

PART 418--HOSPICE CARE

1. The authority citation for part 418 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Provision and Definitions

2. Section 418.2 is revised to read as follows:

§418.2 Scope of the part.

This part establishes requirements and the conditions of participation that hospices must meet, and be in compliance with, in order to participate in the Medicare program. Subpart A of this part sets forth the statutory basis and scope and defines terms used in this part. Subpart B of this part specifies the eligibility requirements and the benefit periods. Subpart C of this part specifies the conditions of participation that hospice providers must meet regarding patient and family care. Subpart D of this part specifies the organizational environment that hospice providers must meet as conditions of participation. Subpart E is reserved for future use. Subpart F specifies coinsurance amounts applicable to hospice care.

3. Section 418.3 is amended by:

§418.3 Definitions.

For the purposes of this part—

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 a thorough evaluation of the patient's physical, psychosocial, emotional and spiritual status related to the terminal illness and related conditions. This includes a thorough evaluation of the caregiver's and family's willingness and capability to care for the patient.

Dietary counseling means 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.

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; or (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.

Hospice means a public agency or private organization or subdivision of either of these that is primarily engaged in providing hospice care as defined in this section.

Hospice care means a comprehensive set of services described in 1861(dd)(1) of the Act, identified and coordinated by an interdisciplinary group to provide for the physical, psychosocial, spiritual, and emotional needs of a terminally ill patient and/or family members, as delineated in a specific patient plan of care.

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.

Licensed professional means a person licensed to provide patient care services by the State in which services are delivered.

Multiple location means a Medicare-approved location from which the hospice provides the same full range of hospice care and services that is required of the hospice issued the certification number. A multiple location must meet all of the conditions of participation applicable to hospices.

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.

Physician means an individual who meets the qualifications and conditions as defined in section 1861(r) of the Act and implemented at §410.20 of this chapter.

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

Representative means an individual who has the authority under State law (whether by statute or pursuant to an appointment by the courts of the State) to authorize or terminate medical care or to elect or revoke the election of hospice care on behalf of a terminally ill patient who is mentally or physically incapacitated. This may include a legal guardian.

Restraint means—

(1) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely, not including devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort); or

(2) A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.

Seclusion means the involuntary confinement of a patient alone in a room or an area from which the patient is physically prevented from leaving.

Terminally ill means that the individual has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course.

4. Subparts C and D are revised and Subpart E is removed and reserved to read as follows:

Subpart C—Conditions of Participation: Patient Care

Sec.

- 418.52 Condition of participation: Patient's rights.
- 418.54 Condition of participation: Initial and comprehensive assessment of the patient.
- 418.56 Condition of participation: Interdisciplinary group, care planning, and coordination of services.
- 418.58 Condition of participation: Quality assessment and performance improvement.
- 418.60 Condition of participation: Infection control.
- 418.62 Condition of participation: Licensed professional services.

Core Services

- 418.64 Condition of participation: Core services.
- 418.66 Condition of participation: Nursing services waiver of requirement that substantially all nursing services be routinely provided directly by a hospice.

Non-Core Services

- 418.70 Condition of participation: Furnishing of non-core services.
- 418.72 Condition of participation: Physical therapy, occupational therapy, and speech-language pathology.
- 418.74 Waiver of requirement-Physical therapy, occupational therapy, speech-language pathology and dietary counseling.
- 418.76 Condition of participation: Hospice aide and homemaker services.
- 418.78 Condition of participation: Volunteers.

Subpart D—Conditions of Participation: Organizational Environment

- 418.100 Condition of participation: Organization and administration of services.
- 418.102 Condition of participation: Medical director.
- 418.104 Conditions of participation: Clinical records.
- 418.106 Condition of participation: Drugs and biologicals, medical supplies, and durable medical equipment.
- 418.108 Condition of participation: Short-term inpatient care.
- 418.110 Condition of participation: Hospices that provide inpatient care directly.
- 418.112 Condition of participation: Hospices that provide hospice care to residents of a SNF/NF or ICF/MR.
- 418.114 Condition of participation: Personnel qualifications.
- 418.116 Condition of participation: Compliance with Federal, State, and local laws and regulations related to the health and safety of patients.

Subpart E [Removed and Reserved]

Subpart C—Conditions of Participation: Patient Care

§418.52 Condition of participation: Patient's rights.

The patient has the right to be informed of his or her rights, and the hospice must protect and promote the exercise of these rights.

(a) Standard: Notice of rights and responsibilities

(1) During the initial assessment visit in advance of furnishing care the hospice must 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 must comply with the requirements of subpart I of part 489 of this chapter regarding advance directives. The hospice must inform and distribute written information to the patient concerning its policies on advance directives, including a description of applicable state law.

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

(b) Standard: Exercise of rights and respect for property and person.

(l) The patient has the right:

- (i) To exercise his or her rights as a patient of the hospice;
- (ii) To have his or her property and person treated with respect;
- (iii) 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
- (iv) 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 must:

- i. 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;
- ii. 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 must be conducted in accordance with established procedures;
- iii. 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
- iv. Ensure that verified violations are reported to State and local bodies having jurisdiction (including to the State survey and certification agency) within 5 days of becoming aware of the violation.

(c) Standard: 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 45 CFR parts 160 and 164.
- (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;
- (8) Receive information about the scope of services that the hospice will provide and specific limitations on those services.

§418.54 Condition of participation: Initial and comprehensive assessment of the patient.

The hospice must 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.

(a) Standard: Initial assessment.

The hospice registered nurse must complete an initial assessment within 48 hours after the election of hospice care in accordance with §418.24 is complete (unless the physician, patient, or representative requests that the initial assessment be completed in less than 48 hours.)

(b) Standard: Time frame for completion of the comprehensive assessment.

The hospice interdisciplinary group, in consultation with the individual's attending physician (if any), must complete the comprehensive assessment no later than 5 calendar days after the election of hospice care in accordance with §418.24.

(c) Standard: Content of the comprehensive assessment.

The comprehensive assessment must identify the physical, psychosocial, emotional, and spiritual needs related to the terminal illness that must be addressed in order to promote the hospice patient's well-being, comfort, and dignity throughout the dying process. The comprehensive assessment must 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) Drug profile. 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:
 - i. Effectiveness of drug therapy.
 - ii. Drug side effects.
 - iii. Actual or potential drug interactions.
 - iv. Duplicate drug therapy.
 - v. Drug therapy currently associated with laboratory monitoring.
- 7) Bereavement. 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 must be incorporated into the plan of care and considered in the bereavement plan of care.
- 8) The need for referrals and further evaluation by appropriate health professionals.

(d) Standard: Update of the comprehensive assessment.

The update of the comprehensive assessment must be accomplished by the hospice interdisciplinary group (in collaboration with the individual's attending physician, if any) and must consider changes that have taken place since the initial assessment. It must 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 must be accomplished as frequently as the condition of the patient requires, but no less frequently than every 15 days.

(e) Standard: Patient outcome measures.

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

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

§418.56 Condition of participation: Interdisciplinary group, care planning, and coordination of services.

The hospice must designate an interdisciplinary group or groups as specified in paragraph (a) of this section which, in consultation with the patient's attending physician, must prepare a written plan of care for each patient. The plan of care must 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.

(a) Standard: Approach to service delivery.

(1) The hospice must designate 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 must provide the care and services offered by the hospice, and the group, in its entirety, must supervise the care and services. The hospice must 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 must include, but is not limited to, individuals who are qualified and competent to practice in the following professional roles:

- i. A doctor of medicine or osteopathy (who is an employee or under contract with the hospice)
- ii. A registered nurse
- iii. A social worker
- iv. A pastoral or other counselor

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

(b) Standard: Plan of care.

All hospice care and services furnished to patients and their families must 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 if any of them so desire. The hospice must 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.

(c) Standard: Content of the plan of care

The hospice must develop an individualized written plan of care for each patient. The plan of care must reflect patient and family goals and interventions based on the problems identified in the initial, comprehensive, and updated comprehensive assessments. The plan of care must include all services necessary for the palliation and management of the terminal illness and related conditions, including 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.
- (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.

(d) Standard: Review of the plan of care.

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

(e) Standard: Coordination of services.

