

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH

CHAPTER 661. HOSPICE

SUBCHAPTER 1. GENERAL PROVISIONS

310:661-1-2. Definitions

The following words and terms, when used in this Chapter, shall have the following meaning, unless the context clearly indicates otherwise.

"Act" means the Oklahoma Hospice Licensing Act, 63 O.S. 1991, §§ 1-860.1 et seq.

"Alternate Administrative Office" means an approved location from which the hospice provides the same full range of hospice care and services that is required of the hospice issued the license and meets the requirements of 310:661-2-1(f)(2). Each location shall meet all of the applicable requirements of Chapter 661. Hospice.

"Attending physician" means a doctor of medicine or osteopathy, identified by the patient or representative at the time the patient or representative elects to receive hospice care, as having the most significant role in the determination and delivery of the patient's medical care.

"Bereavement counseling" means emotional, psychosocial, and spiritual support and services provided before and after the death of the patient to assist with issues related to grief, loss, and adjustment.

"Clinical note" means a notation of a contact with the patient and/or the family that is written and dated by any person providing services and that describes signs and symptoms, treatments and medications administered, including the patient's reaction and/or response, and any changes in physical, emotional, psychosocial or spiritual condition during a given period of time.

"Comprehensive assessment" means an evaluation of the patient's physical, psychosocial, emotional and spiritual status related to the terminal illness and related conditions. This includes an evaluation of the caregiver's and family's willingness and capability to care for the patient.

"Continuous care" means nursing care that is provided by a skilled nurse or a qualified hospice aide for as much as 24-hours a day during periods of medical crisis as necessary to maintain a hospice patient at their place of residence.

"Department" means the Oklahoma State Department of Health.

"Dietary counseling" means education and interventions provided to the patient and family regarding nutritional intake as the patient's condition changes. Dietary counseling is provided by qualified individuals, which may include a registered nurse or dietitian, when identified in the patient's plan of care.

"Employed" means contracting with a person for services, regardless of compensation. This term also includes volunteers.

"Employee" means a person who: (1) Works for the hospice and for whom the hospice is required to issue a W-2 form on his or her behalf; (2) if the hospice is a subdivision of an agency or organization, an employee of the agency or organization who is assigned to the hospice; or (3) is a volunteer under the jurisdiction of the hospice.

"Fast-track" The process where advance approval may be secured for construction starts while design details are completed.

"First-year license" means a license issued for the initial twelve (12) month license period.

"Follow-up inspection" means the inspection by representatives of the Department that shall occur after a hospice has provided hospice services for at least six (6) months.

"Governing body" means a person, persons, or legal entity that is legally responsible for the conduct of the facility as an institution and carries out the functions, ownership, and governance in accordance with these regulations and the laws of this state.

"Initial assessment" means an evaluation of the patient's physical, psychosocial and emotional status related to the terminal illness and related conditions to determine the patient's immediate care and support needs.

"License" means a first-year or permanent hospice license issued pursuant to the Act and these rules.

"Licensed independent practitioner" means any individual permitted by law and by the licensed hospice to provide care and services, without direct supervision, within the scope of the individual's license and consistent with clinical privileges individually granted by the licensed hospice. Licensed independent practitioners may include advanced practice nurses with prescriptive authority, physician assistants, dentists, podiatrists, optometrists, chiropractors, and psychologists.

"Medical Crisis" means an event or situation in which a registered nurse, through direct assessment of the hospice patient, determines that the patient has entered into a period of crisis which requires a physician's intervention and continuous nursing care to achieve palliation or management of acute medical symptoms. Peaceful symptom controlled death is an expected patient outcome and is not considered a medical crisis. A medical crisis would include, but not be limited to the following: uncontrolled terminal agitation as demonstrated by hallucinations, confusion, and combativeness; uncontrolled pain; uncontrolled respiratory distress; uncontrolled nausea and vomiting; hemorrhaging; uncontrolled seizures; family distress as a result of ongoing symptom management for the patient requiring administration of medications to maintain the patient's comfort; and, any uncontrolled symptom that requires the administration of medications with ongoing assessment of the effectiveness and adjustment of the medication regimen to achieve control of symptoms.

"Palliative care" means patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of

illness involves addressing physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice.

"Permanent license" means a license first issued to a hospice program after the first-year license period has been completed and the required follow-up inspection has been conducted.

"Physician designee" means a doctor of medicine or osteopathy designated by the hospice who assumes the same responsibilities and obligations as the medical advisor when the medical advisor is not available.

"Registered nurse" means a person who is currently licensed to practice registered nursing in the State of Oklahoma.

"Representative" or "Court appointed guardian" means a person who is authorized in accordance with State law to execute or revoke an election for hospice care or terminate medical care on behalf of the terminally ill individual.

"Skilled nurse" means a person who is currently licensed to practice registered nursing or practical nursing in the State of Oklahoma.

"Social worker" means a person who has a degree from a school accredited or approved by the Council on Social Work Education and conforms to the requirements of the State Licensure Laws of Oklahoma for Social Workers.

SUBCHAPTER 2. LICENSES

310:661-2-1. Licensure

(a) **Applicant.** Any public or private agency or person desiring to establish a hospice in Oklahoma shall apply for and obtain a license from the Department.

(b) **Application.** An application for a hospice license shall be filed on a form prescribed by the Department and shall be accompanied by the information required by the Act.

(c) **Plan of delivery.** The initial application shall be accompanied by a plan of delivery of home and inpatient hospice services to patients and their families. The plan shall include, but not be limited to, those items listed in the Act.

