Submitter : **Mrs. Christine Corriveau** **Date: 07/26/2005**

Organization : **Community Health and Nursing Services**

Category : **Nurse**

Issue Areas/Comments

GENERAL

GENERAL

We would like to record the following comments about the new proposed Hospice COP's:

1. We suggest that the home health aide supervision requirement mirror the Medicare skilled home health regulations requirement. 418.76h

2. We suggest the Hospice Certification periods be simplified by changing to all 90 day periods, no need for 60 day periods.

3. Might the proposed regulation not requiring a 24 hour RN on site at the inpatient hospice program lead to opportunities for fraud and abuse and patient neglect? The inpatient respite care does not need the RN for every shift. The general inpatient level of care does need an RN on for every shift. 418.110a&b

4. We suggest that language to require accountability from hospice programs that use proprietary sales and marketing techniques to provide evidence of meeting community needs and offering services to all without regard for ability to pay be added to the new COP's.

5. We suggest that the language regarding drug disposal be revolked or revised, due to questions about how to account for policy complience in the home. 418.106

6. We suggest adjusting compensation to the hospice provider based on hospice admission during the last 14 days of life. And /or based on the acuity or severity of symptoms, or needs by the patient and family at end of life

7. We suggest that the initial assessment be completed 24 hrs after the physician certification, when the patient has agreed to services. 418.54

8. We suggest that the comprehensive assessment be completed within 7 days after the pt elects the benifit. 418.54b

9. We suggest that the hospice medical director may communicate with the hospice nusre on the IDT who visits the facility rather than the facility's medical director when insuring quality care for the facility hospice pt patient. 418.112

Submitter : Ms. Jean Obermiller

Organization : Hospice of Holland

Category : Hospice

Date: 07/26/2005

Issue Areas/Comments

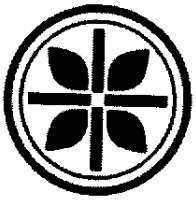
GENERAL

GENERAL

See attachment

CMS-3844-P-115-Attach-1.DOC

National Hospice and Palliative Care Organization



2005 PROPOSED MEDICARE CONDITIONS OF PARTICIPATION FOR HOSPICE PROGRAMS

REQUEST FOR COMMENTS
Version 2

June 14, 2005

Summary of Questions and Comments
Train the Trainer Session
June 9-10, 2005
Holiday Inn Inner Harbor
Baltimore, MD

Comments are due back to NHPCO on June 30.

Comments can be sent to copcomments@nhpco.org
by fax: (703) 837-1233
by mail: 1700 Diagonal Road, Suite 625
Alexandria, VA 22314
Attention: Elizabeth Cantrell

2005 CMS PROPOSED COPS	*REQUEST FOR COMMENTS*
§ 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.	
§ 418.3 Definitions For the purposes of this part—	
Attending physician means a— (1) (i) Doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she performs that function or action; or (ii) Nurse practitioner who meets the training, education and experience requirements as the Secretary may prescribe; and (2) Is identified by the individual, at the time he or she elects to receive hospice care, as having the most significant role in the determination and delivery of the individual's medical care.	
Bereavement counseling means emotional, psychosocial, and spiritual support and services provided after the death of the patient to assist with issues related to grief, loss, and adjusting.	
Cap period means the 12-month period ending October 31 used in the application of the cap on overall hospice reimbursement specified in §418.309.	
Clinical note means a notation of a contact with the patient 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 or emotional condition.	

2005 PROPOSED MEDICARE CONDITIONS OF PARTICIPATION FOR HOSPICE PROGRAMS WITH REQUEST FOR COMMENTS
June 8, 2005

2005 CMS PROPOSED COPS	*REQUEST FOR COMMENTS*
Drug restraint means a medication used to control behavior or to restrict the patient's freedom of movement, which is not a standard treatment for a patient's medical or psychiatric condition.	
Employee means a person who works for the hospice and for whom the hospice is required to issue a W–2 form on his or her behalf, or if the hospice is a subdivision of an agency or organization, an employee of the agency or organization who is appropriately trained and assigned to the hospice or 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 team 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.	
Licensed professional means a licensed person sanctioned by the State in which services are delivered, furnishing services such as skilled nursing care, physical therapy, speech-language pathology, occupational therapy, and medical social services.	
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.	
Physical restraint means any manual method or physical or mechanical device, material, or equipment attached to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body.	

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Progress note means a written notation, dated and signed by any person providing services, that summarizes facts about the care furnished and the patient's response during a given period of time.	
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 either a physical restraint or a drug used as a restraint.	
Satellite location means a Medicare-approved location from which the hospice provides hospice care and services within a portion of the total geographic area served by the hospice location issued the provider agreement number. The satellite location is part of the hospice and shares administration, supervision, and services in a manner that renders it unnecessary for the satellite location to independently meet the conditions of participation as a hospice.	
Seclusion means the confinement of a person in a room or an area where a person is isolated and physically prevented from leaving.	
Terminally ill means that the patient has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course.	

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§ 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. (1) The hospice must provide the patient or representative with verbal and written notice of the patient's rights and responsibilities in a language and manner that the patient understands during the initial evaluation visit in advance of furnishing care. (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 inform the patient and family of the hospice's drug policies and procedures, including the policies and	

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procedures regarding the tracking and disposing of controlled substances. (4) The hospice must maintain documentation showing that it has complied with the requirements of this section and that the patient or representative has demonstrated an understanding of these rights.	
(b) *Standard: Exercise of rights and respect for property and person.* (1) 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; and (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	

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misappropriation of patient property are reported to State and local bodies having jurisdiction (including to the State survey and certification agency) within at least 5 working days of the incident, and immediately to the hospice administrator. Investigations and/or documentation of all alleged violations must be conducted in accordance with established procedures. (ii.) Immediately investigate all alleged violations and immediately take action to prevent further potential abuse while the alleged violation is being verified; (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.) Investigate complaints made by a patient or the patient's family or representative regarding treatment or care that is (or fails to be) furnished, lack of respect for the patient or the patient's property by anyone furnishing services on behalf of the hospice, and document both the existence of the complaint and the steps taken to resolve the complaint.	
(c) *Standard: Pain management and symptom control.* The patient has a right to receive effective pain management and symptom control from the hospice.	
(d) *Standard: Confidentiality of clinical records.* The hospice must maintain the confidentiality of clinical records. Access to or release of patient information and clinical records is permitted in accordance with 45 CFR parts 160 and 164.	
(e) *Standard: Patient liability.* Before care is initiated, the patient must be informed, verbally and in writing, and in a language that he or she can understand, of the extent to which payment may be expected from the patient, Medicare or Medicaid, third-party payers, or other resources of funding known to the hospice.	

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§ 418.54 Condition of participation: 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 medical, nursing, psychosocial, emotional, and spiritual care. This care includes, but is not limited to, the palliation and management of the terminal illness and related medical conditions.	
(a) *Standard: Initial assessment.* The hospice registered nurse must make an initial assessment visit within 24 hours after the hospice receives a physician's admission order for care (unless ordered otherwise by the physician), to determine the patient's immediate care and support needs.	
(b) *Standard: Time frame for completion of the comprehensive assessment.* The hospice interdisciplinary group in consultation with the individual's attending physician must complete the comprehensive assessment no later than 4 calendar days after the patient elects the hospice benefit.	
(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 describes— (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) Factors that must be considered in developing individualized care plan interventions, including— *(i.)* *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 bereavement plan of care. *(ii.)* *Drug therapy.* A review of the patient's prescription and over-the-counter drug	

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profile, including but not limited to identification of the following— (i.) Ineffective drug therapy; (ii) Unwanted drug side and toxic effects; and (iii) Drug interactions. (4) 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 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— (1) As frequently as the condition of the patient requires, but no less frequently than every 14 days; and (2) At the time of each recertification.	
(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.	

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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 and as it relates 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, social, 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 qualified health care professional 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 not the patient's attending physician). (ii) A registered nurse. (iii) A social worker. (iv) A pastoral, clergy, or other spiritual counselor. (2) If the hospice has more than one interdisciplinary group, it must designate in advance only one of those groups 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 a written plan of care established by the hospice interdisciplinary group in collaboration with the attending physician. The hospice must ensure that each patient and family and primary caregiver(s) receive education and training provided by the hospice as appropriate to the care and services identified in the plan of care.	

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(c) *Standard: Content of the plan of care.* The hospice must develop a written plan of care for each patient that reflects prescribed interventions based on the problems identified in the initial comprehensive and updated comprehensive assessments, and other assessments. The plan of care must include but not be limited to— (1) Interventions to facilitate the management of 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 targeted outcomes anticipated from implementing and coordinating the plan of care; (4) Drugs and treatment necessary to meet the needs of the patient; (5) Medical supplies and appliances necessary to meet the needs of the patient; and (6) The interdisciplinary group's documentation of patient and family 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 medical director or physician designee, and the hospice interdisciplinary team (in collaboration with the individual's attending physician to the extent possible) must review, revise and document the plan as necessary at intervals specified in the plan but no less than every 14 calendar days. A revised plan of care must include information from the patient's updated comprehensive assessment and the patient's progress toward outcomes 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 the interdisciplinary group, through its designated professionals, maintains responsibility for directing, coordinating, and supervising the care and services provided; (2) Ensure that 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; and (4) Provide for and ensure the ongoing sharing of information between all disciplines providing care and services in the home, in outpatient settings, and in inpatient settings, irrespective whether the care and services are provided directly or under arrangement.	

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§ 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; focuses on the end-of-life support services provided; 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 for which there is evidence that improvement in those indicators will improve palliative outcomes and end-of-life support 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 utilize 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— (i) Monitor the effectiveness and safety of services and quality of care; and (ii) Identify opportunities for improvement. (3) The frequency and detail of the data collection must be specified 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; and (iii) Affect palliative outcomes, patient safety, and quality of care.	

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(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.* (1) The number and scope of distinct improvement projects conducted annually must reflect the scope, complexity, and past performance of the hospice's services and operations. (2) The hospice must document what quality 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; (2) That the hospice-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety, and that all improvement actions are evaluated for effectiveness; and (3) That clear expectations for patient safety are established.	
§418.60 Condition of participation: Infection control. The hospice must maintain and document an effective infection control program that protects patients, families and hospice personnel by preventing and controlling infection 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	

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assessment and performance improvement program; and (2) Includes: (i.) A method of identifying infectious; and communicable disease problems; and (ii.) A plan for the appropriate actions that are expected to result in improvement and disease prevention.	
(c) *Standard: Education.* The hospice must provide infection control education to staff, patients, and family members or 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 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 § 418.64(a). A hospice may, under extraordinary or other non-routine circumstances, 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	

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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, conditions related to the terminal illness, and the general medical needs of the patient. (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 comprehensive assessment and updated assessments. (2) If State law permits nurse practitioners (NPs) to see, treat and write orders for patients, then NPs may provide services to beneficiaries receiving hospice care. The role and scope of the services provided by a NP that is not the individual's attending physician must be specified in the individual's plan of 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 for adjustment to death and dying must be available to	

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both the patient and the family. 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 in grief/loss counseling. (ii) Make bereavement services available to the family and other individuals in the bereavement plan of care up to one year following the death of the patient. Bereavement counseling also extends to residents and employees of a SNF/NF, ICF/MR, or other facility 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 provided and the frequency of service delivery. A special coverage provision for bereavement counseling is specified in § 418.204(c). (2) *Nutritional counseling.* Nutritional 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) Facilitate visits by local clergy, pastoral counselors, or other individuals who can support the patient's spiritual needs to the best of its ability. The hospice is not required to go to extraordinary lengths to do so; and (iv) Advise the patient and family of this service.	
§ 418.66 Condition of participation: Nursing	

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services—Waiver of requirement that substantially all nursing services be routinely provided 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 nonurbanized 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 nonurbanized 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— (1) Proof that the organization was established to provide hospice services on or before January 1, 1983; (2) Evidence that hospice-type services were furnished to patients on or before January 1, 1983; and (3) 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; and (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) CMS may approve a maximum of two 1-year extensions for each initial waiver. 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	