The hospice must 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.
- (5) Provide for an ongoing sharing of information with other non-hospice healthcare providers furnishing services unrelated to the terminal illness and related conditions.

§418.58 Condition of participation: Quality assessment and performance improvement.

The hospice must develop, implement, and maintain an effective, ongoing, hospice-wide data-driven quality assessment and performance improvement program. The hospice's governing body must 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 must maintain documentary evidence of its quality assessment and performance improvement program and be able to demonstrate its operation to CMS.

(a) Standard: Program scope.

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

(b) Standard: Program data

- (1) The program must use quality indicator data, including patient care, and other relevant data, in the design of its program.
- (2) The hospice must use the data collected to do the following:
 - (i) Monitor the effectiveness and safety of services and quality of care.
 - (ii) Identify opportunities and priorities for improvement.

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

(c) Standard: Program activities.

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

- (i) Focus on high risk, high volume, or problem-prone areas.
- (ii) Consider incidence, prevalence, and severity of problems in those areas.
- (iii) Affect palliative outcomes, patient safety, and quality of care.

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

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

(d) Standard: Performance improvement projects.

Beginning **[OFR--INSERT 240 days AFTER THE PUBLICATION DATE OF THIS FINAL RULE]** hospices must 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, must reflect the scope, complexity, and past performance of the hospice's services and operations.

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

(e) Standard: 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.

(3) That one or more individual(s) who are responsible for operating the quality assessment and performance improvement program are designated.

§418.60 Condition of participation: Infection control.

The hospice must maintain and document an effective infection control program that protects patients, families, visitors, and hospice personnel by preventing and controlling infections and communicable diseases.

(a) Standard: Prevention.

The hospice must follow accepted standards of practice to prevent the transmission of infections and communicable diseases, including the use of standard precautions.

(b) Standard: Control.

The hospice must 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:

- (i) A method of identifying infectious and communicable disease problems; and
- (ii) A plan for implementing the appropriate actions that are expected to result in improvement and disease prevention.

(c) Standard: Education.

The hospice must provide infection control education to employees, contracted providers, patients, and family members and other caregivers.

§418.62 Condition of participation: Licensed professional services

(a) Licensed professional services provided directly or under arrangement must be authorized, delivered, and supervised only by health care professionals who meet the appropriate qualifications specified under §418.114 and who practice under the hospice's policies and procedures.

(b) Licensed professionals must 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; and

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

§418.64 Condition of participation: Core services.

A hospice must routinely provide substantially all core services directly by hospice employees. These services must be provided in a manner consistent with acceptable standards of practice. These services include nursing services, medical social services, and counseling. The hospice may contract for physician services as specified in paragraph (a) of this section. A hospice may use contracted staff, if necessary, to supplement hospice employees in order to meet the needs of patients under extraordinary or other non-routine circumstances. A hospice may also enter into a written arrangement with another Medicare certified hospice program for the provision of core services to supplement hospice employee/staff to meet the needs of patients. Circumstances under which a hospice may enter into a written arrangement for the provision of core services include: unanticipated periods of high patient loads, staffing shortages due to illness or other short-term temporary situations that interrupt patient care; and temporary travel of a patient outside of the hospice's service area.

(a) Standard: Physician services.

The hospice medical director, 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, must function under the supervision of the hospice medical director.

(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 director, contracted physician, and/or hospice physician employee is responsible for meeting the medical needs of the patient.

(b) Standard: Nursing services.

(1) The hospice must provide nursing care and services by or under the supervision of a registered nurse. Nursing services must 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 beneficiaries 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.

(c) Standard: Medical social services.

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

(d) Standard: Counseling services.

Counseling services must 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 must include, but are not limited to, the following:

(1) *Bereavement counseling.* The hospice must:

- (i) 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.
- (ii) Make bereavement services available to the family and other individuals in the bereavement plan of care up to 1 year following the death of the patient. Bereavement counseling also extends to residents of a SNF/NF or ICF/MR when appropriate and identified in the bereavement plan of care.
- (iii) Ensure that bereavement services reflect the needs of the bereaved.
- (iv) Develop a bereavement plan of care that notes the kind of bereavement services to be offered and the frequency of service delivery. A special coverage provision for bereavement counseling is specified in §418.204(c).

(2) *Dietary counseling.* Dietary counseling, when identified in the plan of care, must 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 must:

- (i) Provide an assessment of the patient's and family's spiritual needs.
- (ii) 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.
- (iii) 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.
- (iv) Advise the patient and family of this service.

§418.66 Condition of participation: Nursing services – Waiver of requirement that substantially all nursing services be routinely provide directly by a hospice.

(a) CMS may waive the requirement in §418.64(b) that a hospice provide nursing services directly, if the hospice is located in a non-urbanized area. The location of a hospice that operates in several areas is considered to be the location of its central office. The hospice must provide evidence to CMS that it has made a good faith effort to hire a sufficient number of nurses to provide services. CMS may waive the requirement that nursing services be furnished by employees based on the following criteria:

(1) The location of the hospice's central office is in a non-urbanized area as determined by the Bureau of the Census.

(2) There is evidence that a hospice was operational on or before January 1, 1983 including the following:

- (i) Proof that the organization was established to provide hospice services on or before January 1, 1983.
- (ii) Evidence that hospice-type services were furnished to patients on or before January 1, 1983.
- (iii) Evidence that hospice care was a discrete activity rather than an aspect of another type of provider's patient care program on or before January 1, 1983.

(3) By virtue of the following evidence that a hospice made a good faith effort to hire nurses:

- (i) Copies of advertisements in local newspapers that demonstrate recruitment efforts.
- (ii) Job descriptions for nurse employees.
- (iii) Evidence that salary and benefits are competitive for the area.
- (iv) Evidence of any other recruiting activities (for example, recruiting efforts at health fairs and contacts with nurses at other providers in the area).

(b) Any waiver request is deemed to be granted unless it is denied within 60 days after it is received.

(c) Waivers will remain effective for 1 year at a time from the date of the request.

(d) If a hospice wishes to receive a 1-year extension, it must submit a request to CMS before the expiration of the waiver period, and certify that the conditions under which it originally requested the initial waiver have not changed since the initial waiver was granted.

Non- Core Services

§418.70 Condition of participation: Furnishing of non-core services.

A hospice must ensure that the services described in §418.72 through §418.78 are provided directly by the hospice or under arrangements made by the hospice as specified in §418.100. These services must be provided in a manner consistent with current standards of practice.

§418.72 Condition of participation: Physical therapy, occupational therapy, and speech-language pathology

Physical therapy services, occupational therapy services, and speech-language pathology services must be available, and when provided, offered in a manner consistent with accepted standards of practice.

§418.74 Waiver of requirement Physical therapy, occupational therapy, speech-language pathology, and dietary counseling.

(a) A hospice located in a non-urbanized area may submit a written request for a waiver of the requirement for providing physical therapy, occupational therapy, speech-language pathology, and dietary counseling services. The hospice may seek a waiver of the requirement that it make physical therapy, occupational therapy, speech-language pathology, and dietary counseling services (as needed) available on a 24-hour basis. The hospice may also seek a waiver of the requirement that it provide dietary counseling directly. The hospice must provide evidence that it has made a good faith effort to meet the requirements for these services before it seeks a waiver. CMS may approve a waiver application on the basis of the following criteria:

(1) The hospice is located in a non-urbanized area as determined by the Bureau of the Census.

(2) The hospice provides evidence that it had made a good faith effort to make available physical therapy, occupational therapy, speech-language pathology, and dietary counseling services on a 24-hour basis and/or to hire a dietary counselor to furnish services directly. This evidence must include the following:

- (i) Copies of advertisements in local newspapers that demonstrate recruitment efforts.
- (ii) Physical therapy, occupational therapy, speech- language pathology, and dietary counselor job descriptions.
- (iii) Evidence that salary and benefits are competitive for the area.
- (iv) Evidence of any other recruiting activities (for example, recruiting efforts at health fairs and contact discussions with physical therapy, occupational therapy, speech-language pathology, and dietary counseling service providers in the area).

(b) Any waiver request is deemed to be granted unless it is denied within 60 days after it is received.