(d) **Expiration/renewal.**

(1) **First-year license.**

(A) The first-year license shall expire one (1) year from the date of issuance unless suspended or revoked. A hospice holding a first-year license is required to successfully complete an initial inspection by representatives of the Department prior to the provision of services and shall be subject to a follow-up inspection after providing hospice services for at least six (6) months. The Department may require any hospice to renew the first-year license for one additional year. A hospice shall not hold a first-year license for more than twenty-four (24) months.

(B) A follow-up survey that demonstrates compliance with the Act and these rules shall be required prior to a hospice program being issued a permanent license.

(2) **Permanent license.** The permanent license shall expire one

(1) year from the date of issuance, unless suspended or revoked.

An application for renewal shall be submitted according to the Act. Only hospice programs in compliance with the Act and these rules shall be issued a permanent license.

(e) **Base of operation.** Every hospice providing hospice services shall operate from a place of business which is accessible to the public and physically located in Oklahoma. Staff providing services from the hospice shall be supervised by personnel at that location.

(f) **Eligibility for license.**

(1) A hospice making appropriate application that has been determined to be compliant with this Chapter and the Act is eligible for a license.

(2) A hospice may operate alternate administrative offices under one (1) license as long as the following requirements are met:

(A) The offices shall be located within a geographical area with a radius of no more than fifty (50) miles from the main hospice.

(B) The mileage limit used for approval of each administrative office shall be the mileage between town centers of the parent location town and the proposed administrative office location town as reported by the Oklahoma Department of Transportation as approximately the shortest route between town centers utilizing both State Highways System (free) and State Turnpike System (toll) roads.

(C) The offices shall be operated under the same administration and governing body as an extension site for services of the main hospice.

These offices shall operate under the same name(s) as the licensee.

(D) An application for license, or renewal thereof, to establish or operate each hospice alternate administrative office of an agency licensed in the State of Oklahoma shall be accompanied by a nonrefundable licensing fee of five hundred dollars (\$500.00) and application at least thirty (30) days before beginning operations.

(g) **Compliance with Federal, State and local laws and regulations.** The hospice and its staff shall operate and furnish services that comply with all applicable Federal, State, and local laws and rules. The hospice shall ensure that staff comply with applicable State practice acts and rules in the provision of hospice services.

(h) **Hospice inpatient facility.**

(1) Each licensed hospice program may operate one (1) hospice inpatient facility with twelve (12) or fewer inpatient beds as long as the facility complies with hospice inpatient facility service requirements at OAC 310:661-6 and hospice inpatient facility physical plant requirements at OAC 310:661-8.

(2) A hospice inpatient facility may not be independently licensed as a hospice unless the hospice provides a full continuum of hospice program services to patients in their homes

and temporary places of residence including the inpatient hospice facility.

310:661-2-4. Transfer of ownership of a licensed hospice [AMENDED]

(a) The license of a hospice shall not be subject to sale, assignment, or other transfer, voluntary or involuntary.

(b) If an entity is considering acquisition of a licensed hospice, an application for first-year license with an initial application fee of five hundred dollars (\$500.00) and a first-year license fee of one thousand five hundred dollars (\$1500.00) and five hundred dollars (\$500.00) for each alternate administrative office operated by the agency shall be submitted to the Department at least thirty (30) days prior to the effective date of the change. A copy of the executed sales agreement shall be provided to the Department.

(c) The following actions shall not be considered a transfer of ownership or change in control requiring this subsection to apply:

- (1) Change of a corporate or limited liability company licensee's name through amendments of the articles of incorporation or membership agreement.
- (2) Sale of stock of a corporation.
- (3) Sale or merger of a corporation that owns the hospice operating entity.
- (4) Sale of membership interest of a limited liability company.

SUBCHAPTER 3. ADMINISTRATION

310:661-3-2. Organization [AMENDED]

(a) Organization and administration of services.

The hospice shall organize, manage, and administer its resources to provide the hospice care and services to patients, caregivers and families necessary for the palliation and management of the terminal illness and related conditions.

(b) Serving the hospice patient and family. The hospice shall provide hospice care that:

- (1) Optimizes comfort and dignity; and
- (2) Is consistent with patient and family needs and goals, with patient needs and goals as priority.

(c) Continuation of care. A hospice shall not discontinue or reduce care provided because of the inability to pay for that care.

(d) Professional management responsibility. A hospice that has a written agreement with another agency, individual, or organization to furnish any services under arrangement shall retain administrative and financial management, and oversight of staff and services for all arranged services, to ensure the provision of quality care. Arranged services shall be supported by written agreements that require that all services be:

- (1) Authorized by the hospice;
- (2) Furnished in a safe and effective manner by qualified personnel; and
- (3) Delivered in accordance with the patient's plan of care.

(a)(e) **Narrative program.** Each Hospice shall provide a narrative program with its application which describes the functions, staffing, services available to the patient and other basic information relating to the fulfillment of the facility's objectives.

(b)(f) **Governing body.** A hospice shall have a governing body that assumes full legal responsibility for determining, implementing and monitoring policies governing the total operations of the hospice. The governing body shall designate an individual who is responsible for the day-to-day management of the hospice program.

The governing body shall also ensure that all services provided are consistent with accepted standards of practice.

(c)(g) **Hospice team.** A hospice team shall be developed and function according to the Act. The hospice team is responsible for:

- (1) Participation in the establishment of the plan of care.
- (2) Provision or supervision of hospice care and services.
- (3) Periodic review and updating of the plan of care for each individual receiving hospice care.
- (4) Implementation of policies governing the day-to-day provisions of hospice care and services.