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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— (i) Copies of advertisements in local newspapers that demonstrate recruitment efforts; (ii) Physical therapy, occupational therapy, speech-language pathology, and dietary counselor job descriptions;	

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(iii) Evidence that salary and benefits are competitive for the area; and (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. (d) CMS may approve a maximum of two 1-year extensions for each initial waiver. If a hospice wishes to receive a 1-year extension, it must submit a request to CMS prior to 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: Home health aide and homemaker services. All home health 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: Home health aide qualifications.* (1) A qualified home health aide is a person who has successfully completed— (i) A training program and competency evaluation as specified in paragraphs (b) and (c) (ii) of this section respectively; or (iii) A competency evaluation program; or (iv) A State licensure program that meets the requirements of paragraphs (b) and (c) of this section. A home health aide is not considered to have completed a training program, or a competency evaluation program 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	

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this chapter were for compensation. If there has been a 24-month lapse in furnishing services, the individual must complete another training and/or competency evaluation program before providing services, as specified in paragraph (a)(1) of this section.	
(b) *Standard: Content and duration of home health aide classroom and supervised practical training.* (1) Home health aide training must include classroom and supervised practical classroom 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 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 home health 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;	

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(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; and (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 home health 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 home health 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 paragraphs (b)(1) through (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 home health aide with a patient. (2) A home health aide competency evaluation program may be offered by any organization, except as specified in paragraph (f) of this section. (3) The competency evaluation must be performed by a registered nurse in	

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consultation with other skilled professionals, as appropriate. (4) A home health 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. (5) The hospice must maintain documentation that demonstrates the requirements of this standard are being met.	
(d) *Standard: In-service training.* A home health 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 except one that is excluded by paragraph (f) of this section, 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 supervised practical training, competency evaluations and in-service training.* Classroom supervised practical training must be performed by or under the supervision of a registered nurse who possesses a minimum of two years nursing experience, at least one year of which must be in home health care. Other individuals may provide instruction under the general supervision of a registered nurse.	
(f) *Standard: Eligible training organizations.* A home health aide training program may be offered by any organization except by a home health agency that, within the previous 2 years— (1) Was out of compliance with the requirements of paragraphs (b) or (c) of this section; (2) Permitted an individual that does not meet the definition of a ''qualified home health aide'' as specified in paragraph (a) of this section to furnish home health aide services (with the exception of licensed health professionals and volunteers); (3) Was subjected to an extended (or partial extended) survey as a result of having been	

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found to have furnished substandard care (or for other reasons at the discretion of CMS or the State); (4) Was assessed a civil monetary penalty of $5,000 or more as an intermediate sanction; (5) Was 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; or (7) Was 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; or (v) Been closed by CMS or the State, or had its patients transferred by the State.	
(g) *Standard: Home health aide assignments and duties.* A registered nurse or the appropriate qualified therapist that is a member of the interdisciplinary team makes home health aide assignments. (1) Home health aides are assigned to a specific patient by a registered nurse or the appropriate qualified therapist. Written patient care instructions for a home health aide must be prepared by a registered nurse or other appropriate skilled professional (*i.e.*, a physical therapist, speech-language pathologist, or occupational therapist) who is responsible for the supervision of a home health aide as specified under paragraph (h) of this section. (2) A home health aide provides services that are:	

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(i) Ordered by the physician or nurse practitioner; (ii) Included in the plan of care; (iii) Permitted to be performed under State law by such home health aide; and (iv) Consistent with the home health aide training. (3) The duties of a home health aide include: (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; and (iv) Assistance in administering medications that are ordinarily self-administered. (4) Home health aides must report changes in the patient's medical, nursing, rehabilitative, and social needs to a registered nurse or other appropriate licensed professional, as the changes relate to the plan of care and quality assessment and improvement activities. Home health aides must also complete appropriate records in compliance with the hospice's policies and procedures.	
(h) *Standard: Supervision of home health aides.* i. A registered nurse or qualified therapist must make an onsite visit to the patient's home no less frequently than every 14 days to assess the home health aide's services. The home health aide does not have to be present during this visit. A registered nurse or qualified therapist must make an onsite visit to the location where the patient is receiving care in order to observe and assess each aide while he or she is performing care no less frequently than every 28 days. ii. The supervising nurse or therapist 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 home health aide by the registered nurse or qualified therapist; (ii) Creating successful interpersonal relationships with the patient and	

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family; (iii) Demonstrating competency with assigned tasks; (iv) Complying with infection control policies and procedures; and (v) Reporting changes in the patient's condition. (3) If the hospice chooses to provide home health aide services under contract with another organization, the hospice's responsibilities include, but are not limited to— (i.) Ensuring the overall quality of care provided by an aide; (ii.) Supervising an aide's services as described in paragraphs (h)(1) and (h)(2) of this section; and (iii.)Ensuring that home health aides who provide services under arrangement have met the training and/ or competency evaluation requirements of this 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 the Code of Federal Regulations, on behalf of a hospice or home health agency. Before the individual may furnish personal care services, the individual must be found competent by the State to furnish those services. The individual only needs to demonstrate competency in the services the individual is required to furnish.	
(j) *Standard: Homemaker qualifications.* A qualified homemaker is a home health aide as described in § 418.76 or 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.	
(k) *Standard: Homemaker supervision and duties.* (1) Homemaker services must be coordinated 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	

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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— (1) The identification of each position that is occupied by a volunteer; (2) The work time spent by volunteers occupying those positions; and (3) 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.	

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§ 418.100 Condition of participation:	

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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 terminal illness.	
(a) *Standard: Serving the hospice patient and family.* The hospice must ensure— (1) That each patient receives and experiences hospice care that optimizes comfort and dignity; and (2) That each patient experience hospice care that is consistent with patient and family needs and desires.	
(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 reports to the governing body and 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 within 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) Home health aide, volunteer, and homemaker services. (vi) Physical therapy, occupational therapy and speech-language pathology therapy 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	

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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 supervision 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 personnel having at least the same qualifications as hospice employees; and (3) Delivered in accordance with the patient's plan of care.	
(f) *Standard: Hospice satellite locations.* (1) All hospice satellite locations must be approved by CMS before providing hospice care and services to Medicare patients. The determination that a satellite location does or does not meet the definition of a satellite 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.	
(g) *Standard: In-service training.* 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.	

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The hospice must designate a physician to serve as medical director. The medical director must be a doctor of medicine or osteopathy who is either employed by, or under contract with, the hospice. When the medical director is not available, a physician designated by the medical director assumes the same responsibilities and obligations as the medical director. The medical director and physician designee coordinate with other physicians and health care professionals to ensure that each patient experiences medical care that reflects hospice policy.	
(a) *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 criteria 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. (5) Information about the medical management of any of the patient's conditions unrelated to the terminal illness.	
(b) *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: (1) The patient's clinical information; and (2) The patient's and family's expectations and wishes for the continuation of hospice care.	
(c) *Standard: Coordination of medical care.* The medical director or physician designee, and the other members of the interdisciplinary group are jointly responsible for the coordination of the patient's medical care in its entirety. The medical director or physician designee is also responsible for directing the hospice's quality assessment and performance improvement 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 accurate 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	

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the following: (1) The plan of care, initial assessment, comprehensive assessment, and updated comprehensive assessments, clinical notes, and progress notes. (2) Informed consent, authorization, and election forms. (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 described in § 418.102(a) and § 418.102(b) respectively. (6) Any advance directives as described in § 418.52(a)(3).	
(b) *Standard: Authentication.* All entries must be legible, clear, complete, and appropriately authenticated and dated. All entries must be signed, and the hospice must be able to authenticate each handwritten and electronic signature of a primary author who has reviewed and approved the entry.	
(c) *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 set out at 45 CFR parts 160 and 164.	
(d) *Standard: Retention of records.* Patient clinical records must be retained for 5 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-approved facility, the hospice must forward a copy of the patient's clinical record and the hospice discharge summary to that facility. (2) If a patient revokes the election of hospice care, or is discharged from hospice because eligibility criteria are no longer met, the hospice must provide a copy of the clinical	

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record and the hospice discharge summary of this section to the patient's attending physician. (3) The hospice discharge summary 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.	
(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, controlled 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: Administration of drugs and biologicals.* (1) All drugs and biologicals must be administered in accordance with accepted hospice and palliative care standards of practice and according to the patient's plan of care. (2) 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.	
(b) *Standard: Controlled drugs in the patient's home.* The hospice must have a written policy for tracking, collecting, and disposing of controlled drugs maintained in the patient's home. During the initial hospice assessment, the use and disposal of controlled substances must be discussed with the patient and family to ensure the patient and family are educated regarding the uses and potential dangers of controlled substances. The hospice nurse must document that the policy was discussed with the patient and family.	

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(c) *Standard: Use and maintenance of equipment and supplies.* (1) The hospice must follow manufacturer recommendations for performing routine and preventive maintenance on durable medical equipment. The equipment must be safe and work as intended for use in the patient's environment. Where there is no manufacturer recommendation for a piece of equipment, the hospice must develop in writing its own repair and routine maintenance policy. 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 patient, family, and/or caregiver must be able to demonstrate the appropriate use of durable medical equipment to the satisfaction of the hospice staff.	
§ 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-approved hospice that meets the conditions of participation for providing inpatient care directly as specified in § 418.110. (2) A Medicare-participating hospital or a skilled nursing facility that also meets the standards specified in § 418.110(b) and (f) regarding 24-hour nursing services and patient areas.	
(b) *Standard: Inpatient care for respite purposes.* Inpatient care for respite purposes must be provided by one of the following: (1) A provider specified in paragraph (a) of this section.	

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(2) A Medicare/Medicaid approved nursing facility that also meets the standards specified in § 418.110(b) and (f).	
(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 legally binding written agreement that 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, events regarding care that occurred at the facility, and that a copy of the inpatient clinical record and discharge summary is available to the hospice at the time of discharge; (4) That the inpatient facility has identified a individual within the facility who is responsible for the implementation of the provisions of the agreement; (5) That the hospice retains responsibility for arranging the training of personnel who will be providing the patient's care in the inpatient facility and that a description of the training and the names of those giving the training is documented; and (6) That a way to verify that requirements in paragraphs (c)(1) through (c)(5) of this section have been met is established.	
(d) *Standard: Inpatient care limitation.* The total number of inpatient days used by Medicare beneficiaries who elected hospice coverage in a 12month 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	

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that provide inpatient care directly. A hospice that provides inpatient care directly 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.* 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.	
(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. The hospice must report a breach of safety to appropriate State and local bodies having regulatory jurisdiction and correct it promptly. (ii) The hospice must take steps to prevent equipment failure and when a failure occurs, report it appropriate State and local bodies having regulatory jurisdiction and correct it promptly. (iii) 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 managing the control, reliability, and quality of— (i.) The routine storage and prompt	

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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 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 hospice. (2) In consideration of a recommendation by the State survey agency, CMS may waive, for	

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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) Beginning March 13, 2006, a hospice must be in compliance with Chapter 9.2.9, Emergency lighting. (5) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to hospices. (6) 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 (v)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 CFR part 51. A copy of the amendment is available for inspection at the CMS	

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Information Resource Center, 7500 Security Boulevard, Baltimore MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this amendment, CMS will publish 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; (v) Provide at least 80 square feet for each residing patient in a double room and at least 100 square feet	

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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 an existing building, CMS may waive the space and occupancy requirements of paragraphs (f)(2)(iv) and (f)(2)(v) of this section for a period of time 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/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;	