(c) An initial waiver will remain effective for 1 year at a time from the date of the request. If a hospice wishes to receive a 1-year extension, it must submit a request to CMS before the expiration of the waiver period and certify that conditions under which it originally requested the waiver have not changed since the initial waiver was granted.

§418.76 Condition of participation: Hospice aide and homemaker services.

All hospice aide services must be provided by individuals who meet the personnel requirements specified in paragraph (a) of this section. Homemaker services must be provided by individuals who meet the personnel requirements specified in paragraph (j) of this section.

(a) Standard: Hospice aide qualifications.

(1) A qualified hospice aide is a person who has successfully completed one of the following:

- (i) A training program and competency evaluation as specified in paragraphs (b) and (c) of this section respectively.
- (ii) A competency evaluation program that meets the requirements of paragraph (c) of this section.
- (iii) A nurse aide training and competency evaluation program approved by the State as meeting the requirements of §483.151 through §483.154 of this chapter, and is currently listed in good standing on the State nurse aide registry.
- (iv) A State licensure program that meets the requirements of paragraphs (b) and (c) of this section.

(2) A hospice aide is not considered to have completed a program, as specified in paragraph (a) (1) of this section, if, since the individual's most recent completion of the program(s), there has been a continuous period of 24 consecutive months during which none of the services furnished by the individual as described in §409.40 of this chapter were for compensation. If there has been a 24-month lapse in furnishing

services, the individual must complete another program, as specified in paragraph (a) (1) of this section, before providing services.

(b) Standard: Content and duration of hospice aide classroom and supervised practical training.

(1) Hospice aide training must include classroom and supervised practical training in a practicum laboratory or other setting in which the trainee demonstrates knowledge while performing tasks on an individual under the direct supervision of a registered nurse, or a licensed practical nurse, who is under the supervision of a registered nurse. Classroom and supervised practical training combined must total at least 75 hours.

(2) A minimum of 16 hours of classroom training must precede a minimum of 16 hours of supervised practical training as part of the 75 hours.

(3) A hospice aide training program must address each of the following subject areas:

- (i) Communication skills, including the ability to read, write, and verbally report clinical information to patients, care givers, and other hospice staff.
- (ii) Observation, reporting, and documentation of patient status and the care or service furnished.
- (iii) Reading and recording temperature, pulse, and respiration.
- (iv) Basic infection control procedures.
- (v) Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor.
- (vi) Maintenance of a clean, safe, and healthy environment.
- (vii) Recognizing emergencies and the knowledge of emergency procedures and their application.
- (viii) The physical, emotional, and developmental needs of and ways to work with the populations served by the hospice, including the need for respect for the patient, his or her privacy, and his or her property.
- (ix) Appropriate and safe techniques in performing personal hygiene and grooming tasks, including items on the following basic checklist:
 - A. Bed bath.
 - B. Sponge, tub, and shower bath.
 - C. Hair shampoo (sink, tub, and bed).
 - D. Nail and skin care.
 - E. Oral hygiene.
 - F. Toileting and elimination.
- (x) Safe transfer techniques and ambulation
- (xi) Normal range of motion and positioning.
- (xii) Adequate nutrition and fluid intake.
- (xiii) Any other task that the hospice may choose to have an aide perform. The hospice is responsible for training hospice aides, as needed, for skills not covered

in the basic checklist, as described in paragraph (b) (3) (ix) of this section.

(4) The hospice must maintain documentation that demonstrates that the requirements of this standard are met.

(c) Standard: Competency evaluation.

An individual may furnish hospice aide services on behalf of a hospice only after that individual has successfully completed a competency evaluation program as described in this section.

- 1) The competency evaluation must address each of the subjects listed in paragraph (b) (3) of this section. Subject areas specified under paragraphs (b) (3) (i), (b) (3) (iii), (b)(3)(ix), (b)(3)(x) and (b)(3)(xi) of this section must be evaluated by observing an aide's performance of the task with a patient. The remaining subject areas may be evaluated through written examination, oral examination, or after observation of a hospice aide with a patient.
- 2) A hospice aide competency evaluation program may be offered by any organization, except as described in paragraph (f) of this section.
- 3) The competency evaluation must be performed by a registered nurse in consultation with other skilled professionals, as appropriate.
- 4) A hospice aide is not considered competent in any task for which he or she is evaluated as unsatisfactory. An aide must not perform that task without direct supervision by a registered nurse until after he or she has received training in the task for which he or she was evaluated as "unsatisfactory," and successfully completes a subsequent evaluation. A hospice aide is not considered to have successfully completed a competency evaluation if the aide has an "unsatisfactory" rating in more than one of the required areas.
- 5) The hospice must maintain documentation that demonstrates the requirements of this standard are being met.

(d) Standard: In-service training.

A hospice aide must receive at least 12 hours of in-service training during each 12-month period. In-service training may occur while an aide is furnishing care to a patient.

- 1) In-service training may be offered by any organization, and must be supervised by a registered nurse.
- 2) The hospice must maintain documentation that demonstrates the requirements of this standard are met.

(e) Standard: Qualifications for instructors conducting classroom and supervised practical training.

Classroom and supervised practical training must be performed by a registered nurse who possesses a minimum of 2 years nursing experience, at least 1 year of which must be in home care, or by other individuals under the general supervision of a registered nurse.

(f) Standard: Eligible competency evaluation organizations.

A hospice aide competency evaluation program as specified in paragraph (c) of this section may be offered by any organization except by a home health agency that, within the previous 2 years:

- 1) Had been of compliance with the requirements of §484.36(a) and (b) of this chapter.
- 2) Permitted an individual that does not meet the definition of a “qualified home health aide” as specified in §484.36(a) of this chapter to furnish home health aide services (with the exception of licensed health professionals and volunteers).
- 3) Had been subjected to an extended (or partial extended) survey as a result of having been found to have furnished substandard care (or for other reasons at the discretion of CMS or the State).
- 4) Had been assessed a civil monetary penalty of \$5,000 or more as an intermediate sanction.
- 5) Had been found by CMS to have compliance deficiencies that endangered the health and safety of the home health agency’s patients and had temporary management appointed to oversee the management of the home health agency.
- 6) Had all or part of its Medicare payments suspended.
- 7) Had been found by CMS or the State under any Federal or state law to have:
 - (i) Had its participation in the Medicare program terminated.
 - (ii) Been assessed a penalty of \$5,000 or more for deficiencies in Federal or State standards for home health agencies.
 - (iii) Been subjected to a suspension of Medicare payments to which it otherwise would have been entitled.
 - (iv) Operated under temporary management that was appointed by a governmental authority to oversee the operation of the home health agency and to ensure the health and safety of the home health agency’s patients.
 - (v) Been closed by CMS or the State, or had its patients transferred by the State.

(g) Standard: Hospice aide assignments and duties.

(1) Hospice aides are assigned to a specific patient by a registered nurse that is a member of the interdisciplinary group. Written patient care instructions for a hospice aide must be prepared by a registered nurse who is responsible for the supervision of a hospice aide as specified under paragraph (h) of this section.

(2) A hospice aide provides services that are:

- (i) Ordered by the interdisciplinary group.
- (ii) Included in the plan of care.
- (iii) Permitted to be performed under State law by such hospice aide.
- (iv) Consistent with the hospice aide training.

(3) The duties of a hospice aide include the following:

- (i) The provision of hands-on personal care.
- (ii) The performance of simple procedures as an extension of therapy or nursing services.
- (iii) Assistance in ambulation or exercises.
- (iv) Assistance in administering medications that are ordinarily self-administered.

(4) Hospice aides must report changes in the patient's medical, nursing, rehabilitative, and social needs to a registered nurse, as the changes relate to the plan of care and quality assessment and improvement activities. Hospice aides must also complete appropriate records in compliance with the hospice's policies and procedures.

(h) Standard: Supervision of hospice aides.

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

- (i) No less frequently than every 14 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.
- (ii) If an area of concern is noted by the supervising nurse, then the hospice must 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.
- (iii) If an area of concern is verified by the hospice during the on-site visit, then the hospice must conduct, and the hospice aide must complete a competency evaluation in accordance with §418.76(c).

(2) A registered nurse must 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.