(d)(h) **Medical director advisor.** The medical—director advisor shall be a medical doctor or osteopathic physician and shall assume overall responsibility for the medical component of the patient care program for the hospice. The physician shall also serve as medical advisor to the hospice and shall possess a license free of sanctions. The medical advisor shall be a doctor of medicine or osteopathy who is an employee, or be under contract with the hospice. When the medical advisor is not available, a physician designated by the hospice assumes the same responsibilities and obligations as the medical advisor.

(1) **Medical advisor contract.** When contracting for medical advisor services, the contract shall specify the physician who assumes the medical advisor responsibilities and obligations. A hospice may contract with either of the following:

- (A) A self-employed physician; or
- (B) A physician employed by a professional entity or physicians group.

(2) **Initial certification of terminal illness.** The medical advisor or physician designee reviews the clinical information for each hospice patient and provides written certification that it is anticipated that the patient's life expectancy is one (1) year or less if the illness runs its normal course. The physician shall consider the following when making this determination:

- (A) The primary terminal condition;
- (B) Related diagnosis(es), if any;
- (C) Current subjective and objective medical findings;
- (D) Current medication and treatment orders; and
- (E) Information about the medical management of any of the patient's conditions unrelated to the terminal illness.

(3) Medical advisor responsibility. The medical advisor or physician designee has responsibility for the medical component of the hospice's patient care program.

~~(e)~~(i) **Patient care coordinator.** A registered nurse shall be appointed and approved by the hospice governing body and employed by the hospice as patient care coordinator to supervise and coordinate the palliative and supportive care for patients and families provided by a hospice team.

~~(f)~~(j) **Medical social services.** Medical social services shall be provided by a social worker employed by the hospice.

~~(g)~~(k) **Support services.** Support services shall be available to both the individual and the family. These services include bereavement support provided ~~after~~ before the patient's death, spiritual support and any other support or service needed by the patient or family. These services may be provided by members of the interdisciplinary group as well as other qualified professionals as determined by the hospice.

(l) Training.

(1) A hospice shall provide orientation about the hospice philosophy to all employees and contracted staff who have patient and family contact.

(2) A hospice ~~must~~ shall provide an initial orientation for each employee that addresses the employee's specific job duties.

(3) A hospice shall assess the skills and competence of all individuals furnishing care, including volunteers furnishing services, and, as necessary, provide in-service training and education programs where required. The hospice shall have written policies and procedures describing its method(s) of assessment of competency and maintain a written description of the inservice training provided during the previous twelve(12) months.

~~(h)~~(m) **Volunteers.** Volunteers shall be used in defined roles and under the supervision of a designated hospice employee. The hospice shall provide appropriate orientation and training.

(1) Training. The hospice shall maintain, document, and provide volunteer orientation and training.

(2) Role. Volunteers shall be used in day-to-day administrative and/or direct patient care roles.

(3) Recruiting and retaining. The hospice shall document and demonstrate viable and ongoing efforts to recruit and retain volunteers.

(4) Utilization. The hospice shall document

(A) The identification of each position that is occupied by a volunteer.

(B) The work time spent by volunteers occupying those positions.

(n) Criminal background checks.

(1) The hospice shall obtain a criminal background check on all hospice employees who have direct patient contact or access to patient records. Hospice contracts shall require that all contracted entities obtain criminal background checks

on contracted employees who have direct patient contact or access to patient records.

(2) Each such criminal background check shall meet the criteria established for certified nurse aides as provided for in O.S. Title 63 Section 1-1950.1. [The Nursing Home Care Act] shall be obtained in accordance with State requirements.

310:661-3-3.1. Clinical records. [NEW]

(a) **General.** A clinical record containing past and current findings is maintained for each hospice patient. The clinical record shall contain accurate clinical information that is available to the patient's attending physician and hospice staff. The clinical record may be maintained electronically.

(b) **Content.** Each patient's record shall include at least the following:

(1) The initial plan of care, updated plans of care, initial assessment, comprehensive assessment, updated comprehensive assessments, and clinical notes;

(2) Signed copies of the notice of patient rights;

(3) Responses to medications, symptom management, treatments, and services;

(4) Outcome measure data elements, as described in 310:661-5-3.1;

(5) Physician certification of terminal illness;

(6) Any advance directives; and

(7) Physician orders.

(c) **Authentication.** All entries shall be legible, clear, complete, and appropriately authenticated and dated in accordance with hospice policy.

(d) **Protection of information.** The clinical record, its contents and the information contained therein shall be safeguarded against loss or unauthorized use. The hospice shall be in compliance with all Federal and State privacy laws.

(e) **Discharge or transfer of care.**

(1) If the care of a patient is transferred to another licensed hospice, the hospice shall forward to the receiving hospice within twenty-four (24) hours, a copy of:

(A) The hospice discharge summary; and

(B) The patient's clinical record, as requested.

(2) If a patient revokes the election of hospice care, or is discharged from hospice, the hospice shall forward to the patient's attending physician within twenty-four (24) hours, a copy of:

(A) The hospice discharge summary; and

(B) The patient's clinical record, if requested.

(3) The hospice discharge summary as required above shall include:

(A) A summary of the patient's stay including treatments, symptoms and pain management;

(B) The patient's current plan of care;

(C) The patient's current physician orders; and

(D) Any other documentation that will assist in post-discharge continuity of care or that is requested by the attending physician or receiving hospice.

(f) Retrieval of clinical records. The clinical record, whether hard copy or in electronic form, shall be made readily available on request.

