the care, treatment, and services provided by the Hospice.

B. The quality improvement program, at a minimum, shall:

1. Establish desired outcomes and the criteria by which policy and procedure effectiveness is regularly, systematically, and objectively accomplished;

2. Identify, evaluate, and determine the causes of any deviation from the desired outcomes;

3. Identify the action taken to correct deviations and prevent future deviation, and the person(s) responsible for implementation of these actions;

4. Establish ways to measure the quality of patient care and staff performance as well as the degree to which the policies and procedures are followed;

5. Analyze the appropriateness of the POC and the necessity of care, treatment, and services rendered;

6. Analyze the effectiveness of the fire plan (hospice facility only);

7. Analyze all accidents and incidents, to include all medication errors and unexpected patient deaths;

8. Analyze any infection, epidemic outbreaks, or other unusual occurrences which threaten the health, safety, or well-being of the patients.

C. A Hospice shall establish a method of obtaining feedback from patients, families, and other interested persons regarding the level of satisfaction with services, treatment, and care provided by the Hospice.

SECTION 1600 - MEDICATION MANAGEMENT

1601. General (I)

A. Medications, including controlled substances, medical supplies, and those items necessary for the rendering of first aid shall be properly managed in accordance with local, state, and federal laws and regulations. Such management shall address the securing, storing, and administering of medications, medical supplies, first aid supplies, and biologicals, their disposal when discontinued or outdated, and their disposition at discharge, death, or transfer of a patient.

B. The Hospice Facility shall provide appropriate methods and procedures for the dispensing and administering of medications or biologicals. Whether medications or biologicals are obtained from community or institutional pharmacies or stocked by the Hospice Facility, the Hospice Facility is responsible for ensuring the availability of medications and biologicals for its patients and for ensuring that pharmaceutical services are provided in accordance with accepted professional principles and appropriate federal, state, and local laws.

C. Applicable reference materials, such as Physician's Desk Reference (PDR), current Drug Reference Book, published within the previous year shall be available at the Hospice Facility in order to provide staff members and volunteers with adequate information concerning medications.

1602. Medications and Treatment Orders (I)

A. Orders for medications and treatment shall be signed by a physician and incorporated in the patient's record maintained by the Hospice. Verbal and telephonic orders shall be received by an authorized healthcare provider. Therapists, pharmacists and social workers can receive only those orders pertinent to their specialty. The Hospice, to include a representation by physicians treating patients at the Hospice, a pharmacist, and the administrator may establish lists of categories of diagnostic or therapeutic verbal orders associated with any potential hazard to the patient that must be authenticated by the physician within a limited Hospice determined time period, but in no case shall any orders be authenticated later than forty-eight (48) hours from the date of the order. Controlled substances shall be included on the list to be authenticated within seven (7) days of the order and all other orders shall be authenticated within thirty (30) days.

B. Stop-Order Policies. All medication orders which do not specifically indicate the number of doses to be administered or the length of time the medication is to be administered shall automatically be stopped in accordance with written policies established by the Hospice Facility.

C. Standing Orders. Standing orders may be utilized if signed by the attending physician or medical director and updated not less than annually.

1603. Emergency Medications (I)

A. A Hospice Facility shall maintain a kit containing medications for emergency use. The kit shall be readily available but must be properly secured. The kit shall contain such medications as selected and approved consistent with Hospice Facility policy and state and federal regulations. An inventory of medications maintained in the kit shall be attached to or placed in the kit.

B. The emergency kit shall be reviewed at least monthly to ensure that all medications are accounted for, unexpired, and properly replaced when used.

C. There shall be at least one (1) emergency kit on each patient floor.

1604. Administering Medication (I)

A. Medication, to include oxygen, shall be administered to patients only upon orders (to include standing orders) of a physician or other authorized healthcare provider. Medications accompanying patients at admission may be administered to patients provided the medication is in the original labeled container and the order is subsequently obtained as a part of the admission physical assessment. Hospice staff members shall consult with the attending physician or medical director for clarification if there are concerns regarding the appropriateness of administering medications due to the condition and/or state of the medication, for example, expired, makeshift or illegible labels, or the condition and/or state of health of the newly-admitted patient.

B. Doses of medication shall be administered by the same licensed nurse who prepared them for administration. Preparation shall occur no earlier than one hour prior to administering. Preparation of doses for more than one scheduled administration shall not be permitted. Each medication dose administered or supervised shall be properly recorded by initialing on the patient's medication record as the medication is administered. Recording medication administration shall include medication name, dosage, mode of administration, date, time, and the signature of the individual administering or supervising the taking of the medication. Recording shall include the medication, dosage, and mode of administration, date, time and identification of the person administering the medication(s). Initials are acceptable when they can be identified readily by signatures.

C. Medications shall be administered in accordance with state practice acts by a physician or other authorized healthcare provider, or licensed nurse.

D. Medications ordered for a specific patient shall not be provided or administered to any other patient. Medications prescribed for a specific patient cannot be administered to another person.

E. Self-administration of medications shall be allowed only on the specific written orders of the patient's attending physician. (Self-administered medications shall be recorded on the medication administration records by the appropriate licensed staff.) Prescribed and over-the-counter medications, such as nitroglycerin, skin ointments, may be kept at bedside upon physician orders if kept in a closed area, such as the drawer of the patient's night stand, in accordance with Hospice Facility policy.

F. The Hospice Facility shall have a policy related to self-administration of medication.

1605. Pharmacy Services (I)

A. The Hospice Facility shall ensure pharmacy operations are in compliance with all applicable state and federal regulations regarding ordering, storage, administration, disposal, and record keeping of medications and biologicals.