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

- (i) Following the patient's plan of care for completion of tasks assigned to the hospice aide by the registered nurse.
- (ii) Creating successful interpersonal relationships with the patient and family.
- (iii) Demonstrating competency with assigned tasks.
- (iv) Complying with infection control policies and procedures.
- (v) Reporting changes in the patient's condition.

(i) Standard: Individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit.

An individual may furnish personal care services, as defined in §440.167 of this chapter, on behalf of a hospice agency.

- 1) Before the individual may furnish personal care services, the individual must be found competent by the State (if regulated by the State) to furnish those services. The individual only needs to demonstrate competency in the services the individual is required to furnish.
- 2) Services under the Medicaid personal care benefit may be used to the extent that the hospice would routinely use the services of a hospice patient's family in implementing a patient's plan of care.
- 3) The hospice must coordinate its hospice aide and homemaker services with the Medicaid personal care benefit to ensure the patient receives the hospice aide and homemaker services he or she needs.

(j) Standard: Homemaker qualifications.

A qualified homemaker is—

- 1) An individual who meets the standards in §418.202(g) and has successfully completed hospice orientation addressing the needs and concerns of patients and families coping with a terminal illness; or
- 2) A hospice aide as described in §418.76.

(k) Standard: Homemaker supervision and duties.

- 1) Homemaker services must be coordinated and supervised by a member of the interdisciplinary group.

- 2) Instructions for homemaker duties must be prepared by a member of the interdisciplinary group.
- 3) Homemakers must report all concerns about the patient or family to the member of the interdisciplinary group who is coordinating homemaker services.

§418.78 Conditions of participation–Volunteers.

The hospice must use volunteers to the extent specified in paragraph (e) of this section. These volunteers must be used in defined roles and under the supervision of a designated hospice employee.

(a) Standard: Training.

The hospice must maintain, document and provide volunteer orientation and training that is consistent with hospice industry standards.

(b) Standard: Role.

Volunteers must be used in day- to-day administrative and/or direct patient care roles.

(c) Standard: Recruiting and retaining.

The hospice must document and demonstrate viable and ongoing efforts to recruit and retain volunteers.

(d) Standard: Cost saving.

The hospice must document the cost savings achieved through the use of volunteers. Documentation must include the following:

- 1) The identification of each position that is occupied by a volunteer.
- 2) The work time spent by volunteers occupying those positions.

Estimates of the dollar costs that the hospice would have incurred if paid employees occupied the positions identified in paragraph (d) (1) of this section for the amount of time specified in paragraph (d) (2) of this section.

(e) Standard: Level of activity.

Volunteers must provide day-to-day administrative and/or direct patient care services in an amount that, at a minimum, equals 5 percent of the total patient care hours of all paid hospice employees and contract staff. The hospice must maintain records on the use of volunteers for patient care and administrative services, including the type of

services and time worked.

Subpart D—Conditions of participation: Organizational Environment

§418.100 Condition of Participation: Organization and administration of services.

The hospice must 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.

(a) Standard: Serving the hospice patient and family.

The hospice must 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.

(b) Standard: Governing body and administrator.

A governing body (or designated persons so functioning) assumes full legal authority and responsibility for the management of the hospice, the provision of all hospice services, its fiscal operations, and continuous quality assessment and performance improvement. A qualified administrator appointed by and reporting to the governing body is responsible for the day-to-day operation of the hospice. The administrator must be a hospice employee and possess education and experience required by the hospice's governing body.

(c) Standard: Services.

(1) A hospice must be primarily engaged in providing the following care and services and must do so in a manner that is consistent with accepted standards of practice:

- (i) Nursing services.
- (ii) Medical social services.
- (iii) Physician services.
- (iv) Counseling services, including spiritual counseling, dietary counseling, and bereavement counseling.
- (v) Hospice aide, volunteer, and homemaker services.
- (vi) Physical therapy, occupational therapy, and speech-language pathology services.
- (vii) Short-term inpatient care.
- (viii) Medical supplies (including drugs and biologicals) and medical appliances.

(2) Nursing services, physician services, and drugs and biologicals (as specified in §418.106) must be made routinely available on a 24-hour basis 7 days a week. Other covered services must be available on a 24-hour basis when reasonable and necessary to meet the needs of the patient and family.

(d) Standard: Continuation of care.

A hospice may not discontinue or reduce care provided to a Medicare or Medicaid beneficiary because of the beneficiary's inability to pay for that care.

(e) Standard: Professional management responsibility.

A hospice that has a written agreement with another agency, individual, or organization to furnish any services under arrangement must retain administrative and financial management, and oversight of staff and services for all arranged services, to ensure the provision of quality care. Arranged services must 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.

(f) Standard: Hospice multiple locations.

If a hospice operates multiple locations, it must meet the following requirements:

(1) Medicare approval.

- (i) All hospice multiple locations must be approved by Medicare before providing hospice care and services to Medicare patients.
- (ii) The multiple location must be part of the hospice and must share administration, supervision, and services with the hospice issued the certification number.
- (iii) The lines of authority and professional and administrative control must be clearly delineated in the hospice's organizational structure and in practice, and must be traced to the location that issued the certification number.
- (iv) The determination that a multiple location does or does not meet the definition of a multiple location, as set forth in this part, is an initial determination, as set forth in §498.3.

(2) The hospice must continually monitor and manage all services provided at all of its locations to ensure that services are delivered in a safe and effective manner and to ensure that each patient and family receives the necessary care and services outlined in the plan of care, in accordance with the requirements of this subpart and subparts A and C of this section.

(g) Standard: Training.

- 1) A hospice must provide orientation about the hospice philosophy to all employees and contracted staff who have patient and family contact.
- 2) A hospice must provide an initial orientation for each employee that addresses the employee's specific job duties.
- 3) A hospice must 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 must have written policies and procedures describing its method(s) of assessment of competency and maintain a written description of the in-service training provided during the previous 12 months.

§418.102 Condition of participation: Medical director.

The hospice must designate a physician to serve as medical director. The medical director must be a doctor of medicine or osteopathy who is an employee, or is under contract with the hospice. When the medical director is not available, a physician designated by the hospice assumes the same responsibilities and obligations as the medical director.

(a) Standard: Medical director contract.

- (1) A hospice may contract with either of the following—
 - (i) A self-employed physician; or
 - (ii) A physician employed by a professional entity or physicians group. When contracting for medical director services, the contract must specify the physician who assumes the medical director responsibilities and obligations.

(b) Standard: Initial certification of terminal illness.

The medical director 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 6 months or less if the illness runs its normal course. The physician must consider the following when making this determination:

- 1) The primary terminal condition;
- 2) Related diagnosis(es), if any;
- 3) Current subjective and objective medical findings;
- 4) Current medication and treatment orders; and
- 5) Information about the medical management of any of the patient's conditions unrelated to the terminal illness.

(c) Standard: Recertification of the terminal illness.

Before the recertification period for each patient, as described in §418.21(a), the medical director or physician designee must review the patient's clinical information.

(d) Standard: Medical director responsibility.

The medical director or physician designee has responsibility for the medical component of the hospice's patient care program.

§418.104 Condition of participation: Clinical records.

A clinical record containing past and current findings is maintained for each hospice patient. The clinical record must contain correct clinical information that is available to the patient's attending physician and hospice staff. The clinical record may be maintained electronically.

(a) Standard: Content.

Each patient's record must include 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 in accordance with §418.52 and election statement in accordance with §418.24.
- 3) Responses to medications, symptom management, treatments, and services.
- 4) Outcome measure data elements, as described in §418.54(e) of this subpart.
- 5) Physician certification and recertification of terminal illness as required in §418.22 and §418.25 and described in §418.102(b) and §418.102(c) respectively, if appropriate.
- 6) Any advance directives as described in §418.52(a)(2).
- 7) Physician orders.

(b) Standard: Authentication.

All entries must be legible, clear, complete, and appropriately authenticated and dated in accordance with hospice policy and currently accepted standards of practice.

Standard: Protection of information. The clinical record, its contents and the information contained therein must be safeguarded against loss or unauthorized use. The hospice must be in compliance with the Department's rules regarding personal health information as set out at 45 CFR parts 160 and 164.