SUBCHAPTER 5. MINIMUM STANDARDS

310:661-5-1.1. Admission to hospice care. [NEW]

(a) The hospice admits a patient only on the recommendation of the medical advisor in consultation with, or with input from, the patient's attending physician (if any).

(b) In reaching a decision to certify that the patient is terminally ill, the hospice medical advisor shall consider at least the following information:

- (1) Diagnosis of the terminal condition of the patient;
- (2) Other health conditions, whether related or unrelated to the terminal condition; and
- (3) Current clinically relevant information supporting all diagnoses.

310:661-5-1.2. Discharge from hospice care. [NEW]

(a) Reasons for discharge. A hospice may discharge a patient if:

- (1) The patient moves out of the hospice's service area or transfers to another hospice;
- (2) The hospice determines that the patient is no longer terminally ill; or
- (3) The hospice determines, under a policy set by the hospice for the purpose of addressing discharge for cause that meets the requirements of paragraphs (a)(3)(A) through (a)(3)(D) of this section, that the patient's (or other persons in the patient's home) behavior is disruptive, abusive, or uncooperative to the extent that delivery of care to the patient or the ability of the hospice to operate effectively is seriously impaired. The hospice shall do the following before it seeks to discharge a patient for cause:

- (A) Advise the patient that a discharge for cause is being considered;
- (B) Document efforts to resolve the problem(s) presented by the patient's behavior or situation;
- (C) Ascertain that the patient's proposed discharge is not due to the patient's use of necessary hospice services; and
- (D) Document the problem(s) and efforts made to resolve the problem(s) and enter this documentation into its medical records.

(b) Discharge order. Prior to discharging a patient for any reason listed in paragraph (a) of this section, the hospice must obtain a written physician's discharge order from the hospice medical advisor. If a patient has an attending physician involved in his or her care, this physician shall be consulted before discharge and his or her review and decision included in the discharge note.

(c) Discharge planning.

(1) The hospice shall have in place a discharge planning process that takes into account the prospect that a patient's condition might stabilize or otherwise change such that the patient cannot continue to be certified as terminally ill.

(2) The discharge planning process shall include planning for any necessary family counseling, patient education, or other services before the patient is discharged because he or she is no longer terminally ill.

310:661-5-1.3. Initial and comprehensive assessment of the patient [NEW]

(a) General. The hospice shall conduct and document in writing a patient-specific comprehensive assessment that identifies the patient's need for hospice care and services, and the patient's need for physical, psychosocial, emotional, and spiritual care. This assessment includes all areas of hospice care related to the palliation and management of the terminal illness and related conditions.

(b) Initial assessment. The hospice registered nurse shall complete an initial assessment within forty-eight (48) hours after the physician's order for hospice care is received(unless the physician, patient, or representative requests that the initial assessment be completed in less than 48 hours.)

(c) Timeframe for completion of the comprehensive assessment. The hospice interdisciplinary group, in consultation with the individual's attending physician (if any), shall complete the comprehensive assessment no later than five (5) calendar days after the election of hospice care .

(d) Content of the comprehensive assessment. The comprehensive assessment shall identify the physical, psychosocial, emotional, and spiritual needs related to the terminal illness that shall be addressed in order to promote the hospice patient's well-being, comfort, and dignity throughout the dying process. The comprehensive assessment shall take into consideration the following factors:

(1) The nature and condition causing admission (including the presence or lack of objective data and subjective complaints);

(2) Complications and risk factors that affect care planning;

(3) Functional status, including the patient's ability to understand and participate in his or her own care;

(4) Imminence of death;

(5) Severity of symptoms;

(6) A review of all of the patient's prescription and over-the-counter drugs, herbal remedies and other alternative treatments that could affect drug therapy. This includes, but is not limited to, identification of the following:

(A) Effectiveness of drug therapy;

(B) Drug side effects;

(C) Actual or potential drug interactions;

(D) Duplicate drug therapy; and

(E) Drug therapy currently associated with laboratory monitoring.

(7) An initial bereavement assessment of the needs of the patient's family and other individuals focusing on the social, spiritual, and cultural factors that may impact their ability to cope with the patient's death. Information gathered from the initial bereavement assessment shall be incorporated into the plan of care and considered in the bereavement plan of care; and

(8) The need for referrals and further evaluation by appropriate health professionals.

(e) Update of the comprehensive assessment.

The update of the comprehensive assessment shall be accomplished by the hospice interdisciplinary group (in collaboration with the individual's attending physician, if any) and shall consider changes that have taken place since the initial assessment. It shall include information on the patient's progress toward desired outcomes, as well as a reassessment of the patient's response to care. The assessment update shall be accomplished as frequently as the condition of the patient requires, but no less frequently than every fifteen(15) days.

(f) Patient outcome measures.

(1) The comprehensive assessment shall include data elements that allow for measurement of outcomes. The hospice shall measure and document data in the same way for all patients. The data elements shall take into consideration aspects of care related to hospice and palliation.

(2) The data elements shall be an integral part of the comprehensive assessment and shall be documented in a systematic and retrievable way for each patient. The data elements for each patient shall be used in individual patient care planning and in the coordination of services, and shall be used in the aggregate for the hospice's quality assessment and performance improvement program.

310:661-5-2. Plan of care [AMENDED]

(a) A written plan of care shall be established and maintained for each patient admitted to a hospice program and the care provided to an individual shall be in accordance with the plan.

(b) The plan shall be established by the attending physician, the medical advisor, and the interdisciplinary group.

(c) The plan of care shall be reviewed and updated by the hospice team at intervals specified in the plan. These reviews shall be documented by the team members.