B. Any pharmacy services within a Hospice Facility shall be provided by or under the direction of a pharmacist in accordance with accepted professional principles and appropriate local, state, and federal laws and regulations.

C. Labeling of medications dispensed to patients shall be in compliance with local, state, and federal laws and regulations, to include expiration date.

D. The pharmaceutical services shall establish procedures for control and accountability of all medications and biologicals throughout the facility. Medications shall be dispensed in compliance with federal and state laws. Records of receipt and disposition of all controlled substances shall be maintained in sufficient detail to enable an accurate reconciliation.

1606. Medication Containers (I)

Medications for patients shall be obtained from a permitted pharmacy or prescriber on an individual prescription basis. The labeling of medications administered to inpatients shall be in compliance with applicable federal, state, and local laws and regulations. The labeling information may also be available through electronic means. The label shall be in accordance with the directions of the physician or other authorized healthcare provider each time the prescription is refilled. Medication containers having soiled, damaged, incomplete, illegible, or makeshift labels shall be returned to the pharmacy for re-labeling or disposal.

1607. Medication Storage (I)

A. A Hospice Facility shall properly store and safeguard medications to prevent access by unauthorized persons. Expired or discontinued medications shall not be stored with current medications. Storage areas shall be secured and of sufficient size for clean and orderly storage. Storage areas shall not be located near sources of heat, humidity, or other hazards that may negatively impact medication effectiveness or shelf life. Medications requiring refrigeration shall be stored in a refrigerator at the temperature established by the U.S. Pharmacopeia. Medications requiring refrigeration shall be kept in a secured refrigerator used exclusively for medications, or in a secured manner, such as a Lock Box, in which medications are separated from other items kept in a refrigerator.

B. A Hospice Facility shall store medications:

1. Separately from poisonous substances or body fluids;
2. In a manner that provides for separation between topical and oral medications and separation of each individual patient's medication.

C. A Hospice Facility shall maintain a record of the stock and distribution of all controlled substances in such a manner that the disposition of each dose of any particular item may be readily traced.

D. Any stock of legend medications or biologicals shall be maintained in a Hospice Facility by the Hospice, and the Hospice Facility shall obtain and maintain a valid, current pharmacy permit from the South Carolina Board of Pharmacy. Otherwise, Legend medications shall not be stored except those specifically prescribed for individual patients. Nonlegend medications which may be purchased without a prescription such as aspirin, milk of magnesia and mineral oil, may be retained as stock by a Hospice for administration as ordered by the attending physician.

1608. Disposition of Medications (I)

A. Upon discharge or death of a patient, a Hospice in possession of unused medications belonging to the patient that do not constitute a controlled substance under 21 U.S.C. Section 802

shall release the unused medications to the patient, family member, or responsible party, as appropriate.

B. Upon death of a patient, a Hospice in possession of unused medications belonging to the patient that constitutes a controlled substance under 21 U.S.C. Section 802 shall release the unused medication to an applicable person under 21 C.F.R. Section 1317.30 for disposal in accordance with requirements of the federal Drug Enforcement Administration. In the alternative, a facility that constitutes a long-term care facility under 21 C.F.R. 1300.01 may dispose of the unused medications in accordance with 21 C.F.R. Sections 1317.30 and 1317.80.

C. Upon discharge of a patient, a Hospice in possession of unused medications belonging to the patient that constitutes a controlled substance under 21 U.S.C. Section 802 shall release the unused medication to the “ultimate user” under 21 U.S.C. Section 802. In the alternative, a facility that constitutes a long-term care facility under 21 C.F.R. 1300.01 may dispose of the unused medications in accordance with 21 C.F.R. Sections 1317.30 and 1317.80 if authorized by the patient.

D. Expired biologicals, medical supplies, and solutions shall be disposed of in accord with Hospice Facility policy.

SECTION 1700 - MEAL SERVICE

1701. General (II)

A. Hospice Facility food preparation shall be approved by the Department and shall be regulated, inspected, and graded pursuant to Regulation 61-25, Retail Food Establishments.

B. When catered meals are served in a Hospice Facility, such meals shall be obtained from a food service establishment graded by the Department, pursuant to R.61-25, and there shall be a written executed contract with the food service establishment.

1702. Meals and Services

A. A Hospice Facility shall include dietary services to meet the daily nutritional needs of the patients in accordance with the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences. (II)

B. Unless otherwise directed by the patient’s physician or other authorized healthcare provider or by the wishes of the patient, a Hospice Facility shall provide a minimum of three (3) nutritionally-adequate meals, in accordance with Section 1702.A above, in each twenty-four (24) hour period for each patient. Professional judgment may dictate that meal service is adjusted to meet variations in the condition of individual patients. This may include offering smaller, more frequent meals, or snacks, or postponing meals to honor a patient’s request (for example, to sleep or not to eat). Not more than fourteen (14) hours shall elapse between the serving of the evening meal and breakfast the following day. (II)

C. Special attention shall be given to preparation and prompt serving in order to maintain correct food temperatures for serving. (II)

D. Suitable food and snacks shall be available and offered between meals at no additional cost to the patients. (II)

E. Tray service shall be permitted when the patient is medically unable to access the dining area for meals or if the Hospice has received notice from the patient of a preference to receive tray service.

1703. Meal Service Staff (II)

A. Sufficient staff members and volunteers shall be available to serve food and to provide individual attention and assistance, as needed.

B. Employees shall wear clean garments, maintain a high degree of cleanliness, and conform to hygienic practices while on duty. Individuals engaged in the preparation and service of food shall wear clean hair restraints, such as hair nets, hair wraps, hats, that will properly restrain all hair of the face and head and prevent contamination of food and food contact surfaces. They shall wash their hands thoroughly in an approved hand washing lavatory before starting work, after visiting the bathroom and as often as may be necessary to remove soil and contamination.