(c) Standard: Retention of records.

Patient clinical records must be retained for 6 years after the death or discharge of the patient, unless State law stipulates a longer period of time. If the hospice discontinues operation, hospice policies must provide for retention and storage of clinical records. The hospice must inform its State agency and its CMS Regional office where such clinical records will be stored and how they may be accessed.

(e) Standard: Discharge or transfer of care.

(1) If the care of a patient is transferred to another Medicare/Medicaid-certified facility, the hospice must forward to the receiving facility, a copy of-

- (i) The hospice discharge summary; and
- (ii) The patient's clinical record, if requested.

(2) If a patient revokes the election of hospice care, or is discharged from hospice in accordance with §418.26, the hospice must forward to the patient's attending physician, a copy of-

- (i) The hospice discharge summary; and
- (ii) The patient's clinical record, if requested.

(3) The hospice discharge summary as required in paragraph (e) (1) and (e) (2) of this section must include—

- (i) A summary of the patient's stay including treatments, symptoms and pain management.
- (ii) The patient's current plan of care.
- (iii) The patient's latest physician orders. and
- (iv) Any other documentation that will assist in post- discharge continuity of care or that is requested by the attending physician or receiving facility.

(f) Standard: Retrieval of clinical records.

The clinical record, whether hard copy or in electronic form, must be made readily available on request by an appropriate authority.

§418.106 Condition of participation: Drugs and biologicals, medical supplies, and durable medical equipment.

Medical supplies and appliances, as described in §410.36 of this chapter; durable medical equipment, as described in §410.38 of this chapter; 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, must be provided by the hospice while the patient is under hospice care.

(a) Standard: Managing drugs and biologicals.

(1) The hospice must 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. A hospice that provides inpatient care directly in its own facility must 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 must include evaluation of a patient's response to medication therapy, identification of potential adverse drug reactions, and recommended appropriate corrective action.

(b) Standard: Ordering of drugs.

- 1) Only a physician as defined by section 1861(r) (1) of the Act, or a nurse practitioner 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—
 - (i) It must be given only to a licensed nurse, nurse practitioner (where appropriate), pharmacist, or physician; and
 - (ii) The individual receiving the order must record and sign it immediately and have the prescribing person sign it in accordance with State and Federal regulations.

(c) Standard: Dispensing of drugs and biologicals.

The hospice must—

- 1) Obtain drugs and biologicals from community or institutional pharmacists or stock drugs and biologicals itself.
- 2) The hospice that provides inpatient care directly in its own facility must:
 - (i) Have a written policy in place that promotes dispensing accuracy; and
 - (ii) Maintain current and accurate records of the receipt and disposition of all controlled drugs.

(d) Standard: Administration of drugs and biologicals.

- 1) The interdisciplinary group, as part of the review of the plan of care, must determine the ability of the patient and/or family to safely self-administer drugs and biologicals

to the patient in his or her home.

- 2) Patients receiving care in a hospice that provides inpatient care directly in its own facility may only be administered medications by the following individuals:
 - (i) A licensed nurse, physician, or other health care professional in accordance with their scope of practice and State law;
 - (ii) An employee who has completed a State-approved training program in medication administration; and
 - (iii) The patient, upon approval by the interdisciplinary group.

(e) Standard: Labeling, disposing, and storing of drugs and biologicals.

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

(2) Disposing.

(i) Safe use and disposal of controlled drugs in the patient's home. The hospice must 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 must:

- 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.

(ii) Disposal of controlled drugs in hospices that provide inpatient care directly. The hospice that provides inpatient care directly in its own facility must dispose of controlled drugs in compliance with the hospice policy and in accordance with State and Federal requirements. The hospice must maintain current and accurate records of the receipt and disposition of all controlled drugs.

(3) Storing. The hospice that provides inpatient care directly in its own facility must comply with the following additional requirements-

- (i) All drugs and biologicals must be stored in secure areas. All controlled drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1976 must be stored in locked compartments within such secure storage areas. Only personnel authorized to administer controlled drugs as noted in paragraph (d) (2) of this section may have access to the locked compartments; and
- (ii) Discrepancies in the acquisition, storage, dispensing, administration, disposal, or return of controlled drugs must be investigated immediately by the pharmacist and hospice administrator and where required reported to the appropriate State authority. A written account of the investigation must be made available to State and Federal officials if required by law or regulation.

(f) Standard: Use and maintenance of equipment and supplies.

(1) The hospice must ensure that manufacturer recommendations for performing routine and preventive maintenance on durable medical equipment are followed. The equipment must 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 must 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 must 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 must be able to demonstrate the appropriate use of durable medical equipment to the satisfaction of the hospice staff.

(3) Hospices may only contract for durable medical equipment services with a durable medical equipment supplier that meets the Medicare DMEPOS Supplier Quality and Accreditation Standards at 42 CFR §424.57.

§418.108 Condition of participation: Short-term inpatient care.

Inpatient care must be available for pain control, symptom management, and respite purposes, and must be provided in a participating Medicare or Medicaid facility.

(a) Standard: Inpatient care for symptom management and pain control.

Inpatient care for pain control and symptom management must be provided in one of the following:

- 1) A Medicare-certified hospice that meets the conditions of participation for providing inpatient care directly as specified in §418.110.

- 2) A Medicare-certified hospital or a skilled nursing facility that also meets the standards specified in §418.110(b) and (e) regarding 24-hour nursing services and patient areas.

(b) Standard: Inpatient care for respite purposes.

- (1) Inpatient care for respite purposes must be provided by one of the following:
 - (i) A provider specified in paragraph (a) of this section.
 - (ii) A Medicare or Medicaid-certified nursing facility that also meets the standards specified in §418.110(f).
- (2) The facility providing respite care must provide 24-hour nursing services that meet the nursing needs of all patients and are furnished in accordance with each patient's plan of care. Each patient must receive all nursing services as prescribed and must be kept comfortable, clean, well-groomed, and protected from accident, injury, and infection.

(c) Standard: Inpatient care provided under arrangements.

If the hospice has an arrangement with a 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;
- (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 is documented; and
- (6) A method for verifying that the requirements in paragraphs(c) (1) through (c) (5) of this section are met.

(d) Standard: Inpatient care limitation.

The total number of inpatient days used by Medicare beneficiaries who elected hospice coverage in a 12-month period in a particular hospice may not exceed 20 percent of the total number of hospice days consumed in total by this group of beneficiaries.

(e) Standard: Exemption from limitation.

Before October 1, 1986, any hospice that began operation before January 1, 1975, is not subject to the limitation specified in paragraph (d) of this section.

§418.110 Condition of participation: Hospices that provide inpatient care directly

A hospice that provides inpatient care directly in its own facility must demonstrate compliance with all of the following standards:

(a) Standard: Staffing.

The hospice is responsible for ensuring that staffing for all services reflects its volume of patients, their acuity, and the level of intensity of services needed to ensure that plan of care outcomes are achieved and negative outcomes are avoided.

(b) Standard: Twenty-four hour nursing services.

(1) The hospice facility must provide 24-hour nursing services that meet the nursing needs of all patients and are furnished in accordance with each patient's plan of care. Each patient must receive all nursing services as prescribed and must be kept comfortable, clean, well-groomed, and protected from accident, injury, and infection.

(2) If at least one patient in the hospice facility is receiving general inpatient care, then each shift must include a registered nurse who provides direct patient care.

(c) Standard: Physical environment.

The hospice must maintain a safe physical environment free of hazards for patients, staff, and visitors.

(1) Safety management.

(i) The hospice must address real or potential threats to the health and safety of the patients, others, and property.

(ii) The hospice must have a written disaster preparedness plan in effect for managing

the consequences of power failures, natural disasters, and other emergencies that would affect the hospice's ability to provide care. The plan must be periodically reviewed and rehearsed with staff (including non-employee staff) with special emphasis placed on carrying out the procedures necessary to protect patients and others.

(2) Physical plant and equipment. The hospice must develop procedures for controlling the reliability and quality of—

- (i) The routine storage and prompt disposal of trash and medical waste;
- (ii) Light, temperature, and ventilation/air exchanges throughout the hospice;
- (iii) Emergency gas and water supply; and
- (iv) The scheduled and emergency maintenance and repair of all equipment.