(d) The content of the plan shall include an assessment of the patient's needs and identify the services provided. The plan shall state in detail the scope and frequency of services needed to meet the patient's and family's needs.

(e) Continuous care shall be provided under a plan of care that shall be developed specifically to resolve the patient's medical crisis. These plans shall include:

- (1) Caregiver education;
- (2) Anticipated duration of the continuous care;
- (3) Necessity of continuous care;
- (4) Interventions required;

- (5) Identification of interdisciplinary team members developing the plan; and,
- (6) Physician orders for continuous care.

310: 661-5-2.1. Interdisciplinary group, care planning, and coordination of services. [NEW]

(a) General. The hospice shall designate an interdisciplinary group or groups which, in consultation with the patient's attending physician, shall prepare a written plan of care for each patient. The plan of care shall specify the hospice care and services necessary to meet the patient and family-specific needs identified in the comprehensive assessment as such needs relate to the terminal illness and related conditions.

(b) Approach to service delivery.

(1) The hospice shall designate in writing an interdisciplinary group or groups composed of individuals who work together to meet the physical, medical, psychosocial, emotional, and spiritual needs of the hospice patients and families facing terminal illness and bereavement. Interdisciplinary group members shall provide the care and services offered by the hospice, and the group, in its entirety, shall supervise the care and services. The hospice shall designate a registered nurse that is a member of the interdisciplinary group to provide coordination of care and to ensure continuous assessment of each patient's and family's needs and implementation of the interdisciplinary plan of care. The interdisciplinary group shall include, but is not limited to, individuals who are qualified and competent to practice in the following professional roles:

(A) A doctor of medicine or osteopathy (who is an employee or under contract with the hospice);

(B) A registered nurse;

(C) A social worker; and

(D) A pastoral or other counselor.

(2) If the hospice has more than one interdisciplinary group, it shall identify a specifically designated interdisciplinary group to establish policies governing the day-to-day provision of hospice care and services.

(c) Plan of care. All hospice care and services furnished to patients and their families shall follow an individualized written plan of care established by the hospice interdisciplinary group in collaboration with the attending physician (if any), the patient or representative, and the primary caregiver in accordance with the patient's needs. The hospice shall ensure that each patient and the primary care giver(s) receive education and training provided by the hospice as appropriate to their responsibilities for the care and services identified in the plan of care.

(d) Content of the plan of care. The hospice shall develop an individualized written plan of care for each patient. The plan of care shall reflect patient and family goals and interventions based on the problems identified in the initial, comprehensive, and updated comprehensive assessments. The plan of

care shall include all services necessary for the palliation and management of the terminal illness and related conditions, including at least the following:

- (1) Interventions to manage pain and symptoms;
- (2) A detailed statement of the scope and frequency of services necessary to meet the specific patient and family needs;
- (3) Measurable outcomes anticipated from implementing and coordinating the plan of care;
- (4) Drugs and treatment necessary to meet the needs of the patient;
- (5) Medical supplies and appliances necessary to meet the needs of the patient; and
- (6) The interdisciplinary group's documentation of the patient's or representative's level of understanding, involvement, and agreement with the plan of care, in accordance with the hospice's own policies, in the clinical record.

(e) **Review of the plan of care.** The hospice interdisciplinary group (in collaboration with the individual's attending physician, if any) shall review, revise and document the individualized plan as frequently as the patient's condition requires, but no less frequently than every fifteen (15) calendar days. A revised plan of care shall include information from the patient's updated comprehensive assessment and shall note the patient's progress toward outcomes and goals specified in the plan of care.

(f) **Coordination of services.** The hospice shall develop and maintain a system of communication and integration, in accordance with the hospice's own policies and procedures, to:

- (1) Ensure that the interdisciplinary group maintains responsibility for directing, coordinating, and supervising the care and services provided;
- (2) Ensure that the care and services are provided in accordance with the plan of care;
- (3) Ensure that the care and services provided are based on all assessments of the patient and family needs;
- (4) Provide for and ensure the ongoing sharing of information between all disciplines providing care and services in all settings, whether the care and services are provided directly or under arrangement; and
- (5) Provide for an ongoing sharing of information with other non-hospice healthcare providers furnishing services unrelated to the terminal illness and related conditions.

310:661-5-2.2. Core Services [NEW]

(a) **General.** A hospice shall provide substantially all core services directly by hospice trained and oriented employees. These services include nursing services, medical social services, and bereavement and spiritual counseling. The hospice may contract for physician services.

(b) **Physician services.** The hospice medical advisor, physician employees, and contracted physician(s) of the hospice, in

conjunction with the patient's attending physician, are responsible for the palliation and management of the terminal illness and conditions related to the terminal illness.

(1) All physician employees and those under contract, shall function under the supervision of the hospice medical advisor.

(2) All physician employees and those under contract shall meet this requirement by either providing the services directly or through coordinating patient care with the attending physician.

(3) If the attending physician is unavailable, the medical advisor, contracted physician, and/or hospice physician employee is responsible for meeting the medical needs of the patient.

c) Nursing services.

(1) The hospice shall provide nursing care by licensed nurses under the supervision of a registered nurse. Nursing services shall ensure that the nursing needs of the patient are met as identified in the patient's initial assessment, comprehensive assessment, and updated assessments.

(2) If State law permits registered nurses to see, treat, and write orders for patients, then registered nurses may provide services to patients receiving hospice care.

(3) Highly specialized nursing services that are provided so infrequently that the provision of such services by direct hospice employees would be impracticable and prohibitively expensive, may be provided under contract.

(d) Medical social services. Medical social services shall be provided by a qualified social worker, under the direction of a physician. Social work services shall be based on the patient's psychosocial assessment and the patient's and family's needs and acceptance of these services.