1704. Diets

A. If a Hospice Facility accepts or retains patients in need of medically-prescribed special diets, the menus for such diets shall be planned by a professionally-qualified dietitian or shall be reviewed and approved by a physician or other authorized healthcare provider. The Hospice Facility shall provide supervision of the preparation and serving of any special diet, such as low-sodium, low-fat, 1200-calorie, diabetic diet. (II)

EXCEPTION: Nonadherence to the special diet shall be acceptable provided there is written consent to such nonadherence from the patient or family or responsible party and the physician.

B. If special diets are required, the necessary equipment for preparation of those diets shall be available and utilized.

C. A diet manual published within the previous five (5) years shall be available and shall address at minimum:

1. Food sources and food quality;
2. Food protection storage, preparation and service;
3. Food worker health and cleanliness;
4. Recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences USDA food serving recommendations;
5. General menu planning;
6. Menu planning appropriate to special needs, such as diabetic, low-salt, low-cholesterol, or other diets appropriate for the elderly and/or infirmed.

1705. Menus

A. Hospice Facility menus shall be planned and written a minimum of one (1) week in advance and dated as served. The current week's menu, including routine and special diets and any substitutions or changes made, shall be readily available and posted in one or more conspicuous places in a public area. All substitutions made on the master menu shall be recorded in writing.

B. A Hospice Facility shall maintain records of menus as served for at least thirty (30) days.

1706. Ice and Drinking Water (II)

A. Ice from a Hospice Facility water system that is in accordance with Regulation 61-58, State Primary Drinking Water Regulations, shall be available and precautions taken to prevent contamination. The ice scoop shall be stored in a sanitary manner outside the ice container.

B. Potable drinking water shall be available and accessible to patients at all times.

C. The use of common cups shall be prohibited in a Hospice Facility.

D. Ice delivered in a Hospice Facility to patient areas in bulk shall be in nonporous, covered containers that shall be cleaned after each use.

1707. Refuse Storage and Disposal (II)

For Hospice Facilities, refuse storage and disposal shall be in accordance with R.61-25.

SECTION 1800 - EMERGENCY PROCEDURES AND DISASTER PREPAREDNESS

1801. Disaster Preparedness (II)

A. A Hospice Facility shall develop, by contact and consultation with their county emergency preparedness agency, a suitable written plan for actions to be taken in the event of a disaster and/or emergency evacuation. Prior to providing services, the Hospice Facility shall submit the completed plan to the Department for review. The Hospice Facility shall update and resubmit the emergency and/or disaster evacuation plan if it proposes a new total licensed bed capacity. All staff members and volunteers shall be made familiar with this plan and instructed as to any required actions. A copy of the disaster plan shall be provided to the patient and/or patient's sponsor at the time of admission. The plan shall be reviewed and updated, as appropriate, annually and rehearsed at least annually.

B. A Hospice Facility shall maintain a means of communication with its local emergency management agency capable of transmitting information and/or data during periods when normal communication systems are inoperable. The Hospice shall also maintain a back-up system. Both systems shall be exercised periodically.

C. Annually, prior to June 1st of each year, each Hospice Facility shall validate and provide the Department the information required by the Department's Critical Data Sheet (CDS) Information system. Hospice data provided to the CDS system will assist the Department, during times of disaster and emergencies, determine the appropriateness of evacuation or shelter-in-place.

D. The disaster and emergency evacuation plan shall include, but not be limited to:

1. A sheltering plan to include:

- a. The licensed bed capacity and average occupancy rate;
 - b. Name, address and phone number of the sheltering facility or facilities to which the patients will be relocated during a disaster; and
 - c. A letter of agreement signed by an authorized representative of each sheltering facility that shall include: the number of relocated patients that can be accommodated; sleeping, feeding, and medication plans for the relocated patients; and provisions for accommodating relocated staff members and volunteers. The letter shall be updated with the sheltering facility at least every three (3) years and whenever significant changes occur. For those facilities located in Beaufort, Charleston, Colleton, Horry, Jasper, and Georgetown counties, at least one (1) sheltering facility shall be located in a county other than these counties.
2. A transportation plan, to include agreements with entities for relocating patients, which addresses:
- a. Number and type of vehicles required;
 - b. How and when the vehicles are to be obtained;
 - c. Who (by name or organization) will provide drivers;
 - d. The relocation needs of the patients and staff contingent upon the type of disaster/emergency confronted;
 - e. Procedures for providing appropriate medical support, food, water, and medications during transportation and relocation based on the needs and number of the patients;
 - f. Estimated time to accomplish the relocation;
 - g. Primary and secondary routes to be taken to the sheltering facility.
3. A staffing plan for the relocated patients, to include:
- a. How care will be provided to the relocated patients, including the number and type of staff members that will accompany patients who are relocated;
 - b. Prearranged transportation arrangements to ensure staff members are relocated to the sheltering facility;
 - c. Co-signed statement by an authorized representative of the sheltering facility if staffing, bedding, or medical supplies is to be provided by the sheltering facility.

1802. Emergency Call Numbers (II)

A Hospice Facility shall post emergency call data in a conspicuous place and shall include at least the telephone numbers of fire and police departments, ambulance service, and the poison control center. Other emergency call information shall be available, to include the names, addresses, and telephone numbers of staff members and/or volunteers to be notified in case of emergency.

1803. Continuity of Essential Services (II)

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

1804. Safety Precautions and Restraints (I)

A. Periodic or continuous mechanical or physical restraints during routine care of a patient shall not be used, nor shall patients be restrained for staff convenience or as a substitute for care, treatment, or services. However, in cases of extreme emergencies when a patient is a danger to him or herself or others, mechanical and/or physical restraints may be used as ordered by a physician or other authorized healthcare provider.