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(2) Palatable, attractive, and served at the proper temperature; and (3) Obtained, stored, prepared, distributed, and served under sanitary conditions.	
(m) *Standard: Pharmaceutical services.* Under the direction of a qualified pharmacist, the hospice must provide pharmaceutical services such as drugs and biologicals and have a written process in place that ensures dispensing accuracy. The hospice will evaluate a patient's response to the medication therapy, identify adverse drug reactions, and take appropriate corrective action. Drugs and biologicals must be obtained from community or institutional pharmacists or stocked by the hospice. The hospice must furnish the drugs and biologicals for each patient, as specified in each patient's plan care. The use of drugs and biologicals must be provided in accordance with accepted professional principles and appropriate Federal, State, and local laws.	
(n) *Pharmacist.* A licensed pharmacist must provide consultation on all aspects of the provision of pharmaceutical care in the facility, including ordering, storage, administration, disposal, and record keeping of drugs and biologicals. (1) *Orders for medications.* (i) 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, must order all medications for the patient. (ii) If the medication order is verbal or given by or through electronic transmission— (a) The physician must give it only to a licensed nurse, nurse practitioner (where appropriate), pharmacist, or another physician; and (b) The individual receiving the order must record and sign it immediately and have the prescribing physician sign it in accordance with State and Federal regulations. (2) *Administration of medications.* Medications must be administered by only the following individuals: (i) A licensed nurse, physician, or other	

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health care professional in accordance with their scope of practice. (ii) An employee who has completed a State-approved training program in medication administration. (iii) The patient, upon approval by the attending physician. (3) *Labeling of drugs and biologicals.* Drugs and biologicals must be labeled in accordance with currently accepted professional practice and must include appropriate accessory and cautionary instructions, as well as an expiration date (if applicable). (4) *Drug management procedures.* (i) All drugs and biologicals must be stored in secure areas. All 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 medications may have access to the locked compartments. (ii) The hospice must keep current and accurate records of the receipt and disposition of all controlled drugs. (iii) Any discrepancies in the acquisition, storage, use, disposal, or return of controlled drugs must be investigated immediately by the pharmacist and hospice administrator and where required reported to the appropriate State agency. A written account of the investigation must be made available to State and Federal officials. (5) *Drug disposal.* Controlled drugs no longer needed by a patient must be disposed of in compliance with the hospice policy and in accordance with State and Federal requirements.	
(o) *Standard: Seclusion and restraint.* (1) The patient has the right to be free from seclusion and restraint, of any form, imposed as a means of coercion, discipline,	

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convenience, or retaliation by staff. The term restraint includes either a physical restraint or a drug that is being used as a restraint. A physical restraint is any manual method or physical or mechanical device, material or equipment attached or adjacent to the patient's body that he or she cannot easily remove, that restricts free movement of, normal function of, or normal access to one's body. *A drug used, as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard treatment for a patient's medical or psychiatric condition. Seclusion is the confinement of a person alone in a room or an area where a person is physically prevented from leaving. (2) Seclusion and restraint can only be used in emergency situations if needed to ensure the patient's or others' physical safety, and only if less restrictive interventions have been tried, determined and documented to be ineffective. (3) The use of restraint and seclusion must be— (i) Selected only when less restrictive measures have been found ineffective to protect the patient or others from harm; (ii) Carried out in accordance with the order of a physician. The following will be superseded by more restrictive State laws: (a) Orders for seclusion or restraints must never be written as a standing order or an as needed basis (that is, PRN). (b) The hospice medical director or physician designee must be consulted as soon as possible if restraint or seclusion is not ordered by the hospice medical director or physician designee. (c) A hospice medical director or physician designee must see the patient and evaluate the need for restraint or seclusion within 1 hour after initiation of this	

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intervention. (d) Each order for a physical restraint or seclusion must be in writing and limited to 4 hours for adults; 2 hours for children and adolescents ages 9 through 17; or 1 hour for patients under the age of 9. The original order may only be renewed in accordance with these limits for up to a total of 24 hours. After the original order expires, a physician must reassess the patient's need before issuing another seclusion and restraint order. (iii) In accordance with the interdisciplinary group and a written modification to the patient's plan of care; (iv) Implemented in the least restrictive manner possible not to interfere with the palliative care being provided; (v) In accordance with safe, appropriate restraining techniques; (vi) Ended at the earliest possible time; and (vii) Supported by medical necessity and the patient's response or outcome, and documented in the patient's clinical record. (4) A restraint and seclusion may not be used simultaneously unless the patient is— (i) Continually monitored face to face by an assigned staff member; or (ii) Continually monitored by staff using video and audio equipment. Staff must be in immediate response proximity to the patient. (5) The condition of the patient who is in a restraint or in seclusion must continually be assessed, monitored, and reevaluated by an assigned staff member. (6) All staff who have direct patient contact must have ongoing education and training in the proper and safe use of seclusion and restraint application and techniques and alternative methods for handling behavior, symptoms, and situations that traditionally have been treated through the use of restraints or	

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seclusion. (7) The hospice must report to the CMS regional office any death that occurs while the patient is restrained or in seclusion, within 24 hours after a patient has been removed from restraint or seclusion.	
§ 418.112 Condition of participation: Hospices that provide hospice care to residents of a SNF/NF, ICF/MR, or other facilities. 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, ICF/MR, or other residential facility 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 other facility must meet the Medicare hospice eligibility criteria as identified in § 418.20 through § 418.30.	
(b) *Standard: Professional management.* The hospice must assume full responsibility for professional management of the resident's hospice care, in accordance with the hospice conditions of participation and make any arrangements necessary for inpatient care in a participating Medicare/Medicaid facility according to §418.100.	
(c) *Standard: Core services.* A hospice must routinely provide all core services. These services include nursing services, medical social services, and counseling services. The hospice may contract for physician services as stated in § 418.64(a). A hospice may use contracted staff provided by another Medicare certified hospice to furnish core services, if necessary, to supplement hospice employees in order to meet the needs of patients under extraordinary or other non-routine circumstances, as described in § 418.64.	
(d) *Standard: Medical director.* The medical director and physician designee of the hospice must provide overall coordination of the medical care of the hospice resident that resides in an SNF, NF, or other facility. The medical director and physician designee must communicate with the medical director of the SNF/NF, the patient's attending physician, and other physicians participating in the provision of care for the terminal and related conditions to ensure quality care for the patient and family.	
(e) *Standard: Written agreement.* The hospice and the facility must have a written agreement that specifies the	

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provision of hospice services in the facility. The agreement must be signed by authorized representatives of the hospice and the facility before the provision of hospice services. The written agreement must include at least the following: (1) The written consent of the patient or the patient's representative that hospice services are desired. (2) The services that the hospice will furnish and that the facility will furnish. (3) The manner in which the facility and the hospice are to communicate with each other to ensure that the needs of the patient are addressed and met 24 hours a day. (4) A provision that the facility immediately notifies the hospice if— (i) A significant change in the 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 life threatening condition appears; (iv) A need to transfer the patient from the facility and the hospice makes arrangements for, and remains responsible for, any necessary continuous care or inpatient care necessary related to the terminal illness; or (v) The patient dies. (5) A provision stating that the hospice assumes responsibility for determining the appropriate course of care, including the determination to change the level of services provided. (6) An agreement that it is the facility's primary responsibility to furnish room and board. (7) A delineation of the hospice's responsibilities, which include, but are not limited to, providing medical direction and management of the patient, nursing, counseling (including spiritual and dietary counseling), social work, bereavement counseling for immediate family members, provision of medical supplies and durable medical equipment, and drugs necessary for the palliation of pain and symptoms associated with the terminal illness, as well as all other hospice services that are necessary for the care of the resident's terminal illness.	

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(8) A provision that the hospice may use the facility's nursing personnel where permitted by law and as specified by the facility to assist in the administration of prescribed therapies included in the plan of care only to the extent that the hospice would routinely utilize the services of a hospice resident's family in implementing the plan of care.	
(f) *Standard: Hospice plan of care.* A written plan of care must be established and maintained for each facility patient and must be developed by and coordinated with the hospice interdisciplinary group in consultation with facility representatives and in collaboration with the attending physician. All care provided must be in accordance with this plan. The plan must reflect the hospice's policies and procedures in all aspects and be based on an assessment of the patient's needs and unique living situation in the facility. It must include the patient's current medical, physical, social, emotional, and spiritual needs. Directives for management of pain and other symptoms must be addressed and updated as necessary to reflect the patient's status. (1) The 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 plan of care. (2) The plan of care reflects the participation of the hospice, the facility, and the patient and family to the extent possible. (3) In conjunction with representatives of the facility, the plan of care must be reviewed at intervals specified in the plan but no less often than every 14-calendar day. (4) Any changes in the plan of care must be discussed among all caregivers and must be approved by the hospice before implementation.	
(g) *Standard: Coordination of services.* The hospice must designate a member of its interdisciplinary group to coordinate the implementation of the plan of care with the representatives of the facility. The hospice must provide the facility with the following information: (1) Plan of care. (2) Patient or patient's representative hospice consent form and advance directives. (3) Names and contact information for hospice personnel involved in hospice care of the patient. (4) Instructions on how to access the hospice's	

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24-hour on-call system. (5) Medication information specific to the patient (6) Physician orders.	
(h) *Standard: Transfer, revocation, or discharge from hospice care.* Requirements for discharge or revocation from hospice care, § 418.104(e), apply. Discharge from or revocation of hospice care does not directly impact the eligibility to continue to reside in an SNF, NF, ICF/ MR, or other facility.	
(i) *Standard: Orientation and training of staff.* Hospice staff must orient facility 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 for licensed professionals. (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) to practice by the State in which he or she performs such functions or actions, 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 physicians, speech-language pathologists, and home health aides. The following qualifications must be met: (1) *Physicians.* 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) *Speech language pathologists.* Speech language pathologists must meet the qualifications specified in section 1861(ll)(1) of the Act. The individual must have a master's or doctoral degree in speech-language pathology and must— (i) Be licensed as a speech-language pathologist by the State in which the individual furnishes such services, or, (ii) In the case of an individual who	

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furnishes services in a State which does not license speech-language pathologists, must: (a) Have successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating such supervised clinical experience), (b) Have performed not less than 9 months of supervised full-time speech language pathology services after obtaining a master's or doctoral degree in speech-language pathology or a related field, and successfully completed the Praxis National Examination in Speech-Language Pathology. (3) *Home health aides.* Home health aides must meet the qualifications required by section 1891(a)(3) of the Act and implemented at § 484.75.	
(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) *Occupational therapist.* An occupational therapist must— (i) Be a graduate of an occupational therapy curriculum accredited by the American Occupational Therapy Association, and be eligible for the National Registration Examination of the American Occupational Therapy Association; or (ii) Have 2 years of appropriate experience as an occupational therapist, and have achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as an	

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occupational therapist after December 31, 1977. (2) *Occupational therapy assistant.* An occupational therapy assistant must— (i) Meet the requirements for certification as an occupational therapy assistant established by the American Occupational Therapy Association; or (ii) Have 2 years of appropriate experience as an occupational therapy assistant, and have achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapy assistant after December 31, 1977. (3) *Physical therapist.* A person who— (i) Has graduated from a physical therapy curriculum approved by— (a) The American Physical Therapy Association; (b) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association; or (ii) Prior to 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; or (c) Has graduated from a physical therapy curriculum in a 4-year college or university approved by a State department of education; or (iii) Has 2 years of appropriate experience as a physical therapist, and has achieved a satisfactory grade on a proficiency examination conducted, approved,	

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or sponsored by the U.S. Public Health Service except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking qualification as a physical therapist after December 31, 1977; or (iv) Was licensed or registered prior to January 1, 1966, and prior to January 1, 1970, had 15 years of full-time 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; or (v) If trained outside the United States— (a) Has 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. (4) *Physical therapist assistant.* A person who— (i) Has graduated from a 2-year college-level program approved by the American Physical Therapy Association; or (ii) Has 2 years of appropriate experience as a physical therapy assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that these determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as a physical therapy assistant after December 31, 1977.	