(d) Standard: Fire protection.

(1) Except as otherwise provided in this section—

- (i) The hospice must meet the provisions applicable to nursing homes of the 2000 edition of the Life Safety Code (LSC) of the National Fire Protection Association (NFPA). The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal/register/code-of-federal-regulations/ibr-locations.html>. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in the edition of the Code are incorporated by reference, CMS will publish a notice in the **Federal Register** to announce the changes.
- (ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the LSC does not apply to hospices.

(2) In consideration of a recommendation by the State survey agency, CMS may waive, for periods deemed appropriate, specific provisions of the Life Safety Code which, if rigidly applied would result in unreasonable hardship for the hospice, but only if the waiver would not adversely affect the health and safety of patients.

(3) The provisions of the adopted edition of the Life Safety Code do not apply in a State if CMS finds that a fire and safety code imposed by State law adequately protects patients in hospices.

(4) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the

contrary, a hospice may place alcohol-based hand rub dispensers in its facility if-

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00-1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00-1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 C.F.R. part 51. A copy of the code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA) . For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in the edition of the Code are incorporated by reference, CMS will publish a notice in the **Federal Register** to announce the changes.

(e) Standard: Patient areas.

The hospice must provide a home-like atmosphere and ensure that patient areas are designed to preserve the dignity, comfort, and privacy of patients.

(1) The hospice must provide—

(i) Physical space for private patient and family visiting;

(ii) Accommodations for family members to remain with the patient throughout the night; and

(iii) Physical space for family privacy after a patient's death.

(2) The hospice must provide the opportunity for patients to receive visitors at any hour, including infants and small children.

(f) Standard: Patient rooms.

(1) The hospice must ensure that patient rooms are designed and equipped for nursing care, as well as the dignity, comfort, and privacy of patients.

(2) The hospice must accommodate a patient and family request for a single room whenever possible.

(3) Each patient's room must—

- (i) Be at or above grade level;
- (ii) Contain a suitable bed and other appropriate furniture for each patient;
- (iii) Have closet space that provides security and privacy for clothing and personal belongings;
- (iv) Accommodate no more than two patients and their family members;
- (v) Provide at least 80 square feet for each residing patient in a double room and at least 100 square feet for each patient residing in a single room; and
- (vi) Be equipped with an easily-activated, functioning device accessible to the patient, that is used for calling for assistance.

(4) For a facility occupied by a Medicare- participating hospice on December 2, 2008, CMS may waive the space and occupancy requirements of paragraphs (f) (2) (iv) and (f) (2) (v) of this section if it determines that—

- (i) Imposition of the requirements would result in unreasonable hardship on the hospice if strictly enforced; or jeopardize its ability to continue to participate in the Medicare program; and
- (ii) The waiver serves the needs of the patient and does not adversely affect their health and safety.

(g) Standard: Toilet and bathing facilities.

Each patient room must be equipped with, or conveniently located near, toilet and bathing facilities.

(h) Standard: Plumbing facilities.

The hospice must—

- (1) Have an adequate supply of hot water at all times; and
- (2) Have plumbing fixtures with control valves that automatically regulate the temperature of the hot water used by patients.

(i) Standard: Infection control.

The hospice must maintain an infection control program that protects patients, staff and others by preventing and controlling infections and communicable disease as stipulated in §418. 60.

(j) Standard: Sanitary environment.

The hospice must provide a sanitary environment by following current standards of practice, including nationally recognized infection control precautions, and avoid sources and transmission of infections and communicable diseases.

(k) Standard: Linen.

The hospice must have available at all times a quantity of clean linen in sufficient amounts for all patient uses. Linens must be handled, stored, processed, and transported in such a manner as to prevent the spread of contaminants.

(l) Standard: Meal service and menu planning.

The hospice must furnish meals to each patient that are—

- 1) Consistent with the patient's plan of care, nutritional needs, and therapeutic diet;
- 2) Palatable, attractive, and served at the proper temperature; and
- 3) Obtained, stored, prepared, distributed, and served under sanitary conditions.

(m) Standard: Restraint or seclusion.

All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.

- 1) Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient, a staff member, or others from harm.
- 2) The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm.
- 3) The use of restraint or seclusion must be—
 - i. In accordance with a written modification to the patient's plan of care; and
 - ii. Implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospice policy in accordance with State law.

- 4) The use of restraint or seclusion must be in accordance with the order of a physician authorized to order restraint or seclusion by hospice policy in accordance with State law.
- 5) Orders for the use of restraint or seclusion must never be written as a standing order or on an as needed basis (PRN).
- 6) The medical director or physician designee must be consulted as soon as possible if the attending physician did not order the restraint or seclusion.
- 7) Unless superseded by State law that is more restrictive—
 - (i) Each order for restraint or seclusion used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others may only be renewed in accordance with the following limits for up to a total of 24 hours:
 - (A) 4 hours for adults 18 years of age or older;
 - (B) 2 hours for children and adolescents 9 to 17 years of age; or
 - (C) 1-hour for children under 9 years of age; and

After 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician authorized to order restraint or seclusion by hospice policy in accordance with State law must see and assess the patient.

- (ii) Each order for restraint used to ensure the physical safety of the non-violent or non-self-destructive patient may be renewed as authorized by hospice policy.
- (i) Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order.
- (ii) The condition of the patient who is restrained or secluded must be monitored by a physician or trained staff that have completed the training criteria specified in paragraph (n) of this section at an interval determined by hospice policy.
- (iii) Physician, including attending physician, training requirements must be specified in hospice policy. At a minimum, physicians and attending physicians authorized to order restraint or seclusion by hospice policy in accordance with State law must have a working knowledge of hospice policy regarding the use of restraint or seclusion.
- (iv) When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen face-to-face within 1 hour after the initiation of the intervention –

- (i) By a--
 - (A) Physician; or
 - (B) Registered nurse who has been trained in accordance with the requirements specified in paragraph (n) of this section.

- (ii) To evaluate--
 - (A) The patient's immediate situation;
 - (B) The patient's reaction to the intervention;
 - (C) The patient's medical and behavioral condition; and
 - (D) The need to continue or terminate the restraint or seclusion.

- (v) States are free to have requirements by statute or regulation that are more restrictive than those contained in paragraph (m) (11) (i) of this section.

- (vi) If the face-to-face evaluation specified in §418.110(m)(11) is conducted by a trained registered nurse, the trained registered nurse must consult the medical director or physician designee as soon as possible after the completion of the 1-hour face-to-face evaluation.

- (vii) All requirements specified under this paragraph are applicable to the simultaneous use of restraint and seclusion. Simultaneous restraint and seclusion use is only permitted if the patient is continually monitored—
 - (i) Face-to-face by an assigned, trained staff member; or
 - (ii) By trained staff using both video and audio equipment. This monitoring must be in close proximity to the patient.

- (viii) When restraint or seclusion is used, there must be documentation in the patient's clinical record of the following:
 - (i) The 1-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior;
 - (ii) A description of the patient's behavior and the intervention used;
 - (iii) Alternatives or other less restrictive interventions attempted as applicable);
 - (iv) The patient's condition or symptom(s) that warranted the use of the restraint or seclusion; and the patient's response to the intervention(s) used, including the rationale for continued use of the intervention.

(n) Standard: Restraint or seclusion staff training requirements.

The patient has the right to safe implementation of restraint or seclusion by trained staff.

(1) Training intervals. All patient care staff working in the hospice inpatient facility must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion--

- (i) Before performing any of the actions specified in this paragraph;
- (ii) As part of orientation; and
- (iii) Subsequently on a periodic basis consistent with hospice policy.

(2) Training content. The hospice must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:

- (i) Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of a restraint or seclusion.
- (ii) The use of nonphysical intervention skills.
- (iii) Choosing the least restrictive intervention based on an individualized assessment of the patient's medical, or behavioral status or condition.
- (iv) The safe application and use of all types of restraint or seclusion used in the hospice, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia).
- (v) Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary.
- (vi) Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospice policy associated with the 1-hour face-to-face evaluation.
- (vii) The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification.

(3) Trainer requirements. Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors.