(e) Counseling services. Counseling services shall be available to the patient and family to assist the patient and family in minimizing the stress and problems that arise from the terminal illness, related conditions, and the dying process. Counseling services shall include, but are not limited to, the following:

(1) Bereavement counseling. The hospice shall:

(A) Have an organized program for the provision of bereavement services furnished under the supervision of a qualified professional with experience or education in grief or loss counseling;

(B) Make bereavement services available to the family and other individuals in the bereavement plan of care up to one (1) year following the death of the patient. Bereavement counseling also extends to residents of a care facility when appropriate and identified in the bereavement plan of care;

(C) Ensure that bereavement services reflect the needs of the bereaved; and

(D) Develop a bereavement plan of care that notes the kind of bereavement services to be offered and the frequency of service delivery.

(2) Dietary counseling. Dietary counseling, when identified in the plan of care, shall be performed by a qualified

individual, which include dietitians as well as nurses and other individuals who are able to address and assure that the dietary needs of the patient are met.

(3) **Spiritual counseling.** The hospice shall:

(A) Provide an assessment of the patient's and family's spiritual needs;

(B) Provide spiritual counseling to meet these needs in accordance with the patient's and family's acceptance of this service, and in a manner consistent with patient and family beliefs and desires;

(C) Make all reasonable efforts to facilitate visits by local clergy, pastoral counselors, or other individuals who can support the patient's spiritual needs to the best of its ability; and

(D) Advise the patient and family of this service.

310:661-5-2.3. Physical therapy, occupational therapy, speech-language pathology. [NEW]

Physical therapy services, occupational therapy services, and speech-language pathology services shall be available.

310:661-5-2.4. Licensed Professional Services [NEW]

(a) Licensed professional services provided directly or under arrangement shall be authorized, delivered, and supervised only by health care professionals who meet the appropriate qualifications specified by the State and who practice under the hospice's policies and procedures.

(b) Licensed professionals shall actively participate in the coordination of all aspects of the patient's hospice care, in accordance with current professional standards and practice, including participating in ongoing interdisciplinary comprehensive assessments, developing and evaluating the plan of care, and contributing to patient and family counseling and education.

(c) Licensed professionals shall participate in the hospice's quality assessment and performance improvement program and hospice sponsored in-service training.

310:661-5-3.1. Quality Assessment/Performance Improvement [NEW]

(a) The hospice shall develop, implement, and maintain an effective, ongoing, hospice-wide data-driven quality assessment and performance improvement program. The hospice's governing body shall ensure that the program: Reflects the complexity of its organization and services; involves all hospice services (including those services furnished under contract or arrangement); focuses on indicators related to improved palliative outcomes; and takes actions to demonstrate improvement in hospice performance. The hospice shall maintain documentary evidence of its quality assessment and performance improvement program and be able to demonstrate its operation to the Department of Health.

(b) **Program scope.**

(1) The program shall at least be capable of showing measurable improvement in indicators related to improved palliative outcomes and hospice services.

(2) The hospice shall measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that enable the hospice to assess processes of care, hospice services, and operations.

(c) Program data.

(1) The program shall use quality indicator data, including patient care, and other relevant data, in the design of its program.

(2) The hospice shall use the data collected to do the following:

(A) Monitor the effectiveness and safety of services and quality of care; and

(B) Identify opportunities and priorities for improvement.

(3) The frequency and detail of the data collection shall be approved by the hospice's governing body.

(d) Program activities.

(1) The hospice's performance improvement activities shall:

(A) Focus on high risk, high volume, or problem-prone areas;

(B) Consider incidence, prevalence, and severity of problems in those areas; and

(C) Affect palliative outcomes, patient safety, and quality of care.

(2) Performance improvement activities shall track adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospice.

(3) The hospice shall take actions aimed at performance improvement and, after implementing those actions, the hospice shall measure its success and track performance to ensure that improvements are sustained.

(e) Performance improvement projects. Hospices shall develop, implement, and evaluate performance improvement projects.

(1) The number and scope of distinct performance improvement projects conducted annually, based on the needs of the hospice's population and internal organizational needs, shall reflect the scope, complexity, and past performance of the hospice's services and operations.

(2) The hospice shall document what performance improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.

(f) Executive responsibilities. The hospice's governing body is responsible for ensuring the following:

(1) That an ongoing program for quality improvement and patient safety is defined, implemented, and maintained, and is evaluated annually;

(2) That the hospice-wide quality assessment and performance improvement efforts address priorities for improved quality of

care and patient safety, and that all improvement actions are evaluated for effectiveness; and
(3) That one or more individual(s) who are responsible for operating the quality assessment and performance improvement program are designated.

310:661-5-4.1. Additional rights of the patient [NEW]

(a) **General.** The patient has the right to be informed of his or her rights, and the hospice shall protect and promote the exercise of these rights.

(b) **Notice of rights and responsibilities.**

(1) During the initial assessment visit in advance of furnishing care the hospice shall provide the patient or representative with verbal (meaning spoken) and written notice of the patient's rights and responsibilities in a language and manner that the patient understands.

(2) The hospice shall inform and distribute written information to the patient concerning its policies on advance directives, including a description of applicable State law.

(3) The hospice shall obtain the patient's or representative's signature confirming that he or she has received a copy of the notice of rights and responsibilities.