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

C. Emergency restraint orders shall specify the reason for the use of the restraint, the type of restraint to be used, the maximum time the restraint may be used, and instructions for observing the patient while restrained, if different from the Hospice's written procedures.

D. During emergency restraint, patients shall be monitored at least every hour. Prescribed medications and treatments shall be administered as ordered and nourishment and fluids provided as needed.

SECTION 1900 - MAINTENANCE (II)

The Hospice Facility shall maintain its institutional structure, component parts, and equipment in good repair and operating condition.

SECTION 2000 - ENVIRONMENT

2001. Housekeeping (II)

A. The Hospice Facility and its grounds shall be uncluttered, clean, and free of vermin and offensive odors.

B. The Hospice Facility grounds shall be reasonably free of weeds, rubbish, overgrown landscaping, and other potential breeding sources for vermin.

C. Interior housekeeping of a Hospice Facility shall, at a minimum, include:

1. Cleaning each specific area of the Hospice Facility;
2. Cleaning and disinfection, as needed, of equipment used and/or maintained in each area appropriate to the area and the equipment's purpose or use; and
3. Safe storage and use of chemicals indicated as harmful on the product label, cleaning materials, and supplies in cabinets or well-lighted closets and/or rooms, inaccessible to patients.

D. Exterior housekeeping at a Hospice Facility shall, at a minimum, include:

1. Cleaning of all exterior areas, such as porches and ramps, and removal of safety impediments such as snow and ice; and

2. Keeping Hospice Facility grounds reasonably free of weeds, rubbish, overgrown landscaping, and other potential breeding sources of vermin.

2002. Pets (II)

A. If a Hospice Facility permits pets, healthy animals that are free of fleas, ticks, and intestinal parasites, and have been screened by a veterinarian prior to entering the Hospice Facility, have received required inoculations, if applicable, and that present no apparent threat to the health, safety, and well-being of the patients, may be permitted in the Hospice Facility, provided they are sufficiently fed and cared for and that both the pets and their housing are kept clean.

B. Pets shall not be allowed near patients who have allergic sensitivities to pets, or for other reasons such as patients who do not wish to have pets near them.

C. Pets shall not be allowed in the kitchen area. Pets shall be permitted in patient dining areas only during times when food is not being served. If the dining area is adjacent to a food preparation or storage area, those areas shall be effectively separated by walls and closed doors while pets are present.

D. If personal pets are permitted in a Hospice Facility, the housing of those pets shall be in either a patient private room or outside the Hospice Facility.

2003. Clean and Soiled Linen (II)

A. Clean Linen. A Hospice Facility shall have available a supply of clean, sanitary linen at all times. In order to prevent the contamination of clean linen by dust or other airborne particles or organisms, clean linen shall be stored and transported in a sanitary manner, for example, enclosed and covered. Clean linen storage rooms shall be used only for the storage of clean linen and other clean materials. Clean linen shall be separated from storage of other materials.

B. Soiled Linen.

1. For Inpatient Services, a Hospice shall not sort, rinse, or wash soiled linen outside of a laundry service area;

2. A Hospice Facility shall have provisions for collecting, transporting, and storing soiled linen;

3. A Hospice Facility shall keep soiled linen in enclosed or covered containers; and

4. For Inpatient Services, a Hospice shall not conduct laundry operations in patient rooms, dining rooms, or in locations where food is prepared, served, or stored. Freezers and refrigerators may be stored in laundry areas, provided sanitary conditions are maintained.

2004. Exit Egress

Hospice Facility halls, corridors and all other means of egress shall be free from obstructions.

SECTION 2100 - DESIGN AND CONSTRUCTION

2101. General (II)

A Hospice Facility shall be planned, designed, and equipped to provide and promote the health, safety, and well-being of each patient. Hospice Facility design shall be such that all patients have access to required services. There shall be two hundred (200) gross square feet per licensed bed in a Hospice Facility licensed for ten (10) beds or less. In a Hospice Facility licensed for more than ten (10) beds, there shall be an additional one hundred (100) gross square feet per licensed bed.

2102. Adopted Codes and Standards (II)

A. Buildings shall comply with pertinent local and state laws, codes, ordinances, and standards with reference to design and construction. No Hospice Facility shall be licensed unless the Department has assurance that responsible local officials (zoning and building) have approved the Hospice Facility for code compliance.

B. Facility design and construction shall comply with the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal.

C. Unless required otherwise by the Department or specific provision(s) of this regulation, all Hospice Facilities shall comply with the construction codes and construction regulations applicable at the time its license was issued.

D. Any Hospice Facility that closes, has its license revoked, or surrenders its license, and applies for re-licensure at the same site, shall be considered a new building and shall meet the current codes, regulations, and requirements for the building and its essential equipment and systems in effect at the time of application for re-licensing.

2103. Submission of Plans (II)

A. Plans and specifications shall be submitted to the Department for review and approval for new construction, additions or alterations to existing buildings, replacement of major equipment, buildings being licensed for the first time, buildings changing license type, and for facilities increasing occupant load or licensed capacity. Final plans and specifications shall be prepared by an architect and/or engineer registered in South Carolina and shall bear their seals and signatures. Architectural plans shall also bear the seal of a South Carolina registered architectural corporation. Unless directed otherwise by the Department, submit plans at the schematic, design development, and final stages. All plans shall be drawn to scale with the title, stage of submission and date shown thereon. Any construction changes from the approved documents shall be approved by the Department. Construction work shall not commence until a plan approval has been received from the Department. During construction the owner shall employ a registered architect and/or engineer for observation and inspections. Upon approval of the Department, construction administration may be performed by an entity other than the architect. The Department shall conduct periodic inspections throughout each project.