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(5) *Registered nurse.* A graduate of a school of professional nursing. (6) *Licensed practical nurse.* A person who has completed a practical nursing program. (7) *Social worker.* A person who has a baccalaureate degree from a school of social work accredited by the Council on Social Work Education.	
(d) *Standard: Criminal background checks.* The hospice must obtain a criminal background check on each hospice employee and contracted employee before employment at the hospice.	
§ 418.116 Condition of participation: Compliance with Federal, State, and local laws and regulations related to 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: Licensure of staff.* Any persons who provide hospice services must be licensed, certified, or registered in accordance with applicable Federal, State and local laws.	
(b) *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 satellite locations must be approved by CMS and licensed in accordance with State licensure laws, if applicable, before providing Medicare reimbursed services.	
(c) *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.	
§ 418.200 [Amended] 6. Section 418.200 is amended by revising the reference	

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"§ 418.58" to read "§418.56".	
§ 418.202 [Amended] 7. In § 418.202, paragraph (e) is amended by revising the reference "§ 418.98(b)" to read "§ 418.108(b)" and paragraph (g) is amended by revising the reference "§ 418.94" to read "§ 418.76".	

Subpart G – Payment for Hospice Care	*2005 CMS PROPOSED COPS*
	No changes are proposed to this Subpart at this time.

Subpart H – Coinsurance	*2005 CMS PROPOSED COPS*
	No changes are proposed to this Subpart at this time.

Submitter : **Ms. Lores Vlaminck** **Date: 07/26/2005**

Organization : **Minnesota Home Care Association**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

It is most exciting to review the level of discussion that was integrated into the proposed conditions of participation for hospice. The process has been ardous and significantly collaborative. We are looking forward to changes that will impact our patients for the positive.

Issues 1 - 10

Personnel Qualifications

418.114 (7) d Clarification for all hospice employees with direct patient contact and what about including all hospice volunteers with direct patient contact.

Residents Residing in a Facility

418.112 (d) Requiring the hospice medical director communicate with the LTCF medical director would not ensure communication about the individual hospice patient. While the hospice medical director and LTCF medical director may communicate from a programmatic standpoint, the communication patient by patient may not be timely nor helpful. Often the LTCF medical director is not aware of each resident, nor has direct involvement with their care. Realistically, it is the IDG that is interfacing with the staff of the LTCF which may include the medical director.
418.112 (e) 1 The contract with the LTCF doesn't include individual patient consent. Under the contract with the LTCF facility, CMS may require that each resident's clinical record contain a signed consent for hospice care.
418.112 (d) Requiring the hospice medical director communicate with the LTCF medical director would not ensure communication about the individual hospice patient. While the hospice medical director and LTCF medical director may communicate from a programmatic standpoint, the communication patient by patient may not be timely nor helpful. Often the LTCF medical director is not aware of each resident, nor has direct involvement with their care. Realistically, it is the IDG that is interfacing with the staff of the LTCF which may include the medical director.
418.64 Bereavement services provided in LTCF would be appropriate. Collaboration with the LTCF to assess and meet needs should be ongoing. Each LTCF may have different expectations of their staff's needs. There will be increasing needs for the staff of assisted living, adult day, etc to have access to grief support. Ways that hospice agencies might currently be meeting those needs are through invitations of LTCF staff to memorial services, grief support groups, access to the grief library, inservices, etc What is the expectation of CMS as the duration of bereavement care to LTCF staff?

Organization and Administration

418.100 Subscribe to the recommendations of NHPCO

Inpatient Care

418.108 Suggest the inclusion of caregiver breakdown or significant change in support systems due to emotional crises.
418.108 (b) Much appreciated change in removing the requirement for 24 hour RN coverage for respite care. This has basically eliminated hospices from contracting with LTCF's many have RN/LPN's around the clock. Hospice agencies already have a RN on call 24/7.
418.110 c (3) Requiring the entire clinical record is cumbersome. Requiring the appropriate records to provide the assurance of continuity of care with the access to the complete record would be reasonable. Discharge summaries from LTCF or Acute care settings is not usually available upon discharge

Medical Director

418.102 Recommend the hospice agency may appoint an alternate medical director, not the Medical Director. The hospice agency has to establish the contract, orientation, etc, not the Medical Director.
418 102 (b)

418 102 (b)How would the physician assess the patient/family wishes for continued care? Could the wording state ?Members of the IDG team will assess the patient/family wishes for continued care at recertification and the Medical Director will assess for appropriateness of hospice care
418.102 (c) As in Medicare certified home care agencies, a designee of the agency is assigned the responsibility of QAPI.. not the Medical Director. Reporting requirements then could include the Medical Director, Governing Body, or IDG

Social Work

418.114 (7) Concur with the SW having a minimum of a bachelors degree in social work

Clinical Records

418.104

Electronic records are widely used in home care settings and increasingly so in hospice. Systems written for hospice provide excellent information that is current for staff that are on call and need to share the file of the client. Obviously safeguards for confidentiality and HIPAA are respected and adhered to. However, some agencies do not have electronic records and possibly will not for some time. Allowing agencies the flexibility of method of capturing the clinical record but mandating the minimum data is appropriate.
418.104 (d) Retention for six years would correspond with HIPAA

418.104 (2) Most physicians would not want the entire client record for a discharged or transferred patient. Certainly, they have access to the record and it should be provided as requested. Requirements for a discharge/transfer summary to be submitted to the MD would be appropriate.

Drugs, Supplies, and DME

418.106 What does the proposed language mean for tracking of the controlled substance in a patient's home mean? Using the words of patient and family are educated in the uses and potential dangers might be reworded to include the following: action, side effects, and safety of patient use or alternate use of words that doesn't promote fear.

Issues 11 - 18

Outcome Measures

418.54 We would recommend that CMS work with the industry to develop outcome measures, while reviewing the current methods that have been in practice.

QAPI

418.58 This entire section will be more challenging for some providers with current methods of charting than for others. Allowing flexibility for the providers, but also requiring measure of quality improvement and quality assessment is appropriate. Some states are currently requiring such levels of indicators with the state licensure rules. Language that allows the agency to choose their method, but with guidelines from CMS would be helpful. (This may be adopting several different templates already available in the industry, NHPCO, HHA, etc)

Patients Rights

418.52 (2) Is a copy of the agency's written policy on controlled substance destruction adequate as part of the admission packet and signature obtained that it was received by the patient? We recommend that the agency policy on the destruction of narcotics be included in the admission packet.
418.52 (c) Suggest a requirement that written information be provided upon admission for those residing in LTCF or other facilities in which they are financially responsible for room and board. This may include hospice residential hospices, adult foster care, assisted living, etc

Assessment Time Frames

418.54 (a) If the requirement for the initial assessment be made within 24 hours after the hospice receives the order for admission, it may be appropriate that in select cases, the social worker be allowed the opportunity for the assessment. There are times in which the needs are not primarily physical in nature and certainly appropriate that a RN make the second visit for physical assessment. The requirement of an assessment within 24 hours of physician's order for care will be cumbersome for agencies. Also, possibly not appropriate for some clients who desire family to be present at the first visit, reside in a LTCF, or other exceptions.
418.54 (b) Completion of the comprehensive assessment by the IDG team and the attending physician in 4 days will be difficult. Some agencies have part-time chaplains, social workers that may be not available until day 5? for example. We recommend 7 days to be the window of allowance for completion.
Expanding the requirement for the attending physician to read, individual's attending physician or the hospice medical director provides latitude to the hospice agency, but still provides the physician's oversight of the care plan.
418.54 (c) Specifications of the comprehensive assessment should be prioritized to the needs of the terminal illness. Would it seem appropriate to do the bereavement assessment outside of the window of the requirement for the comprehensive assessment? (perhaps during the after the first IDG meeting following admission) If the RN is required to provide the initial assessment, it would seem there is a greater window of time in which to conduct the bereavement assessment than 4 days. It is difficult to assess the bereavement needs of the family whose relative has been admitted to hospice near imminent death. Priorities of palliation, spiritual needs, etc should take precedence. Bereavement assessments could be required with a larger window for the time of completion.

Plan Of Care or Coordination of Services

418.56 (a) Appreciate the fact that an IDG team member can be the designee for the plan of care rather than specifically and only the RN?.
418.56 (c) What does it mean to have the family agree with the plan of care, not all do. Is the intent that the care plan be shared with family which may be verbally or in writing?
418.56 (e) 4) that sharing of information regarding the plan of care is documented regardless of the method: electronic, electronic means, fax, tele-health, etc
418.76 4 (h) Supervision of HHA's in Medicare home care agencies for client's with skilled needs is every 14 days. It would seem that in keeping with this standard, the home healthaide services in hospice would be supervised every 14 days by a qualified professional. Allowing the flexibility for supervision to be on-site with the patient only then alternating on-site with the HHA and patient meets the standard of care need in our experience. Certainly the agency can supervise more frequently as they determine necessary. To require on site with the HHA present every 14 days is cumbersome. Another suggestion might be to consider every 2 weeks rather than every 14 days or less. We would suggest consideration of expanding the supervision to every month or two months as requirements for this level of care is specifically that of a Home Healthaide, not a personal care aide.

Submitter : Ms. Kimberly Ashcraft **Date:** 07/26/2005

Organization : Charleston Area Medical Center

Category : Nurse Practitioner

Issue Areas/Comments

GENERAL

GENERAL

As an NP, in order to better be able to provide continuity of services for Hospice patients, NPs need to be able to certify and re-certify the terminal illness. Prescription authority varies per state.

NPs hired by Hospice, should have the ability to charge for home visits or I/P visits as the Medical Director does for those instances when the Medical Director isn't able to provide that service. This ability would allow a greater number of patients in Hospice to be served as the Hospice is able to expand their patient base and number of services. The need continues to increase with little ability for a Medical Director to provide adequate services in a large geographical area.

Submitter : Trude Powers

Organization : Trude Powers

Category : Social Worker

Date: 07/26/2005

Issue Areas/Comments

Issues 1 - 10

Social Work

I am writing to voice my opposition to the proposed change which would require an MSW rather than the present regulation which calls for MSW supervision of the BSW. I practice in a rural area which does have a limited number of master's prepared social workers. We have many experienced BSW's who are currently employed in hospice agencies. The proposed rule, allowing a "social work assistant" in lieu of the MSW, would cause a further dilution of the social work profession and would not necessarily provide hospice patients with the skills that are learned in a social work curriculum.

Submitter : Ms. Barbara Biglieri

Date: 07/26/2005

Organization : California Association for Health Services at Home

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment. Please feel free to e-mail me at bbiglieri@cahsah.org or call me at (916) 569-2469 requesting me to e-mail you the document or with questions. Thank you, Barbara

Submitter : **Mr. James Keresztury** **Date: 07/26/2005**

Organization : **West Virginia University**

Category : **Social Worker**

Issue Areas/Comments

GENERAL

GENERAL

To: Centers for Medicare and Medicaid Services

West Virginia University is providing comment on the CMS-3844-P, Hospice Conditions for Participation. Specifically, the personnel qualifications for a hospice social worker. A hospice social worker needs to have a high level of expertise to practice with individuals and their families affected by dying, death, and bereavement. CMS is specifically soliciting comments on the standard qualification for a hospice social worker. Our organization is in agreement with and supports the National Association of Social Workers comments submitted to raise the standard qualification of a hospice social worker to a Master of Social Work degree from an accredited program. In rural areas where an MSW is not available, a BSW who is supervised by an MSW or a licensed mental health professional, is the minimum requirement recommended for a hospice social worker. These regulations would then correspond to the home health conditions of participation.

Thanks for the opportunity to comment.

Sincerely,

James Keresztury, ACSW, MBA

Submitter : Saundra Stark

Organization : Saundra Stark

Category : Individual

Date: 07/26/2005

Issue Areas/Comments

Issues 1 - 10

Clinical Records

Providing for the voluntary adoption of EHR's by Hospices is important; however, other CMS/Federal regulations need to address the ability of hospitals, hospices, physicians and other caregivers to work collaboratively to develop personal health records that can be accessed and used in multiple care sites, including the patient's home.