(4) Training documentation. The hospice must document in the staff personnel records that the training and demonstration of competency were successfully completed.

(o) Standard: Death reporting requirements.

Hospices must report deaths associated with the use of seclusion or restraint.

- (1) The hospice must report the following information to CMS:
 - (i) Each unexpected death that occurs while a patient is in restraint or seclusion.
 - (ii) Each unexpected death that occurs within 24 hours after the patient has been removed from restraint or seclusion.
 - (iii) Each death known to the hospice that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in

seclusion contributed directly or indirectly to a patient's death. "Reasonable to assume" in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation.

(2) Each death referenced in this paragraph must be reported to CMS by telephone no later than the close of business the next business day following knowledge of the patient's death.

(3) Staff must document in the patient's clinical record the date and time the death was reported to CMS.

§418.112 Condition of participation: Hospices that provide hospice care to residents of a SNF/NF or ICF/MR.

In addition to meeting the conditions of participation at §418.10 through §418.116, a hospice that provides hospice care to residents of a SNF/NF or ICF/MR must abide by the following additional standards.

(a) Standard: Resident eligibility, election, and duration of benefits.

Medicare patients receiving hospice services and residing in a SNF, NF, or ICF/MR are subject to the Medicare hospice eligibility criteria set out at §418.20 through §418.30.

(b) Standard: Professional management.

The hospice must assume responsibility for professional management of the resident's hospice services provided, in accordance with the hospice plan of care and the hospice conditions of participation, and make any arrangements necessary for hospice-related inpatient care in a participating Medicare/Medicaid facility according to §418.100 and §418.108.

(c) Standard: Written agreement.

The hospice and SNF/NF or ICF/MR must have a written agreement that specifies the provision of hospice services in the facility. The agreement must be signed by authorized representatives of the hospice and the SNF/NF or ICF/MR before the provision of hospice services. The written agreement must include at least the following:

- 1) The manner in which the SNF/NF or ICF/MR and the hospice are to communicate with each other and document such communications to ensure that the needs of patients are addressed and met 24 hours a day.
- 2) A provision that the SNF/NF or ICF/MR immediately notifies the hospice if—

- (i) A significant change in a patient's physical, mental, social, or emotional status occurs;
 - (ii) Clinical complications appear that suggest a need to alter the plan of care;
 - (iii) A need to transfer a patient from the SNF/NF or ICF/MR, and the hospice makes arrangements for, and remains responsible for, any necessary continuous care or inpatient care necessary related to the terminal illness and related conditions; or
 - (iv) A patient dies.
- 3) A provision stating that the hospice assumes responsibility for determining the appropriate course of hospice care, including the determination to change the level of services provided.
- 4) An agreement that it is the SNF/NF or ICF/MR responsibility to continue to furnish 24 hour room and board care, meeting the personal care and nursing needs that would have been provided by the primary caregiver at home at the same level of care provided before hospice care was elected.
- 5) An agreement that it is the hospice's responsibility to provide services at the same level and to the same extent as those services would be provided if the SNF/NF or ICF/MR resident were in his or her own home.
- 6) A delineation of the hospice's responsibilities, which include, but are not limited to the following: providing medical direction and management of the patient; nursing; counseling (including spiritual, dietary and bereavement); social work; provision of medical supplies, durable medical equipment and drugs necessary for the palliation of pain and symptoms associated with the terminal illness and related conditions; and all other hospice services that are necessary for the care of the resident's terminal illness and related conditions.
- 7) A provision that the hospice may use the SNF/NF or ICF/MR nursing personnel where permitted by State law and as specified by the SNF/NF or ICF/MR to assist in the administration of prescribed therapies included in the plan of care only to the extent that the hospice would routinely use the services of a hospice patient's family in implementing the plan of care.
- 8) A provision stating that the hospice must report 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 unrelated to the hospice to the SNF/NF or ICF/MR administrator within 24 hours of the hospice becoming aware of the alleged violation.
- 9) A delineation of the responsibilities of the hospice and the SNF/NF or ICF/MR to provide bereavement services to SNF/NF or ICF/MR staff.

(d) Standard: Hospice plan of care.

In accordance with §418.56, a written hospice plan of care must be established and maintained in consultation with SNF/NF or ICF/MR representatives. All hospice care provided must be in accordance with this hospice plan of care.

- (1) The hospice plan of care must identify the care and services that are needed and specifically identify which provider is responsible for performing the respective functions that have been agreed upon and included in the hospice plan of care.
- (2) The hospice plan of care reflects the participation of the hospice, the SNF/NF or ICF/MR, and the patient and family to the extent possible.
- (3) Any changes in the hospice plan of care must be discussed with the patient or representative, and SNF/NF or ICF/MR representatives, and must be approved by the hospice before implementation.

(e) Standard: Coordination of services.

The hospice must:

- (1) Designate a member of each interdisciplinary group that is responsible for a patient who is a resident of a SNF/NF or ICF/MR. The designated interdisciplinary group member is responsible for:
 - i. Providing overall coordination of the hospice care of the SNF/NF or ICF/MR resident with SNF/NF or ICF/MR representatives; and
 - ii. Communicating with SNF/NF or ICF/MR representatives and other health care providers participating in the provision of care for the terminal illness and related conditions and other conditions to ensure quality of care for the patient and family.
- (2) Ensure that the hospice IDG communicates with the SNF/NF or ICF/MR medical director, the patient's attending physician, and other physicians participating in the provision of care to the patient as needed to coordinate the hospice care of the hospice patient with the medical care provided by other physicians.
- (3) Provide the SNF/NF or ICF/MR with the following information:
 - (i) The most recent hospice plan of care specific to each patient;
 - (ii) Hospice election form and any advance directives specific to each patient;
 - (iii) Physician certification and recertification of the terminal illness specific to each patient;
 - (iv) Names and contact information for hospice personnel

- involved in hospice care of each patient;
- (v) Instructions on how to access the hospice's 24-hour on-call system;
- (vi) Hospice medication information specific to each patient; and
- (vii) Hospice physician and attending physician (if any) orders specific to each patient.

(f) Standard: Orientation and training of staff.

Hospice staff must assure orientation of SNF/NF or ICF/MR staff furnishing care to hospice patients in the hospice philosophy, including hospice policies and procedures regarding methods of comfort, pain control, symptom management, as well as principles about death and dying, individual responses to death, patient rights, appropriate forms, and record keeping requirements.

§418.114 Condition of participation: Personnel qualifications.

a) General qualification requirements. Except as specified in paragraph (c) of this section, all professionals who furnish services directly, under an individual contract, or under arrangements with a hospice, must be legally authorized (licensed, certified or registered) in accordance with applicable Federal, State and local laws, and must act only within the scope of his or her State license, or State certification, or registration. All personnel qualifications must be kept current at all times.

b) Personnel qualifications for certain disciplines. The following qualifications must be met:

(1) Physician. Physicians must meet the qualifications and conditions as defined in section 1861(r) of the Act and implemented at §410.20 of this chapter.

(2) Hospice aide. Hospice aides must meet the qualifications required by section 1891 (a) (3) of the Act and implemented at §418.76.

(3) Social worker. A person who—

- (i) (A) Has a Master of Social Work (MSW) degree from a school of social work accredited by the Council on Social Work Education; or

(B) Has a baccalaureate degree in social work from an institution accredited by the Council on Social Work Education; or a baccalaureate degree in psychology, sociology, or other field related to social work and is supervised by an MSW as described in paragraph (b) (3) (i) (A) of this section; and

- (ii) Has 1 year of social work experience in a health care setting; or
- (iii) Has a baccalaureate degree from a school of social work accredited by the Council on Social Work Education, is employed by the hospice before DECEMBER 2, 2008, and is not required to be supervised by an MSW

(4) Speech language pathologist. A person who meets either of the following requirements:

- (i) The education and experience requirements for a Certificate of Clinical Competence in speech-language pathology granted by the American Speech-Language-Hearing Association.
- (ii) The educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

(5) Occupational therapist. A person who—

- (i) (A) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing, unless licensure does not apply;

- (B) Graduated after successful completion of an occupational therapist education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA), or successor organizations of ACOTE; and

- (C) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the Board for Certification in Occupational Therapy, Inc. (NBCOT).