B. Plans and specifications shall be submitted to the Department for review and approval for projects that have an effect on:

1. The function of a space;

2. The accessibility to or of an area;
3. The structural integrity of the facility;
4. The active and/or passive fire safety systems (including kitchen equipment such as exhaust hoods or equipment required to be under an exhaust hood);
5. Doors;
6. Walls;
7. Ceiling system assemblies;
8. Exit corridors;
9. Life safety systems; or
10. Increase in occupant load or licensed capacity of the Hospice Facility.

C. All subsequent addenda, change orders, field orders, and documents altering the Department review must be submitted. Any substantial deviation from the accepted documents shall require written notification, review and re-approval from the Department.

D. Cosmetic changes utilizing paint, wall covering, floor covering, or other, that are required to have a flame-spread rating or other safety criteria shall be documented with copies of the documentation and certifications kept on file at the facility and made available to the Department.

2104. Construction Inspections

All projects shall obtain all required permits from the locality having jurisdiction. Construction without proper permitting shall not be inspected by Department.

2105. Patient Rooms

A. Multiple bed rooms shall include cubicle curtains with built-in curtain tracks that shield each patient completely. Curtains shall be flameproof.

B. Hospice Facility beds shall be placed at least three (3) feet apart.

C. A Hospice Facility shall provide at least one (1) private room in each nursing unit for purposes such as medical isolation, incompatibility, and personality conflicts.

2106. Utility Rooms

A. Soiled Utility Room: A Hospice Facility shall include at least one (1) soiled utility room per work station containing a clinical sink, work counter, waste receptacle and soiled linen receptacle.

B. Clean Utility Room: A Hospice Facility shall include at least one (1) clean utility room per work station containing a counter with handwashing sink and space for the storage and assembly of supplies for nursing procedures.

SECTION 2200 - FIRE PROTECTION EQUIPMENT AND SYSTEMS (I)

2201. Fire Protection

A. A Hospice Facility shall include a partial, manual, automatic, and supervised fire alarm system. The system shall be arranged to transmit an alarm automatically to a third party by an approved method. The alarm system shall notify by audible and visual alarm all areas and floors of the building. The alarm system shall shut down central recirculating systems and outside air units that serve the area(s) of alarm origination as a minimum.

B. All fire, smoke, heat, sprinkler flow, or manual fire alarming devices or systems must be connected to the main fire alarm system and trigger the system when they are activated.

C. A Hospice Facility shall include an NFPA 13 sprinkler system.

D. A Hospice Facility shall maintain a fire alarm pull station in or near each work station.

2202. Emergency Generator Service

A. Hospice Facilities shall provide certification that construction and installation of emergency generator service complies with requirements of all adopted codes.

B. In addition to compliance with codes adopted in this regulation, a Hospice Facility shall include an emergency generator to deliver emergency electrical service during interruption of the normal electrical service to the distribution system as follows:

1. Exit lights and exit directional signs;
2. Exit access corridor lighting;
3. Lighting of means of egress and staff work areas;
4. Fire detection and alarm systems;
5. In patient care areas;
6. Signal system;
7. Equipment necessary for maintaining telephone service and all life safety systems;
8. Elevator service that will reach every patient floor when rooms are located on other than the ground floor;
9. Fire pump;
10. Equipment for heating patient rooms;
11. Public restrooms;
12. Essential mechanical equipment rooms;

13. Battery-operated lighting and a receptacle in the vicinity of the emergency generator;
14. Alarm systems, water flow alarm devices, and alarms required for medical gas systems;
15. Patient records when solely electronically based.

SECTION 2300 - FIRE PREVENTION

2301. Arrangements for Fire Department Response and Protection (I)

Hospice Facilities located outside of a service area or range of a public fire department shall arrange by written agreement with the nearest fire department for it to respond in case of fire. A copy of the agreement shall be kept on file in the Hospice Facility and a copy shall be forwarded to the Department. If the agreement is changed, a copy shall be forwarded to the Department.

2302. Tests and Inspections (I)

A Hospice Facility shall maintain and test fire protection and suppression systems in accordance with the applicable codes in Section 2102.

2303. Fire Response Training (I)

A. Fire Response Training. A Hospice with Inpatient Services shall provide training for each staff member and volunteer within twenty-four (24) hours of his or her first day on duty in the Hospice Facility and at least annually thereafter, addressing at a minimum, the following:

1. Fire plan, including the training of staff members and volunteers;
2. Fire evacuation plan, including routes and procedures;
3. Reporting a fire;
4. Use of the fire alarm system;
5. Location and use of fire-fighting equipment;
6. Methods of fire containment;
7. Specific responsibilities, tasks, or duties of each individual.

B. Fire Evacuation Plan. A Hospice Facility shall establish and post a plan for the evacuation of patients, staff members, and visitors, to include evacuation routes and procedures, in case of fire or other emergencies, in conspicuous public areas throughout the Hospice Facility, and a copy of the plan shall be provided to each patient and/or the patient's sponsor at the time of admission.

2304. Fire Drills (I)

A. In addition to compliance with codes adopted in this regulation, a Hospice Facility shall conduct an unannounced fire drill shall at least once every three (3) months for each shift. Each Hospice staff member and volunteer shall participate in a fire drill at least once each year. Records

of drills shall be maintained at the Hospice Facility, indicating the date, time, shift, description, and evaluation of the drill, and the names of staff members, volunteers, and patients directly involved in responding to the drill. If fire drill requirements are mandated by statute or regulation, then provisions of the statute or regulation shall be complied with and shall supersede the provisions of Section 2304.