Submitter : **Mrs. Brenda Wimmer**

Date: **07/26/2005**

Organization : **Burgess Hospice**

Category : **Individual**

Issue Areas/Comments

Issues 1 - 10

Social Work

THe idea of an MSW being the primary counseling service would affect accesibility of hospice patients to care. In rural areas, it is difficult to find a BSW meeting the requirements let alone an MSW.

Clinical Records

Supervisory visits of home health aides every 14 days with aide not present is not an issue. However, the 28 day requirement is troublesom. Home health aides, when nursing service is present in home care, do not need direct observation and assesment. At times in hospice, we purposely schedule nurse and aide visits onopposite days to provide more coverage to the patient/family. This is not a positive outcome for the patient/family.

Sending a copy of the entire hospice rcord upon discharge or transfer of a hospice patient is unwelcome and unnecessary. A concise discharge summary would give the necessary information in a nonburdensome way to physicians and other health care providers.

Medical Director

It seems the Medical Director's role has been elevated above the IDG's in the new COP's. The hospice team has been and should continue to be the driving force behind a hospice patient's care, not a single member.

Daily contact betwen hospice patients, hospice team, and nursing facility staff will not come from the medical directors of the hospice and facility. It wold be more workable to have the designe be a member of the IDG. Why have regulation that will not be followed in "real life" because it is simply not going to be that way.

Issues 11 - 18

QAPI

The statement that the medical director is reponsible for the directing of the quality assessment and performance improvement program is unrealistic. With volunter medical directors in rural areas, they have enough on their plate without directing QA. The chances of this occuring wold be quite remote. Why not place the responsibility with who will direct the QA program in reality: the IDG?/

Submitter : Dr. Joan Zlotnik

Date: 07/26/2005

Organization : Institute for the Advancement of Social Work Resea

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

See Attachment Regarding Social Work Qualifications

CMS-3844-P-123-Attach-1.DOC

RESEARCH • PRACTICE
IASWR
EDUCATION • POLICY

July 26, 2005

The Honorable Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3844-P
P.O. Box 8010
Baltimore, MD 21244-8010

Re: CMS-3844-P, Proposed rule: Medicare and Medicaid Programs: Hospice Conditions of Participation, "PERSONNEL QUALIFICATIONS" and "SOCIAL WORK"

Dear Mr. McClellan:

The Institute for the Advancement of Social Work Research (IASWR) welcomes the opportunity to offer comments regarding the proposed regulations for the Medicare and Medicaid Programs: Hospice Conditions of Participation, referenced as CMS-3844-P, published in the *Federal Register* on May 27, 2005 (70 Fed. Reg. 30,840 (2005), to be codified as 42 CFR Part 418).

The mission of IASWR is to strengthen the connections between research and practice and research and policy and to support the development of knowledge for social work practice. A particular focus for social work research is those populations who are often at highest risk and most vulnerable due to gaps in healthcare quality and access. The critical and often crisis nature of care at the end of life, and the need for intensive interventions is one such area of study and research suggest that the expertise of a qualified professional social worker is required.

This is in keeping with the findings of the National Hospice and Palliative Care Organization (NHPCO) March 2000 study cited by CMS, indicating that "...hospice programs will benefit by hiring the best qualified and most experienced social workers available." Social workers skillfully assess the patient and family situation, and develop an individualized plan of intervention to address the unique psychosocial and emotional needs of that patient and family at this most crucial life juncture. Patients and families deserve to have the most qualified social work professional available to guide them through the patient's terminal illness, dying process, death, and bereavement period.

IASWR supports the recommendation made by Dr. Elizabeth Clark of the National Association of Social Workers (NASW) minimum qualifications for a hospice social workers be a person with an MSW degree from an accredited program, at least two years of health care experience and eligibility for licensing in the state where practicing. In rural areas, where access to an MSW is sometimes limited, we support the NASW recommendation that at a minimum, hospice social workers should possess a Bachelor of Social Work degree and be supervised by a master's level licensed social worker, or, if none is available, a mental health professional licensed at the master's level or higher. IASWR opposes any designation of a social worker that includes bachelor's level workers in a discipline other than social work.

In regards to the remaining proposed rules to improve hospice care, IASWR supports:

- The requirement for more timely patient assessment;

- Replacing the quality assurance requirement with a more comprehensive quality assessment and performance improvement (QAPI) condition of participation that enables hospices to take tailored proactive steps to ensure quality care;

- Allowing hospices to contract for core services in certain situations (NASW recommends the requirement that social work services be in conjunction with the qualifications outlined in our recommendations for a qualified hospice social worker); and

- Adding guidance for hospices that care for residents of nursing facilities. These long-term care residents may be particularly vulnerable and added guidance regarding their hospice care would ensure quality hospice care during the dying and death process.

IASWR has just completed, with support from the Agency for Healthcare Research and Quality (AHRQ) a report on *Evaluating Social Work Services in Nursing Homes: Toward Quality Psychosocial Care and its Measurement (*available at www.iaswresearch.org). The need to ensure that adequate and appropriate end of life care is provided in nursing facilities is a growing concern.

IASWR appreciates the extensive work by CMS to research and develop proposals on these vital needs and issues. Please let us know if we can provide any additional information to substantiate these recommendations or to assist in improvement of end of life, nursing facility and palliative care services. I can be reached at 202 336 8393 or jlziaswr@naswdc.org. Thank you for your careful attention to our comments.

Sincerely,

Joan Levy Zlotnik

Joan Levy Zlotnik, PhD, ACSW
Executive Director

Submitter : Ms. Judy Regotti

Organization : TrinityCare Hospice

Category : Hospice

Date: 07/26/2005

Issue Areas/Comments

Issues 11 - 18

Assessment Time Frames

418.54 (a) Initial Assessment. 1. We recommend a wording change to clarify the nursing process of assessment. The hospice registered nurse must Perform and Document an initial assessment visit (rather than make).....
2. 'physician admission order' should be clarified as well to include evaluation and certification of terminal illness.
3. This standard must include a provision for the patient/family/caregiver to defer the initial visit or change it to meet their individual needs. Suggestion for the wording would be... 'unless ordered otherwise by the physician or requested by the patient and/or family'
4. Also recommend a provision in this standard for the event of another discipline performing the initial assessment as may be indicated by evidence of an acute problem other than one of a medical nature, i.e. it may be more appropriate to have the social worker make an initial visit when the predominant need is assistance with placement of the patient in a facility for safety and/or caregiving issues. Of course a regisitered nurse assessment should follow shortly thereafter.

Submitter : **Ms. Trisha Kurtz** **Date: 07/26/2005**

Organization : **JCAHO**

Category : **Private Industry**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-3844-P-125-Attach-1.DOC

Joint Commission

Setting the Standard for Quality in Health Care

Attachment #125

July 26, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS- 3844-P
P.O. Box 8013
Baltimore, MD 21244-1850

RE: Comments on the proposed rule "Medicare and Medicaid Programs; Hospice Conditions of Participation"

File Code: CMS- 3844-P

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) appreciates the opportunity to comment on the proposed rule that would set forth revisions to the hospice conditions of participation (CoPs) for approval (or continued participation) in the Medicare and Medicaid programs. The Joint Commission evaluates and accredits nearly 15,000 health care organizations in the United States, including the preponderance of our nation's hospitals. Since 1999, the Joint Commission has been approved for hospice deeming authority. More than 800 hospices are currently accredited by the Joint Commission, of which 62 use accreditation for deemed status.

The Joint Commission commends CMS for proposing a comprehensive revision to the hospice CoPs. As we have previously commented, the Joint Commission believes the fragmented approach CMS is using to update the hospital CoPs undermines progress in improving the quality and safety of patient care in our nation's hospitals.

In general, CMS's proposed changes move Medicare's hospice requirements closer to the Joint Commission's accreditation standards. We offer a few specific comments on the following subparts:

- Definitions (§418.3)
- Outcome Based Performance Measures
- Conditions of Participation: Patient Rights (§418.52)
- Conditions of Participation: Comprehensive Assessment of the Patient (§418.54)
- Conditions of Participation: QAPI (§418.58)
- Conditions of Participation: Infection Control (§418.60)
- Conditions of Participation: Waiver of Requirement (§418.74)
- Conditions of Participation: Volunteers (§418.78)
- Conditions of Participation: Medical Director (§418.102)
- Conditions of Participation: Clinical Records (§418.104)
- Conditions of Participation: Drugs and DME (§418.106)
- Conditions of Participation: Short term In-patient Care (§418.108)

If you have any question or require additional information regarding the comments provided below, please contact Trisha Kurtz, Director of Federal Relations at pkurtz@jcaho.org or Laura Blum, Associate Director of Federal Relations, at lblum@jcaho.org. Both Trisha and Laura can be reached by telephone at 202.783.6655.

Definitions *(§418.30)*

The proposed rule would update certain terms used in the hospice CoPs, as well as codify new definitions for hospice care that reflect contemporary practices.

Joint Commission Comment. The Joint Commission asked CMS to consider (1) changing the scope of the definition of attending physician, (2) using the Joint Commission's definition of restraint, 3) defining spiritual assessment and, 4) adopting the Joint Commission's Patient Safety Taxonomy for defining terms such as adverse medical event.

Attending Physician

The Joint Commission supports the inclusion of all providers whose scope of practice allows them to fulfill this role. However, it is confusing to include nurse practitioners under the definition of attending physician. For clarity, CMS should consider a) adding the term attending

nurse practitioner as a separately defined practitioner or b) using the term attending physician/attending nurse practitioner.

Restraint

The Joint Commissions suggests that CMS consider adopting the following definition of restraint, including chemical and physical restraint:

> *Any method (chemical or physical) of restricting a patient's freedom of movement, including seclusion, physical activity, or normal access to his or her body that (1) is not a usual and customary part of a medical diagnostic or treatment procedure to which the patient or his or her legal representative has consented; (2) is not indicated to treat the patient's medical condition or symptoms; or (3) does not promote the patient's independent functioning.*
> *chemical restraint: The inappropriate use of a sedating psychotropic drug to manage or control behavior.*
> *physical restraint: Any method of physically restricting a person's freedom of movement, physical activity, or normal access to his or her body.*

Spiritual Assessment

The Joint Commission recommends defining the term "spiritual assessment" in the context of spiritual counseling (§418.64) to ensure that the patient's spiritual needs are not solely assessed from religious affiliations. Religion may be defined as a specific set of beliefs and practices, usually associated with an organized group. Spirituality may be defined as a person's sense of peace, purpose, beliefs and connection to others. Spirituality can be expressed through an organized religion or in other ways. A spiritual assessment may include questions relating to religious denomination, belief or philosophy on life, important spiritual rituals or practices, loss of faith, concerns about death and the afterlife. In the context of spiritual counseling, it would also be useful to define the type of personnel that is qualified to provide a spiritual assessment[1]

[1] In the oncology community, researchers have developed tools for spiritual assessment for patients receiving radiation therapy for newly diagnosed cancers. Michael L. Revord, Stephen T. Lutz, Methodist Healthcare Systems of Memphis, Memphis, TN. "Spiritual Well-Being Remains High Even as Other Domains Decline: a Quality of Life Study in Patients Receiving Radiation Therapy for Newly Diagnosed Cancers." ASCO Annual Meeting 2001. http://www.asco.org/ac/1,1003,_12-002643-00_18-0010-00_19-002977,00.asp

Adverse Medical Event

The importance of using standardized definitions to improve communication cannot be overemphasized. The Joint Commission's experience in helping our accredited facilities address adverse events prompted us to develop a patient safety event taxonomy. The taxonomy has been endorsed by numerous health care entities, including the World Health Organization. The Joint Commission believes that adoption of the patient safety taxonomy will decrease confusion, improve patient safety and promote quality.[2]

Outcome-Based Performance Measures for Hospice

In the proposed rule, CMS would require hospices to implement an outcome-based internal performance improvement program that can be used for internal quality improvement.