- (ii) On or before December 31, 2009—

- (A) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing; or

- (B) When licensure or other regulation does not apply—

- (1) Graduated after successful completion of an occupational therapist education program accredited by the accreditation Council for Occupational therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or successor organizations of ACOTE; and

- (2) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc., (NBCOT).

- (iii) On or before January 1, 2008—

- (A) Graduated after successful completion of an occupational therapy program accredited jointly by the committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association; or
 - (B) Is eligible for the National Registration Examination of the American Occupational Therapy Association or the National Board for Certification in Occupational Therapy.
- (iv) On or before December 31, 1977—
- (A) Had 2 years of appropriate experience as an occupational therapist; and
 - (B) Had achieved a satisfactory grade on an occupational therapist proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.
- (v) If educated outside the United States—
- (A) Must meet both of the following:
 - (1) Graduated after successful completion of an occupational therapist education program accredited as substantially equivalent to occupational therapist assistant entry level education in the United States by one of the following:
 - (i) The Accreditation Council for Occupational Therapy Education (ACOTE).
 - (ii) Successor organizations of ACOTE.
 - (iii) The World Federation of Occupational Therapists.
 - (iv) A credentialing body approved by the Occupational Therapy Association.
 - (v) Successfully completed the entry level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).
 - (2) On or before December 31, 2009, is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing.

(6) Occupational therapy assistant. A person who—

- (i) Meets all of the following:
 - (A) Is licensed or otherwise regulated, if applicable, as an occupational therapy assistant by the State in which practicing, unless licensure does apply.
 - (B) Graduated after successful completion of an occupational therapy assistant education program accredited by the Accreditation Council for Occupational Therapy Education, (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or its successor organizations.
 - (C) Is eligible to take or successfully completed the entry-level certification examination for occupational therapy assistants developed and

administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(ii) On or before December 31, 2009—

(A) Is licensed or otherwise regulated as an occupational therapy assistant, if applicable, by the State in which practicing; or any qualifications defined by the State in which practicing, unless licensure does not apply; or

(B) Must meet both of the following:

(1) Completed certification requirements to practice as an occupational therapy assistant established by a credentialing organization approved by the American Occupational Therapy Association.

(2) After January 1, 2010, meets the requirements in paragraph (b) (6) (i) of this section.

(iii) After December 31, 1977 and on or before December 31, 2007—

(A) Completed certification requirements to practice as an occupational therapy assistant established by a credentialing organization approved by the American Occupational Therapy Association; or

(B) Completed the requirements to practice as an occupational therapy assistant applicable in the State in which practicing.

(iv) On or before December 31, 1977—

(A) Had 2 years of appropriate experience as an occupational therapy assistant; and

(B) Had achieved a satisfactory grade on an occupational therapy assistant proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(v) If educated outside the United States, on or after January 1, 2008—

(A) Graduated after successful completion of an occupational therapy assistant education program that is accredited as substantially equivalent to occupational therapist assistant entry level education in the United States by—

(1) The Accreditation Council for Occupational Therapy Education (ACOTE).

(2) Its successor organizations.

(3) The World Federation of Occupational Therapists.

(4) By a credentialing body approved by the American Occupational Therapy Association; and

(5) Successfully completed the entry level certification examination for

occupational therapy assistants developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(7) Physical therapist. A person who is licensed, if applicable, by the State in which practicing, unless licensure does not apply and meets one of the following requirements:

- (i) Graduated after successful completion of one of a physical therapist education program approved by one of the following:
 - A. The Commission on Accreditation in Physical Therapy Education (CAPTE).
 - B. Successor organizations of CAPTE.
 - C. An education program outside the United States determined to be substantially equivalent to physical therapist entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or an organization identified in 8 CFR 212.15(e) as it relates to physical therapists.
 - D. Passed an examination for physical therapists approved by the State in which physical therapy services are provided.

- (ii) On or before December 31, 2009—
 - A. Graduated after successful completion of a physical therapy curriculum approved by the Commission on Accreditation in Physical Therapy Education (CAPTE); or
 - B. Meets both of the following:
 - 1. Graduated after successful completion of an education program determined to be substantially equivalent to physical therapist entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or identified in 8 CFR 212.15(e) as it relates to physical therapists.
 - 2. Passed an examination for physical therapists approved by the State in which physical therapy services are provided.

- (iii) Before January 1, 2008—
 - A. Graduated from a physical therapy curriculum approved by one of the following:
 - 1. The American Physical Therapy Association.
 - 2. The Committee on Allied Health Education and Accreditation of the American Medical Association.
 - 3. The Council on Medical Education of the American Medical Association and the American Physical Therapy Association.

- (iv) On or before December 31, 1977 was licensed or qualified as a physical therapist and meets both of the following:
 - A. Has 2 years of appropriate experience as a physical therapist.
 - B. Has achieved a satisfactory grade on a proficiency examination conducted,

approved, or sponsored by the U.S. Public Health Service.

- (v) Before January 1, 1966—
 - A. Was admitted to membership by the American Physical Therapy Association;
 - B. Was admitted to registration by the American Registry of Physical Therapists; and
 - C. Graduated from a physical therapy curriculum in a 4-year college or university approved by a State department of education.
- (vi) Before January 1, 1966 was licensed or registered, and before January 1, 1970, had 15 years of fulltime experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy.
- (vii) If trained outside the United States before January 1, 2008, meets the following requirements:
 - A. Was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy.
 - B. Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy.

(8) Physical therapist assistant. A person who is licensed, registered or certified as a physical therapist assistant, if applicable, by the State in which practicing, unless licensure does not apply and meets one of the following requirements:

- (i) Graduated from a physical therapist assistant curriculum approved by the Commission on Accreditation in Physical Therapy Education of the American Physical Therapy Association; or if educated outside the United States or trained in the United States military, graduated from an education program determined to be substantially equivalent to physical therapist assistant entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or identified at 8 CFR 212.15(e); and
 - (ii) Passed a national examination for physical therapist assistants.
- (A) On or before December 31, 2009, meets one of the following:
- (2) Is licensed, or otherwise regulated in the State in which practicing.
 - (3) In States where licensure or other regulations do not apply, graduated before December 31, 2009, from a 2-year college-level program approved by the American Physical Therapy Association and after January 1, 2010, meets the requirements of paragraph (b) (8) of this section.
 - (4) Before January 1, 2008, where licensure or other regulation does not apply, graduated from a 2-year college level program approved by the American Physical Therapy Association.

- (5) On or before December 31, 1977, was licensed or qualified as a physical therapist assistant and has achieved approved, or sponsored by the U.S. Public Health Service.

(c) Personnel qualifications when no State licensing, certification or registration requirements exist.

If no State licensing laws, certification or registration requirements exist for the profession, the following requirements must be met:

- 1) **Registered nurse.** A graduate of a school of professional nursing.
- 2) **Licensed practical nurse.** A person who has completed a practical nursing program.

(d) Standard: Criminal background checks.

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

(2) Criminal background checks must be obtained in accordance with State requirements. In the absence of State requirements, criminal background checks must be obtained within three months of the date of employment for all states that the individual has lived or worked in the past 3 years.

§418.116 Condition of participation: Compliance with Federal, State, and local laws and regulations related to the health and safety of patients.

The hospice and its staff must operate and furnish services in compliance with all applicable Federal, State, and local laws and regulations related to the health and safety of patients. If State or local law provides for licensing of hospices, the hospice must be licensed.

(a) Standard: Multiple locations.

Every hospice must comply with the requirements of §420.206 of this chapter regarding disclosure of ownership and control information. All hospice multiple locations must be approved by Medicare and licensed in accordance with State licensure laws, if applicable, before providing Medicare reimbursed services.

(b) Standard: Laboratory services.

(1) If the hospice engages in laboratory testing other than assisting a patient in self-administering a test with an appliance that has been approved for that purpose by the FDA, the hospice must be in compliance with all applicable requirements of part 493 of this chapter.

(2) If the hospice chooses to refer specimens for laboratory testing to a reference laboratory, the reference laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the applicable requirements of part 493 of this chapter.

Subpart E [Removed and Reserved]