B. Drills shall be designed and conducted to evaluate the effectiveness of the plans and to ensure that all staff members and volunteers:

1. Are capable of performing assigned tasks and duties;
2. Know the location, use and operation of fire-fighting equipment;
3. Are familiar with the fire plan.

SECTION 2400 - PREVENTIVE MAINTENANCE OF LIFE SUPPORT EQUIPMENT (I)

A written preventive maintenance program for all life support equipment including, but not limited to, all HVAC systems, potable water systems, patient monitoring equipment, isolated electrical systems, conductive flooring, patient grounding systems, and medical gas systems shall be developed and implemented. This equipment shall be checked and/or tested at such intervals to insure proper operation and a state of good repair. After repairs and/or alterations are made to any equipment or system, the equipment or system shall be thoroughly tested for proper operation before returning it to service. Records shall be maintained on each piece of life support equipment to indicate its history of testing and maintenance.

SECTION 2500 - GASES, FURNISHINGS, AND EQUIPMENT

2501. Gases (I)

A. Gases, flammable and nonflammable, shall be handled and stored in accordance with the applicable code in Section 2102.

B. Safety precautions shall be taken against fire and other hazards when oxygen is dispensed, administered, or stored. "No Smoking" signs shall be posted conspicuously, and cylinders shall be properly secured in place. In "Smoke-Free" Hospice Facilities, "No Smoking" signs shall not be required in, or in the vicinity of, patient rooms where oxygen is being administered provided all four (4) of the following conditions are met:

1. Smoking is prohibited;
2. The Hospice Facility nonsmoking policy is strictly enforced;
3. "Smoke-Free" signs are strategically placed at all major entrances; and

4. "No Smoking" signs are required in, and in the vicinity of, patient rooms where oxygen is being stored, as well as all other required areas of the Hospice Facility.

2502. Furnishings and Equipment (I)

A. The physical plant shall be maintained free of fire hazards or impediments to fire prevention.

B. No portable electric or unvented fuel heaters shall be permitted in the Hospice Facility.

C. Fireplaces and fossil-fuel stoves, or wood-burning, shall have partitions or screens or other means to prevent burns. Fireplaces shall be vented to the outside. Unvented gas logs are not allowed. Gas fireplaces shall have a remote gas shutoff within the room and not inside the fireplace.

D. Wastebaskets, window dressings, portable partitions, cubicle curtains, mattresses, and pillows shall be noncombustible, inherently flame-resistant, or treated or maintained flame-resistant.

SECTION 2600 - WATER SUPPLY, HYGIENE, AND TEMPERATURE CONTROL (I)

A. Plumbing fixtures that require hot water and which are accessible to patients shall be supplied with water that is thermostatically controlled to a temperature of at least one hundred (100) degrees Fahrenheit and not to exceed one hundred twenty (120) degrees Fahrenheit at the fixture.

B. The water heater or combination of heaters shall be sized to provide at least six (6) gallons per hour per bed at the above temperature range. (II)

C. Hot water supplied to the kitchen equipment and utensil washing sink shall be supplied at one hundred twenty (120) degrees provided all kitchen equipment and utensils are chemically sanitized. For those Hospice Facilities sanitizing with hot water, the sanitizing compartment of the kitchen equipment and utensil washing sink shall be capable of maintaining the water at a temperature of at least one hundred eighty (180) degrees Fahrenheit.

D. Hot water provided for washing linen shall not be less than one hundred sixty (160) degrees Fahrenheit. Should chlorine additives or other chemicals which contribute to the margin of safety in disinfecting linen be a part of the washing cycle, the minimum hot water temperature shall not be less than one hundred ten (110) degrees Fahrenheit, provided hot air drying is used. (II)

SECTION 2700 - ELECTRICAL

2701. General (I)

All electrical installations and equipment shall be maintained in a safe, operable condition in accordance with the applicable code in Section 2102 and shall be inspected at least annually by a licensed electrician, registered engineer, or certified building inspector.

2702. Panelboards (II)

The directory shall be labeled to conform to the actual room designations. Clear access to the panel shall be maintained. The panelboard directory shall be labeled to conform to the actual room numbers or designations.

2703. Lighting

A. Spaces occupied by persons, machinery, equipment within buildings, approaches to buildings, and parking lots shall be lighted. (II)

B. Adequate artificial light shall be provided to include sufficient illumination for reading, observation, and activities.

C. Patient rooms shall have general lighting in all parts of the room, and shall have at least one (1) light fixture for night lighting. A reading light shall be provided for each client.

D. Hallways, stairs, and other means of egress shall be lighted at all times. (I)

2704. Receptacles (II)

A. Each patient room shall have duplex grounding type receptacles, to include one (1) at the head of each bed in accordance with the applicable code in Section 2102.

B. Each patient bed location shall have a minimum of two (2) duplex receptacles.

C. Each patient bed location shall be supplied by at least two (2) branch circuits.

D. Duplex receptacles for general use shall be installed approximately fifty (50) feet apart in all corridors and within twenty-five (25) feet of the ends of corridors.

2705. Ground Fault Protection (I)

A. Ground fault circuit-interrupter protection shall be provided for all outside receptacles and bathrooms.

B. Ground fault circuit-interrupter protection shall be provided for any receptacles within six (6) feet of a sink or any other wet location. If the sink is an integral part of the metal splashboard grounded by the sink, the entire metal area is considered part of the wet location.

2706. Exit Signs (I)

A. A Hospice Facility shall have exits and ways to access thereto shall be identified by electrically-illuminated exit signs bearing the words "Exit" in red letters, six (6) inches in height, on a white background.