(c) **Exercise of rights and respect for property and person.**

(1) The patient has the right:

(A) To exercise his or her rights as a patient of the hospice;

(B) To have his or her property and person treated with respect;

(C) To voice grievances regarding treatment or care that is (or fails to be) furnished and the lack of respect for property by anyone who is furnishing services on behalf of the hospice; and

(D) To not be subjected to discrimination or reprisal for exercising his or her rights.

(2) If a patient has been adjudged incompetent under state law by a court of proper jurisdiction, the rights of the patient are exercised by the person appointed pursuant to state law to act on the patient's behalf.

(3) If a state court has not adjudged a patient incompetent, any legal representative designated by the patient in accordance with state law may exercise the patient's rights to the extent allowed by state law.

(4) The hospice shall:

(A) Ensure that all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property by anyone furnishing services on behalf of the hospice, are reported immediately by hospice employees and contracted staff to the hospice administrator;

(B) Immediately investigate all alleged violations involving anyone furnishing services on behalf of the hospice and immediately take action to prevent further potential

violations while the alleged violation is being verified. Investigations and/or documentation of all alleged violations shall be conducted in accordance with established procedures;

(C) Take appropriate corrective action in accordance with state law if the alleged violation is verified by the hospice administration or an outside body having jurisdiction, such as the State survey agency or local law enforcement agency; and

(D) Ensure that verified violations are reported to State and local bodies having jurisdiction (including to the State survey and certification agency) within 5 working days of becoming aware of the violation.

(d) **Rights of the patient.** The patient has a right to the following:

(1) Receive effective pain management and symptom control from the hospice for conditions related to the terminal illness;

(2) Be involved in developing his or her hospice plan of care;

(3) Refuse care or treatment;

(4) Choose his or her attending physician;

(5) Have a confidential clinical record. Access to or release of patient information and clinical records is permitted in accordance with State and Federal law.

(6) Be free from mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property;

(7) Receive information about the services covered under the hospice benefit; and

(8) Receive information about the scope of services that the hospice will provide and specific limitations on those services.

310:661-5-6. Infection Control [NEW]

(a) **General.** The hospice shall maintain and document an effective infection control program that protects patients, families, visitors, and hospice personnel by preventing and controlling infections and communicable diseases.

(b) **Prevention.** The hospice shall follow accepted standards of practice to prevent the transmission of infections and communicable diseases, including the use of standard precautions.

(c) **Control.** The hospice shall maintain a coordinated agency-wide program for the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases that:

(1) Is an integral part of the hospice's quality assessment and performance improvement program; and

(2) Includes the following:

(A) A method of identifying infectious and communicable disease problems; and

(B) A plan for implementing the appropriate actions that are expected to result in improvement and disease prevention.

(d) **Education.** The hospice shall provide infection control education to employees, contracted providers, patients, and family members and other caregivers.

310:661-5-7. Supervision of hospice aides. [NEW]

(a) A registered nurse shall make an on-site visit to the patient's home:

(1) No less frequently than every fourteen (14) calendar days to assess the quality of care and services provided by the hospice aide and to ensure that services ordered by the hospice interdisciplinary group meet the patient's needs. The hospice aide does not have to be present during this visit.

(2) If an area of concern is noted by the supervising nurse, then the hospice shall make an on-site visit to the location where the patient is receiving care in order to observe and assess the aide while he or she is performing care.

(3) If an area of concern is verified by the hospice during the on-site visit, then the hospice shall conduct, and the hospice aide shall complete a competency evaluation.

(b) A registered nurse shall make an annual on-site visit to the location where a patient is receiving care in order to observe and assess each aide while he or she is performing care.

(c) The supervising nurse shall assess an aide's ability to demonstrate initial and continued satisfactory performance in meeting outcome criteria that include, but is not limited to:

(1) Following the patient's plan of care for completion of tasks assigned to the hospice aide by the registered nurse;

(2) Creating successful interpersonal relationships with the patient and family;

(3) Demonstrating competency with assigned tasks;

(4) Complying with infection control policies and procedures;
and

(5) Reporting changes in the patient's condition.

310:661-5-8. Drugs and Biologicals, Medical Supplies, Durable Medical Equipment. [NEW]

(a) **General.** Medical supplies and appliances; durable medical equipment; and drugs and biologicals related to the palliation and management of the terminal illness and related conditions, as identified in the hospice plan of care, shall be provided by the hospice while the patient is under hospice care.

(b) **Managing drugs and biologicals.**

(1) The hospice shall ensure that the interdisciplinary group confers with an individual with education and training in drug management as defined in hospice policies and procedures and State law, who is an employee of or under contract with the hospice to ensure that drugs and biologicals meet each patient's needs.

(2) A hospice that provides inpatient care directly in its own facility shall provide pharmacy services under the direction of a qualified licensed pharmacist who is an employee of or under contract with the hospice. The provided pharmacist services shall include evaluation of a patient's response to

medication therapy, identification of potential adverse drug reactions, and recommended appropriate corrective action.

(c) Ordering of drugs.

(1) Only a licensed independent practitioner with prescriptive authority, in accordance with the plan of care and State law, may order drugs for the patient.

(2) If the drug order is verbal or given by or through electronic transmission:

(A) It shall be given only to a licensed health care practitioners within their scope of practice under state law and authorized by hospice policy to receive verbal orders; and

(B) The individual receiving the order shall record and sign it immediately and have the prescribing person sign it in accordance with State and Federal regulations.

(d) Dispensing of drugs and biologicals. The hospice shall obtain drugs and biologicals from community or institutional pharmacists or stock drugs and biologicals itself.

(e) Administration of drugs and biologicals. The interdisciplinary group, as part of the review of the plan of care, shall determine the ability of the patient and/or family to safely self-administer drugs and biologicals to the patient in his or her home.