Joint Commission Comment. The Joint Commission is supportive of hospices collecting data for internal performance improvement. The inclusion of outcome based performance measures such as those developed by the National Hospice and Palliative Care Organization, is a good start. We suggest that hospices be required to collect data on at least two process or outcome measures. In addition to our support of data collection for internal performance measurement and quality improvement, the Joint Commission recommends that CMS consider requiring hospices to publicly report performance measurement results to help consumers and their providers select a hospice that best meets their needs. CMS should consider using NQF's hospice measures following their endorsement, which is expected by Spring, 2006.

Until such time as a consensus set of performance measures is established and implemented for hospice care, we recommend that CMS require hospices to comply with the following requirements as a mechanism to assess quality and target quality improvement efforts. These requirements are adapted from the Joint Commission's hospice accreditation program. Each hospice should:

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2 Chang A, Schyve PM, Croteau RJ, O'Leary DS, Loeb JM. The JCAHO patient safety event taxonomy: a standardized terminology and classification schema for near misses and adverse events. *International Journal for Quality in Health Care* 2005: pp.1-11.

- identify six performances measures from among the universe of ORYX performance measures/collect data internally and generate either run charts or control charts on each measure, at least quarterly for use in internal quality improvement activities;
- make data reports available during on-site surveys; and
- use the data to identify priorities for performance improvement activities.

Conditions of Participation: Patient Rights (§418.52)

CMS proposes to replace the current CoP, which focuses narrowly on informed consent, with a broader condition that addresses patient rights.

Joint Commission Comment. The Joint Commission commends CMS's recognition of the necessity to balance the hospice's flexibility with the protection of an individual patient's rights. The Joint Commission also recommends that CMS consider adopting the language that the Joint Commission uses in our standard RI 2.20 which states:

> *Patients receive information about their rights. The elements of performance are: information on rights is provided to each patient; the patient has the right to access, request amendments to, and receive an accounting of disclosures regarding his or her own health information as permitted under applicable law. The organization provides the patient with a written statement of the scope of care or services provided to the patient directly or through contractual arrangement*

Additionally, for the proposed standard on pain management and symptom control, CMS should consider the Joint Commission's standard (PC 8.10) which states that "when pain is identified, the patient is assessed and treated by the organization or referred for treatment."

Conditions of Participation: Comprehensive Assessment of the Patient (§418.54)

CMS proposes a new CoP on providing a comprehensive assessment of pain. In the preamble CMS states that the intent of this new CoP is to reflect the view that a patient-centered, interdisciplinary, and systematic patient assessment is essential to improving patient quality of care and patient outcomes.

Joint Commission Comment. The Joint Commission supports the initial comprehensive assessment plan as well as the 14-day assessment updates. CMS recognizes that the new 14-day time frame for updating the comprehensive assessment is setting a higher expectation than is currently in effect. Because hospice staff is accustomed to frequently assessing for pain, we do not believe that updating the comprehensive assessment every 14 days will be a burden.

On the issue of whether hospice should accept new patients if it cannot meet the proposed timeframe, CMS should consider the following question: does the risk of impeding access to hospice care outweigh the improved patient outcomes that may result from 14-day assessment updates?

Conditions of Participation: QAPI (§418.58)

CMS proposes to update the quality assurance CoP with a requirement that hospices develop, implement and maintain an effective data driven quality assessment and performance improvement program (QAPI). As part of this condition, hospices will be expected to maintain a program that shows measurable improvement in indicators that are linked to improving palliative outcomes and end-of-life support services. The hospice will be expected to measure, analyze and track these quality indicators including adverse patient events.

Joint Commission Comment: The Joint Commission generally concurs with the process as outlined in this proposed CoP. Further, the Joint Commission stresses the need for a standardized set of quality measures. We encourage CMS to continue to identify (or develop) sets of measures that capture a more complete picture of a hospice's performance. Also, as mentioned above, the Joint Commission recommends that CMS consider public reporting of a standard set of performance data for all of its programs.

The development and implementation of a comprehensive data driven program to monitor and evaluate performance, will promote patient safety and quality driven processes. The elements that the Joint Commission views as essentials for the revised QAPI program are: electronic

prescribing, clinical decision support, bar coding, adverse event reporting systems, and provider and patient education. Because clinical decisions should be made on sound therapeutic choices and not on financial incentives or disincentives, clinical decision support is an essential element of any quality assurance system. The quality improvement system should be able to assess all licensed, independent practitioners' clinical decisions, as well as pharmacists' performance in adhering to the recommended clinical decision protocols. The Joint Commission also supports the use of bar codes. We encourage facilities that we accredit to adopt bar coding or other auto identification methodologies (e.g., RFID) as a mechanism to avoid adverse medical events.

Conditions of Participation: Infection Control (§418.60)

CMS is proposing a new CoP on infection control [as a response to the demand for hospices to address infection control more completely.] Currently, CMS only requires that the hospice ensure that each patient is kept 1) comfortable, 2) clean and 3) protected from accident, injury and infection. However, there is abundant research on the widespread prevalence of infection and communicable diseases in the inpatient setting. Although, there is less evidence on the effect of infections on communicable diseases in out-of-hospital settings, we do know that the impact of infections in the out-of-hospital settings is significant.

Joint Commission Comment. The Joint Commission appreciates the reference to our standards on infection control in the home care environment and applauds the emphasis on infection control. We suggest the following change in language: "...that protects patients, families, visitors, and hospice personnel..."

Conditions of Participation: Waiver of Requirement (§418.74)

The proposed CoP provides for a waiver of the requirement that Physical Therapy, Occupational Therapy, Speech-Language Pathology and Dietary Counseling services be provided as needed on a 24-hour basis.

Joint Commission Comment. CMS should consider allowing urban areas the waiver option. The inability to recruit appropriate personnel either because of professional shortages or because of

the low number of patients may preclude the hospice from accepting certain patients that would benefit from their services. Allowing hospices to contract out some of these services would improve access.

Conditions of Participation: Volunteers (§418.78)

This proposed CoP re-codifies the existing CoP on volunteers with some changes related to the availability of clergy. The role of the clergy is now outlined in the CoP on interdisciplinary group care planning.

Joint Commission Comment. The Joint Commission encourages CMS to clarify all requirements for volunteers by providing a definition of the role of a volunteer and how it differs from staff. The rule includes a revised definition of employee but the term staff and volunteer staff are used throughout the proposed regulation. Specifically, when referring to "staff", is the intent to limit functions to staff or are these requirements also to be performed by an individual functioning as a volunteer?

Conditions of Participation*: Medical Director *(§418.102)

The proposed CoP requires the Medical Director to review clinical information on each patient and provide written certification that the patient's life expectancy is less than 6 months.

Joint Commission Comment. The Joint Commission has concerns about the proposed requirement that the Medical Director is responsible for the hospice's quality assessment and improvement program. Based on the Joint Commission's experiences, most hospices only employ the Medical Director under contract for a specific number of hours. To require the Medical Director to be responsible for the QAPI would be a significant burden. Alternatively, the Joint Commission suggests that the Medical Director is required to be a part of the quality assessment and improvement activities. However, an employee with knowledge of performance improvement should be responsible for the hospice's quality assessment and improvement program.

The Joint Commission stresses the importance of evaluating the 6-month rule. This limitation reduces access and could contribute to poor outcomes. Further consideration should be given to expanding the time frame.

Conditions of Participation*: *Clinical Records (§418.104)

This proposed rule requires a hospice to maintain a clinical record with accurate clinical information for each patient.

Joint Commission Comment. The Joint Commission suggests that CMS add the language: "with the patient's written consent" for the standard on "discharge or transfer of care".

Conditions of Participation: Drugs and DME (§418.106)

This CoP clarifies the durable medical equipment, supplies, appliances and drugs and biologics related to the management of terminal illness and regulations of controlled substances in the home.

Joint Commission Comment. Although the explanation of the requirements is in concert with the Joint Commission's requirements, we are concerned that the language in the proposed regulation implies that the hospice must prevent diversion. While preventing diversion is ideal, it is an unreachable goal. Hospices can limit the amount of drug in the home, but since they do not have control of the home, the possibility of diversion to other parties continues to exist.

Conditions of Participation: Short Term Inpatient Care (§418.108)

The proposed rule on short term in-patient care eliminates the requirement that a registered nurse provide direct patient care on each shift.

Joint Commission Comment. The Joint Commission recognizes and supports the elimination of the nurse in attendance on a particular shift. However, these are hospice patients whose condition may change dramatically quickly. Even though these regulations apply to respite care, the patient is still complex and could have frequent and critical physical or emotional changes

that requires re-assessment. Also, these same patients may be on a variety of medications. The Joint Commission suggests that there be a requirement that the staff has access to nursing consultation or the ability to have a nurse "on-call" for direct care or consultation at all times. This is no less than the patient receives at home. The family can request an assessment or a consultation over the telephone if the patient's condition changes.

Once again, we commend CMS's hard work to modernize the hospice CoPs. The Joint Commission stands ready to work with CMS to share Joint Commission's expertise. Our experience in accrediting and certifying various types of health care organizations, developing performance measurement metrics, convening experts and issuing National Patient Safety Goals provides valuable insights that can facilitate a smooth transition to the revised CoPs for hospices.

Submitter : Ms. Phyllis Wang **Date:** 07/26/2005

Organization : New York State Assoc. of Health Care Providers

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

comments are attached

CMS-3844-P-126-Attach-1.DOC

New York State Association of
Health Care Providers, Inc.

Representing home care and related services since 1974.

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Phyllis A. Wang, *President*

Attachment #126

July 22, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3844-P
P.O. Box 8010
Baltimore, MD 21244-8010

RE: 42 CFR Part 418 Medicare and Medicaid Program: Hospice Conditions of Participation; Proposed Rule

On behalf of the members of the New York State Association of Health Care Providers (HCP), I am writing to provide comments on the proposed changes to the Hospice Conditions of Participation (CoPs). HCP is a statewide trade association representing home care, hospice and community-based providers through advocacy, information and education. Founded in 1974, HCP represents approximately 500 offices of Licensed Home Care Services Agencies (LHCSAs), Certified Home Health Agencies (CHHAs), Long Term Home Health Care Programs (LTHHCPs), Hospices and related health organizations throughout New York State. Through a strong network of regional chapters and an active state office in Albany, HCP is a primary authority of the health care industry.

This is an historic moment for hospice, as the regulations guiding the industry have not been thoroughly updated since their inception over twenty years ago. The regulations that the Centers for Medicare and Medicaid (CMS) anticipates putting in place in 2008 will impact and shape the hospice industry for years to come. HCP recognizes the thoughtfulness and consideration utilized by CMS in developing the four core conditions of participation, but is concerned that some of the requirements, although designed with the best of intentions, may hamper hospices' ability to fulfill these four conditions.

Although the regulations will not be implemented until 2008, it is important to address concerns as soon as possible to ensure that appropriate time and effort is dedicated to this tremendous task. HCP provides the following comments in hopes that CMS makes every effort to consider and incorporate the proposed changes. HCP applauds CMS for soliciting public comment so early in the process to ensure worthwhile involvement and hopes to continue to provide insight and assistance throughout the revision and implementation process of these important regulations.

HCP provides the following in response to CMS' request for comment relative to the proposed regulations.

Section 418.3 Definitions

Attending physician means a—doctor of medicine or osteopathy...or nurse practitioner.

HCP recommends also allowing the hospice medical director, hospice physician or nurse practitioner to act as the patient's attending physician. By allowing one of these individuals to serve as the attending physician, this provides the hospice and family with increased flexibility in fulfilling this obligation.

Drug Restraint means a medication used to control behavior or to restrict the patient's freedom of movement which is not a standard treatment for a patient's medical or psychiatric condition.