B. Changes in egress direction shall be marked with exit signs with directional arrows.

C. Exit signs in corridors shall be provided to indicate two (2) directions of exit.

SECTION 2800 - HEATING, VENTILATION, AND AIR CONDITIONING (HVAC) (II)

A. No HVAC supply or return grill shall be installed within three (3) feet of a smoke detector. (I)

B. HVAC grills shall not be installed in floors.

C. Intake air ducts shall be filtered and maintained to prevent the entrance of dust, dirt, and other contaminating materials. The system shall not discharge in a manner that would be an irritant to the patients, staff, or volunteers.

D. Each bath or restroom shall have either operable windows or have approved mechanical ventilation.

SECTION 2900 - PHYSICAL PLANT

2901. Common Areas

A. There shall be a minimum of thirty (30) square feet per bed of living, recreational, and dining area combined, excluding bedrooms, halls, kitchens, bathrooms, and rooms not available to the patients.

B. Physical space for private patient, family, and responsible party visiting shall be provided.

C. The Hospice Facility shall include accommodations for family privacy after a patient's death.

2902. Patient Rooms

A. With the exception of furniture (unless otherwise allowed by facility policy), a Hospice or Hospice Facility shall not bar a patient from bringing familiar items from home as part of the furnishing to his or her room, such as wall pictures, paintings, vases, or other. Each patient room shall be equipped with the following as a minimum for each patient:

1. A comfortable single bed having a mattress with moisture-proof cover, sheets, blankets, bedspread, pillow, and pillowcases; roll-away type beds, cots, bunkbeds, and folding beds shall not be used. It is permissible to utilize a recliner in lieu of a bed or remove a patient bed and place the mattress on a platform or pallet provided the physician or other authorized healthcare provider has approved it and the decision is documented in the POC. (II)

EXCEPTION: In the case of a married couple sharing the same room, a double bed is permitted if requested. For all other requirements, this shall be considered a bedroom with two (2) beds. A roll-away type bed or cot may be temporarily used for family/responsible party staying overnight with the patient.

2. A closet or wardrobe, a bureau consisting of at least three (3) drawers, and a compartmentalized bedside table or nightstand to adequately accommodate each patient's personal clothing, belongings, and toilet articles shall be provided. Built-in storage is permitted.

3. A comfortable chair shall be available for each patient occupying the room. In Hospice Facilities licensed prior to the promulgation of this regulation, if the available square footage of the patient room will not accommodate a chair for each patient or if the provision of multiple chairs impedes patient ability to freely and safely move about within their room, at least one (1) chair shall be provided and provisions made to have additional chairs available for temporary use in the patient's room by visitors.

B. If hospital-type beds are used, there shall be at least two (2) lockable casters on each bed, located either diagonally or on the same side of the bed.

C. Beds shall not be placed in corridors, solarium, or other locations not designated as patient room areas. (I)

D. No patient room shall contain more than two (2) licensed beds. (II)

E. No patient room shall be located in a basement.

F. Access to a patient room shall not be by way of another patient room, toilet, bathroom, or kitchen.

G. Side rails may be utilized when required for safety and when ordered by a physician or other authorized healthcare provider. When there are special concerns, such as patients with Alzheimer's disease and/or related dementia, side rail usage shall be monitored by staff members as per Hospice Facility policies and procedures. (I)

H. In semi-private rooms, when personal care is being provided, arrangements shall be made to ensure privacy, for example, portable partitions or cubicle curtains when needed or requested by a patient.

I. At least one (1) private room shall be available in the Hospice Facility in order to provide assistance in addressing patient compatibility issues, patient preferences, and accommodations for patients with communicable disease.

J. Infants and small children shall not be assigned to a room with an adult patient unless requested by patients and families.

2903. Patient Room Floor Area

A. Each patient room shall be an outside room with an outside window. This window shall not open onto a common area screened porch. (I)

B. The patient room floor area is a usable or net area and does not include wardrobes (built-in or freestanding), closets, or the entry alcove to the room. The following is the minimum floor space allowed: (II)

1. Rooms for only one (1) patient: one hundred (100) square feet for the licensed bed (there shall be compliance with the minimum square footage requirements of Section 2903.B.2 in instances when family members or responsible party routinely utilize a separate bed for overnight stays with the patient);

2. Rooms for more than one (1) patient: eighty (80) square feet per licensed bed.

C. There shall be at least three (3) feet between beds. (II)

2904. Visitor Accommodations

A. A Hospice Facility shall include accommodating space for family members or responsible party to remain throughout the night. A Hospice Facility may also include nighttime arrangements for visitors through guest room accommodations within the patient room provided space is adequate for such an arrangement.

B. Visitor designated or guest rooms shall not be utilized by patients, prospective patients, or staff members of the Hospice Facility.

C. No supervisory care shall be given to visitors of the Hospice Facility, for example, first aid response by staff, tray service, or other.

D. Visitors shall be made aware of those provisions or accommodations available so that they may serve themselves, such as towels, sheets, soap, or other.

E. Any conduct of the visitors which may have an adverse effect on the patients/Hospice Facility must be promptly and prudently handled, for example, patient or staff abuse.

F. Those visiting as well as the patients with whom they are visiting shall be made fully aware of the conditions under which their stay is acceptable.

G. Adequate space shall be provided for the privacy of the family and significant others at the time of the patient's death.

2905. Bathrooms and Restrooms (II)

A. There shall be an appropriate number of restrooms in the Hospice Facility, to accommodate patients, staff, and visitors. There shall be one (1) bathtub or shower for each four (4) licensed beds or fraction thereof.

B. The restrooms shall be accessible during all operating hours of the Hospice Facility.

C. A restroom(s) shall be equipped with at least one (1) toilet fixture, toilet paper installed in a holder, a lavatory supplied with hot and cold running water, liquid or granulated soap, single-use disposable paper towels or electric air dryer, and a covered waste receptacle.