(f) Labeling, disposing, and storing of drugs and biologicals.

(1) Labeling. Drugs and biologicals shall be labeled in accordance with currently accepted professional practice and shall include appropriate usage and cautionary instructions, as well as an expiration date (if applicable).

(2) Disposing. The hospice shall have written policies and procedures for the management and disposal of controlled drugs in the patient's home. At the time when controlled drugs are first ordered the hospice shall:

(A) Provide a copy of the hospice written policies and procedures on the management and disposal of controlled drugs to the patient or patient representative and family;

(B) Discuss the hospice policies and procedures for managing the safe use and disposal of controlled drugs with the patient or representative and the family in a language and manner that they understand to ensure that these parties are educated regarding the safe use and disposal of controlled drugs; and

(C) Document in the patient's clinical record that the written policies and procedures for managing controlled drugs was provided and discussed.

(g) Use and maintenance of equipment and supplies.

(1) The hospice shall ensure that manufacturer recommendations for performing routine and preventive maintenance on durable medical equipment are followed. The equipment shall be safe and work as intended for use in the patient's environment. Where a manufacturer recommendation for a piece of equipment does not exist, the hospice shall ensure that repair and routine maintenance policies are developed. The hospice may

use persons under contract to ensure the maintenance and repair of durable medical equipment.

(2) The hospice shall ensure that the patient, where appropriate, as well as the family and/or other caregiver(s), receive instruction in the safe use of durable medical equipment and supplies. The hospice may use persons under contract to ensure patient and family instruction. The patient, family, and/or caregiver shall be able to demonstrate the appropriate use of durable medical equipment to the satisfaction of the hospice staff.

310:661-5-9. Short-term inpatient care. [NEW]

(a) Inpatient care shall be available for pain control, symptom management, and respite purposes.

(b) If the hospice has an arrangement with another facility to provide for short-term inpatient care, the arrangement is described in a written agreement, coordinated by the hospice, and at a minimum specifies:

(1) That the hospice supplies the inpatient provider a copy of the patient's plan of care and specifies the inpatient services to be furnished;

(2) That the inpatient provider has established patient care policies consistent with those of the hospice and agrees to abide by the palliative care protocols and plan of care established by the hospice for its patients;

(3) That the hospice patient's inpatient clinical record includes a record of all inpatient services furnished and events regarding care that occurred at the facility; that a copy of the discharge summary be provided to the hospice at the time of discharge; and that a copy of the inpatient clinical record is available to the hospice at the time of discharge;

(4) That the inpatient facility has identified an individual within the facility who is responsible for the implementation of the provisions of the agreement; and

(5) That the hospice retains responsibility for ensuring that the training of personnel who will be providing the patient's care in the inpatient facility has been provided and that a description of the training and the names of those giving the training are documented.

SUBCHAPTER 6. HOSPICE INPATIENT SERVICE REQUIREMENTS

310:661-6-7. Pharmaceutical services [AMENDED]

(a) The hospice inpatient facility shall provide appropriate methods and procedures for dispensing and administering drugs and biologicals. Whether drugs and biologicals are obtained from community or institutional pharmacies or maintained and stocked by the facility, the facility shall be responsible for the pharmaceutical services and ensure services are provided in accordance with accepted professional standards of practice in compliance with Federal, State, and local laws.

(b) Each facility shall employ or contract with a licensed pharmacist to supervise services and ensure drugs and biologicals

are obtained, stored, administered and disposed of as required by Federal and State law.

(c) A physician or licensed independent practitioner shall order all medications for each patient. If the physician or practitioner's order is verbal, the physician or practitioner shall give the order to a licensed nurse or other individual authorized by State law to receive the order. The individual receiving the order shall record and sign the order immediately and have the prescribing physician or practitioner sign as soon as possible in a manner consistent with good medical practice. Another covering or attending physician or practitioner may sign another physician or practitioner's verbal order if the facility allows this practice and specific procedures are approved by the governing body to permit the practice. If a covering or attending physician or practitioner authenticates the ordering physician or practitioner's verbal order, such an authentication indicates that the covering or attending physician or practitioner assumes responsibility for his or her colleague's order and verifies the order is complete, accurate, appropriate, and final.

(d) Drugs and biologicals shall be administered only by a physician, licensed nurse, an individual authorized by State law to administer, or the patient if his or her attending physician has approved.

(e) The pharmaceutical service shall have procedures for control and accountability of all drugs and biologicals in the facility. Drugs are dispensed in compliance with Federal and State law. Records of receipt and disposition of all controlled drugs are maintained in sufficient detail to enable an accurate reconciliation. The pharmacist shall ensure the drug records are in order and that an account of all controlled drugs is maintained and reconciled.

(f) The labeling of drugs and biologicals is based on currently accepted professional principles in compliance with State law, and includes the appropriate accessory and cautionary instructions, as well as the expiration date and lot number when applicable.

(g) All drugs and biologicals shall be stored in locked compartments under proper temperature controls. Only authorized personnel shall have access. Separately locked compartments shall be provided for storage of Schedule II controlled drugs. All stores of Schedule II drugs not individually dispensed to a patient shall be accounted for at regular intervals to ensure the drugs are not diverted.

(h) If the facility only maintains drugs and biologicals by individual patient prescription, an emergency medication kit approved by the ~~Medical-director~~ Medical advisor shall also be maintained.

(i) Controlled drugs no longer needed by the patient shall be disposed of in compliance with Federal and State requirements. The pharmacist and a facility registered nurse or two (2) facility registered nurses shall document disposal and maintain a record.