As proposed, this definition is of critical concern. Patients receiving hospice care may request or need terminal sedation – yet such medication in another setting would be considered a drug restraint. For example, hospice commonly uses Haldol, a psychoactive medication for therapeutic use and to control symptoms. In other settings, however, Haldol would be considered a drug restraint.

The current definition of drug restraint evokes concern related to protecting the patient's rights. This definition could limit a hospice patient's right to control anxiety, terminal restlessness, hallucination, or pain. The final stages of an individual's life are often plagued by such symptoms and the individual or family may request a psychoactive medication to alleviate the patient's suffering. While the need for patient restraint can be understood in the institutional setting, hospice care is provided mostly in the patient's home where there would be no staff benefit to having the patient restrained.

The term drug restraint should be amended as follows: *means a medication used to control behavior or to restrict the patient's freedom of movement,* ***which is not a standard hospice treatment or not requested by the patient or the patient's surrogate.***

Nursing Services. HCP recommends adding a definition for *nursing services*. The proposed CoPs frequently refer to the term *nursing services* yet a definition is never provided. HCP recommends that a definition, such as the following, be included: *Nursing Services mean care provided by a licensed nurse or under the supervision of a licensed nurse as allowed by law.*

Section 418.54 Condition of Participation: Comprehensive Assessment. *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 medical, nursing, psychosocial, emotional, and spiritual care. This care includes, but is not limited to, the palliation and management of the terminal illness and related medical conditions.*

HCP recommends changing the word "care" to "assessment" in the last sentence of the opening paragraph. This would provide the hospice with the flexibility to include in its assessment items unrelated to the terminal illness that might still be important in the patient's overall plan of care. For example, a hospice patient admitted for cancer of the pancreas may also have Chronic Obstructive Pulmonary Disease (COPD). While the COPD would need to be assessed and the medications taken for the COPD would be important to note as decisions are made concerning medication for pain management, etc., the COPD is unrelated to the terminal diagnosis and would not be part of the plan of care for the terminal diagnosis.

Paragraph (b) Standard: Timeframe for completion of the comprehensive assessment. *The hospice interdisciplinary group, in consultation with the individual's attending physician, must complete the comprehensive assessment no later than 4 calendar days after the patient elects the hospice benefit.*

A hospice admission is a very involved process and a family is often overwhelmed by the new people coming into their home and the myriad questions that need to be asked and answered – thoughtful questions and answers that can be emotionally difficult and draining. The proposed four day requirement in which the hospice must complete the comprehensive assessment could be overly intrusive upon the patient and family.

For example, a debilitated, very private individual is admitted to hospice. After the admission nurse does the initial assessment, an LPN begins routine, daily care on the day following admission and the case manager RN also visits. The patient and family may find themselves struggling to adapt to the sudden change in events and may ask if the

Social Worker visit might be delayed until the following week as an additional LPN will be covering the weekend. The admission nurse has not identified any urgent psychosocial needs and the case manager RN concurs. If the comprehensive assessment must be completed within 4 days, the Social Worker would need to visit within the next two days, which could be overwhelming to the patient and family during a very trying period.

If a hospice were given seven days to complete the comprehensive assessment, the social worker visit could wait a few more days and the patient and family could have a bit more time to adjust to the change. HCP strongly recommends that if a true, interdisciplinary, comprehensive assessment is desired, seven days would be a much more reasonable timeframe for the patient, family and hospice.

HCP also recommends that language be added so that the sentence reads as follows: "...attending physician, *if he/she is willing to participate...*" Although it is not required, it is current practice to invite the attending physician to participate in the interdisciplinary group (IDG). This current practice works well and provides the hospice with flexibility in the event the attending is unavailable or does not wish to participate; therefore, HCP would argue this practice does not require change.

Paragraph (d) Standard: Update of the comprehensive assessment. *The assessment update must be accomplished—(1) as frequently as the condition of the patient requires, but no less frequently than every 14 days.*

HCP strongly recommends that "every 14 days" be changed to "every two weeks" or "15 days." This change would provide the Hospice with the needed flexibility to accommodate holidays and emergencies. It would also synchronize the update with Hospice's 90/60/90 day certification periods.

418.56 Condition of Participation: Interdisciplinary group care planning and coordination of services.

Paragraph (d) Standard: Review of plan of care. *The medical director or physician designee, and the hospice interdisciplinary team (in collaboration with the individual's attending physician to the extent possible) must review, revise and document the plan as necessary at intervals specified in the plan but no less than every 14 calendar days.*

HCP has serious concerns with the separation of the medical director or physician designee from the rest of the hospice interdisciplinary team at the beginning of the standard. Such a separation could undermine the structure of the team and one of the very core philosophies of hospice which is to emphasize a team approach to care. A medical director or physician designee must not be viewed as more important than any other member of the team. It is already challenging enough for hospice to involve in team efforts certain physicians who are accustomed to being in charge. The proposed change disrupts rather than encourages the team structure and could create a multi-disciplinary team with strained leadership among several members of the team. HCP recommends revising this part to better emphasize the importance of the group.

HCP again urges CMS to change "every 14 days" to "*every two weeks*," or "*15 days*," in order to provide the hospice with appropriate flexibility to accommodate holidays, emergencies and certification periods. Although this may not seem significant, in smaller hospices especially, there is often a team of part-time members who are available only one day a week or even one day every other week for the several hours needed for Interdisciplinary Team meeting. If this day occurs on a holiday, the hospice has little flexibility in coordinating the team review.

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.

The hospice industry currently is in the development stages of identifying and measuring data for improvement. HCP urges CMS to recognize that, although the preliminary pieces are in place in many hospices, full development of a hospice QAPI will occur over an extended period of time. The increased demands in quality assessment and

performance, however, will add significant cost burdens for hospice. This must be recognized and addressed in the hospice reimbursement system.

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 contract counseling. A hospice may, under extraordinary or other non-routine circumstances, enter into 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.*

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HCP agrees with the proposed changes and appreciates CMS' revision of this section in allowing increased flexibility in the delivery of meal service to hospice patients. It is important that meal service, when possible, adapt to the needs of the resident with less emphasis on the frequency of meals.

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HCP has several concerns with the wording of this section. Restraint and seclusion are perceived so differently in hospice that inclusion of this section could irreparably harm the foundations of a program designed for end of life care. Hospice patients are in the final stages of life and, therefore, often benefit from "seclusion," which in hospice would be considered privacy. Hospice patients also require aggressive symptom control which often warrants medication that in another setting would be used for restraint. While the need for this provision in other settings is clearly understood, it is highly unlikely that hospice would restrain or seclude a patient if this were unnecessary and against the patient's wishes. Hospice patients often choose to remove themselves from their environment as they die and often choose comfort over alertness, particularly as life is ending. HCP urges CMS to remember the uniqueness of the hospice benefit.

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The review and revising of the Hospice Conditions of Participation truly is an historic event that will influence the direction and development of the industry. HCP appreciates the opportunity to provide insight on the proposed conditions and hopes that CMS will find its comments useful and will seriously consider the recommendations made herein. HCP welcomes the chance to continue to participate in this very important process and is willing to assist in any way necessary.

Thank you, again, for your consideration of HCP's comments.

Sincerely,

Phyllis A. Wang
President

Submitter : Mr. David Smith **Date:** 07/26/2005

Organization : American Medical Directors Association

Category : Long-term Care

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-3844-P-127-Attach-1.PDF

New York State Association of
Health Care Providers, Inc.

Representing home care and related services since 1974.

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Attachment #127

July 22, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3844-P
P.O. Box 8010
Baltimore, MD 21244-8010

RE: 42 CFR Part 418 Medicare and Medicaid Program: Hospice Conditions of Participation; Proposed Rule

On behalf of the members of the New York State Association of Health Care Providers (HCP), I am writing to provide comments on the proposed changes to the Hospice Conditions of Participation (CoPs). HCP is a statewide trade association representing home care, hospice and community-based providers through advocacy, information and education. Founded in 1974, HCP represents approximately 500 offices of Licensed Home Care Services Agencies (LHCSAs), Certified Home Health Agencies (CHHAs), Long Term Home Health Care Programs (LTHHCPs), Hospices and related health organizations throughout New York State. Through a strong network of regional chapters and an active state office in Albany, HCP is a primary authority of the health care industry.

This is an historic moment for hospice, as the regulations guiding the industry have not been thoroughly updated since their inception over twenty years ago. The regulations that the Centers for Medicare and Medicaid (CMS) anticipates putting in place in 2008 will impact and shape the hospice industry for years to come. HCP recognizes the thoughtfulness and consideration utilized by CMS in developing the four core conditions of participation, but is concerned that some of the requirements, although designed with the best of intentions, may hamper hospices' ability to fulfill these four conditions.

Although the regulations will not be implemented until 2008, it is important to address concerns as soon as possible to ensure that appropriate time and effort is dedicated to this tremendous task. HCP provides the following comments in hopes that CMS makes every effort to consider and incorporate the proposed changes. HCP applauds CMS for soliciting public comment so early in the process to ensure worthwhile involvement and hopes to continue to provide insight and assistance throughout the revision and implementation process of these important regulations.

HCP provides the following in response to CMS' request for comment relative to the proposed regulations.

Section 418.3 Definitions

Attending physician means a—doctor of medicine or osteopathy...or nurse practitioner.

HCP recommends also allowing the hospice medical director, hospice physician or nurse practitioner to act as the patient's attending physician. By allowing one of these individuals to serve as the attending physician, this provides the hospice and family with increased flexibility in fulfilling this obligation.

Drug Restraint means a medication used to control behavior or to restrict the patient's freedom of movement which is not a standard treatment for a patient's medical or psychiatric condition.

As proposed, this definition is of critical concern. Patients receiving hospice care may request or need terminal sedation – yet such medication in another setting would be considered a drug restraint. For example, hospice commonly uses Haldol, a psychoactive medication for therapeutic use and to control symptoms. In other settings, however, Haldol would be considered a drug restraint.

The current definition of drug restraint evokes concern related to protecting the patient's rights. This definition could limit a hospice patient's right to control anxiety, terminal restlessness, hallucination, or pain. The final stages of an individual's life are often plagued by such symptoms and the individual or family may request a psychoactive medication to alleviate the patient's suffering. While the need for patient restraint can be understood in the institutional setting, hospice care is provided mostly in the patient's home where there would be no staff benefit to having the patient restrained.

The term drug restraint should be amended as follows: *means a medication used to control behavior or to restrict the patient's freedom of movement,* ***which is not a standard hospice treatment or not requested by the patient or the patient's surrogate.***

Nursing Services. HCP recommends adding a definition for *nursing services*. The proposed CoPs frequently refer to the term *nursing services* yet a definition is never provided. HCP recommends that a definition, such as the following, be included: *Nursing Services mean care provided by a licensed nurse or under the supervision of a licensed nurse as allowed by law.*

Section 418.54 Condition of Participation: Comprehensive Assessment. *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 medical, nursing, psychosocial, emotional, and spiritual care. This care includes, but is not limited to, the palliation and management of the terminal illness and related medical conditions.*

HCP recommends changing the word "care" to "assessment" in the last sentence of the opening paragraph. This would provide the hospice with the flexibility to include in its assessment items unrelated to the terminal illness that might still be important in the patient's overall plan of care. For example, a hospice patient admitted for cancer of the pancreas may also have Chronic Obstructive Pulmonary Disease (COPD). While the COPD would need to be assessed and the medications taken for the COPD would be important to note as decisions are made concerning medication for pain management, etc., the COPD is unrelated to the terminal diagnosis and would not be part of the plan of care for the terminal diagnosis.

Paragraph (b) Standard: Timeframe for completion of the comprehensive assessment. *The hospice interdisciplinary group, in consultation with the individual's attending physician, must complete the comprehensive assessment no later than 4 calendar days after the patient elects the hospice benefit.*

A hospice admission is a very involved process and a family is often overwhelmed by the new people coming into their home and the myriad questions that need to be asked and answered – thoughtful questions and answers that can be emotionally difficult and draining. The proposed four day requirement in which the hospice must complete the comprehensive assessment could be overly intrusive upon the patient and family.