D. All toilet fixtures used by patients shall have approved grab bars securely fastened in a usable fashion.

E. Privacy shall be provided at toilet fixtures and urinals.

F. A Hospice Facility shall provide bathrooms and restrooms for persons with disabilities in accordance with codes adopted by this regulation, whether or not any of the staff or patients are classified as disabled.

G. All restroom floors shall be entirely covered with an approved nonabsorbent covering. Walls shall be nonabsorbent, washable surfaces to the highest level of splash.

H. Every toilet shall have grab bars on at least one (1) side.

2906. Work Stations

A. A Hospice Facility shall include work stations for use by nursing and/or other direct care staff. Work stations shall be designed and constructed (or set up) in a manner conducive to the type of care provided by the Hospice Facility or that specific area of the Hospice Facility and the types of patients served.

B. At or near each work station, there shall be a telephone, an area for maintaining patient records and making entries, and toilet and handwashing sink.

C. At or near each work station, provisions shall be made for:

1. Secured storage for medications, which may be accomplished by the use of a separately secured medication cart, container, cabinet, or room, provided:

a. The method or methods used are of sufficient size to allow for neat, clean, and orderly storage of medications;

b. Separations are provided for the storage of each patient's medications;

c. Separations are provided for oral and topical medications.

2. Work space or area for the preparation of medications, which may be a counter, table top, or a separate room, to include being a part of a separate medication room.

D. A work station may not serve more than forty-four (44) beds.

EXCEPTION: A Hospice Facility may include a work station that serves more than forty-four (44) beds if the Hospice Facility provides additional services and facilities, and demonstrates the additional beds served will not adversely affect the health care provided to each patient.

E. A patient room shall not be located more than one hundred fifty (150) feet from the work station that serves that room.

F. At or near each work station, there shall be utility areas or rooms for separate storage of clean and soiled supplies and equipment. Each utility area shall contain a handwashing sink, work counter, waste receptacle, and space for the storage of supplies.

2907. Signal System (II)

All Hospice Facilities shall have a signal system consisting of an electronic device or pull cord for each bed, bath, and toilet. A light shall be at or over each patient room door visible from the corridor. There shall be an audio-visual master station in a location continuously monitored by staff.

2908. Doors (II)

A. All restrooms shall have opaque doors for the purpose of privacy.

B. All glass doors, including sliding or patio type doors, shall have a contrasting or other indicator that causes the glass to be observable, such as a decal located at eye level.

C. Doors that have locks shall be unlockable and openable with one (1) action.

D. If patient room doors are lockable, there shall be provisions for emergency entry.

E. Any locked room door must be unlockable and openable from inside the room.

2909. Elevators (II)

Elevators shall be inspected and tested upon installation, prior to first use, and annually thereafter by a certified elevator inspector.

2910. Handrails and Guardrails (II)

A. Handrails shall be provided on at least one (1) side of each corridor or hallway.

B. All porches, walkways, and recreational areas (such as decks, etc.) that are elevated thirty (30) inches or more above grade shall have guardrails forty-two (42) inches high. Open guardrails shall have intermediate rails less than four (4) inches apart.

2911. Janitor's Closet

There shall be at least one (1) lockable janitor's closet per forty-four (44) licensed beds. Each closet shall be equipped with a mop sink or receptor and space for the storage of supplies and equipment.

2912. Storage Areas

A. The Hospice Facility shall provide adequate general storage areas for patient, staff, and volunteer belongings, equipment, and supplies.

B. Supplies and equipment shall not be stored directly on the floor. Supplies and equipment susceptible to water damage or contamination shall not be stored under sinks or in other areas with a propensity for water leakage. (II)

2913. Telephone Service

A. At least one (1) telephone shall be available and easily accessible on each floor of the Hospice Facility for use by patients and/or visitors for their private, discretionary use. Telephones shall be portable to accommodate bedridden or ambulatory-impaired patients. Telephones capable of only local calls are acceptable for this purpose, provided other arrangements exist to provide patient and visitor discretionary access to a telephone capable of long-distance service.

B. At least one (1) telephone shall be provided on each floor for staff members and volunteers to conduct routine business of the Hospice Facility and to summon assistance in the event of an emergency; pay station phones are not acceptable for this purpose.

2914. Location

A. Transportation. The Hospice Facility shall be served by roads that are passable at all times and are adequate for the volume of expected traffic.

B. Parking. The Hospice Facility shall have a parking area to reasonably satisfy the needs of patients, staff members, volunteers, and visitors.

C. Access to firefighting equipment. The Hospice Facility shall maintain adequate access to and around the building(s) for firefighting equipment. (I)

2915. Outdoor Area

A. Outdoor areas where unsafe, unprotected physical hazards exist shall be enclosed by a fence or a natural barrier of a size, shape, and density that effectively impedes travel to the hazardous area. Such areas include, but are not limited to steep grades, cliffs, open pits, high voltage electrical

equipment, high speed or heavily traveled roads, and/or roads exceeding two (2) lanes, excluding turn lanes, ponds and swimming pools. (I)

B. Where required, fenced areas that are part of a fire exit from the building shall have a gate in the fence that unlocks in case of emergency per Special Locking Arrangements in the applicable codes of Section 2102. (I)

C. Mechanical or equipment rooms that open to the outside of the Hospice Facility shall be protected from unauthorized individuals. (II)

SECTION 3000 - SEVERABILITY

In the event that any portion of these regulations is construed by a court of competent jurisdiction to be invalid, or otherwise unenforceable, such determination shall in no manner affect the remaining portions of these regulations, and they shall remain in effect, as if such invalid portions were not originally a part of these regulations.

SECTION 3100 - GENERAL

Conditions which have not been addressed in the standards shall be managed in accordance with the best practices as interpreted by the Department.