For example, a debilitated, very private individual is admitted to hospice. After the admission nurse does the initial assessment, an LPN begins routine, daily care on the day following admission and the case manager RN also visits. The patient and family may find themselves struggling to adapt to the sudden change in events and may ask if the

Social Worker visit might be delayed until the following week as an additional LPN will be covering the weekend. The admission nurse has not identified any urgent psychosocial needs and the case manager RN concurs. If the comprehensive assessment must be completed within 4 days, the Social Worker would need to visit within the next two days, which could be overwhelming to the patient and family during a very trying period.

If a hospice were given seven days to complete the comprehensive assessment, the social worker visit could wait a few more days and the patient and family could have a bit more time to adjust to the change. HCP strongly recommends that if a true, interdisciplinary, comprehensive assessment is desired, seven days would be a much more reasonable timeframe for the patient, family and hospice.

HCP also recommends that language be added so that the sentence reads as follows: "...attending physician, *if he/she is willing to participate...*" Although it is not required, it is current practice to invite the attending physician to participate in the interdisciplinary group (IDG). This current practice works well and provides the hospice with flexibility in the event the attending is unavailable or does not wish to participate; therefore, HCP would argue this practice does not require change.

Paragraph (d) Standard: Update of the comprehensive assessment. *The assessment update must be accomplished—(1) as frequently as the condition of the patient requires, but no less frequently than every 14 days.*

HCP strongly recommends that "every 14 days" be changed to "every two weeks" or "15 days." This change would provide the Hospice with the needed flexibility to accommodate holidays and emergencies. It would also synchronize the update with Hospice's 90/60/90 day certification periods.

418.56 Condition of Participation: Interdisciplinary group care planning and coordination of services.

Paragraph (d) Standard: Review of plan of care. *The medical director or physician designee, and the hospice interdisciplinary team (in collaboration with the individual's attending physician to the extent possible) must review, revise and document the plan as necessary at intervals specified in the plan but no less than every 14 calendar days.*

HCP has serious concerns with the separation of the medical director or physician designee from the rest of the hospice interdisciplinary team at the beginning of the standard. Such a separation could undermine the structure of the team and one of the very core philosophies of hospice which is to emphasize a team approach to care. A medical director or physician designee must not be viewed as more important than any other member of the team. It is already challenging enough for hospice to involve in team efforts certain physicians who are accustomed to being in charge. The proposed change disrupts rather than encourages the team structure and could create a multi-disciplinary team with strained leadership among several members of the team. HCP recommends revising this part to better emphasize the importance of the group.

HCP again urges CMS to change "every 14 days" to "*every two weeks*," or "*15 days*," in order to provide the hospice with appropriate flexibility to accommodate holidays, emergencies and certification periods. Although this may not seem significant, in smaller hospices especially, there is often a team of part-time members who are available only one day a week or even one day every other week for the several hours needed for Interdisciplinary Team meeting. If this day occurs on a holiday, the hospice has little flexibility in coordinating the team review.

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.

The hospice industry currently is in the development stages of identifying and measuring data for improvement. HCP urges CMS to recognize that, although the preliminary pieces are in place in many hospices, full development of a hospice QAPI will occur over an extended period of time. The increased demands in quality assessment and

performance, however, will add significant cost burdens for hospice. This must be recognized and addressed in the hospice reimbursement system.

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Thank you, again, for your consideration of HCP's comments.

Sincerely,

Phyllis A. Wang
President

Submitter : Ms. Peggy Pettit

Organization : VITAS Healthcare Corporation

Category : Hospice

Date: 07/26/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3844-P-128-Attach-1.DOC

Attachment #128

VITAS®
INNOVATIVE HOSPICE CARE®

VITAS Healthcare Corporation
100 S. Biscayne Boulevard, Suite 1500
Miami, FL 33131

July 26, 2005

Via Electronic Mail And Hand Delivery

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 309-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201
Attn: CMS-3844-P

Re: **Comments On Medicare and Medicaid Programs: Hospice Conditions of Participation, 70 Federal Register 30840 (May 27, 2005), CMS-3844-P**

Dear Dr. McClellan:

VITAS appreciates the opportunity to comment on the above-referenced proposed rule, *Medicare and Medicaid Programs: Hospice Conditions of Participation.*

VITAS is the nation's largest and leading provider of hospice services, serving patients from 34 hospice programs in 12 states. For 25 years, VITAS Healthcare Corporation has been a leader in the American hospice movement, helping to define the standards of care for hospice and working to ensure that terminally ill patients and their families have ready access to compassionate and effective end-of-life care through Medicare and Medicaid. On average, VITAS serves almost 9,000 patients each day and employs nearly 7,000 people. More than half of VITAS' patients receive care in their homes, and nearly 40 percent receive care in skilled nursing and assisted living facilities.

VITAS was founded in 1978 as Hospice Care, Inc., one of the nation's first hospice programs. As a hospice pioneer, VITAS was instrumental in leading a bi-partisan effort to add hospice to the health care payment system. As a result of these efforts, Medicare pays for hospice services, many states have established Medicaid

coverage for hospice, and virtually all private insurers and managed care plans provide coverage for hospice care. Today, VITAS is the leading provider of cost effective end-of-life care, working in cooperation with hospitals, physicians, nursing homes, assisted living facilities, insurers and community-based organizations throughout the nation. Given all of these factors, VITAS has a direct interest in the proposed changes to the Medicare and Medicaid conditions of participation.

CMS Proposal: Section 418.52 – Patient's Rights

The proposed rule generally would require that the patient be informed of his or her rights and that the hospice protect and promote the exercise of those rights. The proposal would add a number of specific requirements in this regard.

VITAS Comment

Although most of the proposed requirements reflect VITAS' current practices, we have a few concerns.

First, while we agree that hospices should inform patients and families of the hospice's drug policies and procedures regarding the monitoring and disposing of controlled substances, we do not believe that this should be required as part of the admissions process. Not every patient needs the use of narcotics, and we are concerned that requiring this discussion upon admission has the potential to instill fear in patients and families alike. Hospices have worked hard to dispel the myths associated with narcotic use with terminally ill patients, and such a discussion can only prolong these myths. During the admission visit, extensive and sometimes difficult information must be conveyed. We believe that information on the safe utilization and destruction of narcotics should not occur until such time as narcotics are ordered for a patient. We also suggest using the word "monitoring" in place of "tracking" as it is more consistent with the procedures used in the home setting.

Second, we recommend that CMS insert language into subsection (b) acknowledging that the patient has the right to refuse treatment.

Subsection (b)(4)(i) would require that violations regarding alleged abuse and the like be reported to state and local bodies including the state survey and certification agency. We believe such a requirement to be redundant because we already are legally required to investigate and report these types of incidents to appropriate authorities. If this proposed requirement is retained, we recommend making any reporting time frame more precise by stating that "validated or confirmed significant violations" must be "reported to the appropriate bodies having jurisdiction within at least five business days of the discovery of the incident" (suggested new language underscored).

Finally, while we fully support informing the patient of his or her financial liability, we are concerned that the requirement that the patient be so informed "in a

language that he or she can understand" goes too far, given the existence of multiple languages and dialects. In such situations, we typically employ family members and others as interpreters and use translation services as necessary. We believe that this accomplishes the goal of informing the patient of his or her liability.

CMS Proposal: Section 418.54 – Comprehensive Assessment/Assessment Time Frames

The proposed rule would require a documented patient-specific comprehensive assessment by a registered nurse, identifying the patient's need for hospice care and services. The initial assessment would have to be made within 24 hours after the hospice received a physician's admission order for care. The interdisciplinary group, in consultation with the individual's attending physician, would then need to complete a comprehensive assessment within 4 days. Finally, the comprehensive assessment would have to be updated every 14 days.

VITAS Comment

While we appreciate the concern for efficiency and the need to address patient needs as quickly as possible, we are concerned that the proposed time frames are unrealistically narrow. Given the current national nursing shortage, the fact that some families need to ease into hospice care, the existence of holidays, and other comparable variables, we recommend extending some of the proposed time frames by several days.

First, we believe that 48 hours represents a more reasonable time frame for conducting the initial assessment, depending upon the patient's condition and the family's request, than does the proposed 24 hours. We also support any member of the core interdisciplinary group being able to complete an initial assessment visit, as opposed to CMS' proposal to limit this function to registered nurses. Similarly, we recommend that the interdisciplinary group have 7 days rather than 4 days to complete the comprehensive assessment. As CMS points out in the Preamble, the overall length of stay in hospices is increasing (70 Fed. Reg. at 30845), and for some patients, 7 days represents a reasonable time frame and provides the hospice with needed scheduling flexibility to "triage," and attend to sicker patients first. Finally, it is VITAS' practice to update the patient's plan of care on an ongoing basis depending upon patient needs; hence, we do not believe it necessary or advisable to establish an arbitrary 14 day time frame for updating the assessment.

On a more fundamental level, we are concerned that the proposed regulation appears to require some type of written forms to evidence that assessments have been conducted. We view initial and comprehensive assessments to be *processes,* with care decisions evolving over time. We are concerned that the regulations' prescriptive provisions on documentation may result in hospices' placing more emphasis on rote data entry than on individual care. Such documentation requirements may also result in increasing numbers of arbitrary survey decisions.

In addition, we request that this segment specify that the comprehensive plan of care may be developed without the need for a face-to-face interaction, but can be developed via electronic or telecommunications.

Last, we note that not every hospice patient has an attending physician; thus, subsection (b) should state that the comprehensive assessment is to be conducted by the interdisciplinary group "in consultation with the individual's attending physician, which may be the hospice physician" (suggested new language underscored).

CMS Proposal: Section 418.56 – Plan of Care and Coordination of Services

The proposed rule would require a hospice to designate an interdisciplinary group, as is current practice. In consultation with the patient's attending physician, the group would prepare a written plan of care for each patient, specifying the "care and services necessary to meet the patient and family-specific needs identified in the comprehensive assessment." In the Preamble, CMS notes that "family plays an important role in the care of a hospice patient," and that it is thus "including a reference to the patient's family when establishing the plan of care." 70 Fed. Reg. at 30846. The proposed rule also would require that the medical director or physician designee and the hospice interdisciplinary team review, revise and document the plan of care no less than every 14 calendar days.

VITAS Comment

Although VITAS strives in every case to involve the patient's family in important decisions, it is sometimes difficult in practice to achieve complete agreement with all choices, particularly when dealing with the last stages of a patient's life. Families are often fractured on difficult emotional decisions regarding the end of a loved one's life. We are concerned that the proposed regulations appear to require that the patient and family agree on all decisions, and that the hospice be required to document that consensus. Better terms might include "family awareness, understanding, and involvement in the decision-making process." We are concerned that requiring unanimous patient/family agreement could hinder the development of some patients' plans of care and ultimately affect them negatively.

In addition, we believe that the proposed language regarding the review of the plan of care in subsection (d) could undermine the interdisciplinary group in favor of review of care by a single physician. Because the medical director or physician designee is separated from the rest of the interdisciplinary team at the beginning of the standard, the proposed rule seems to indicate that the physician's influence would be at least equal to that of the entire interdisciplinary group. The purpose of an interdisciplinary group is to receive equal input from professionals in many areas, and this goal could be undermined by the language of the proposed regulation.

As noted previously, we believe that the plan of care should be updated as often as necessary to meet the individual needs of the patient and family as determined by the outcomes of the interventions, rather than within an arbitrary 14 day time period. Each patient has unique needs that are best addressed without a rigid time requirement. The hospice should not be required to specify when the plan of care will be reviewed again, since the interdisciplinary group cannot predict when symptoms will change. Instead, an outcomes approach to care and the evaluation of symptom management should determine when the plan of care should be updated.

Finally, the term "if any" should follow the reference in subsection (b) to the patient's attending physician. This may be the hospice physician because the family and/or the attending physician want the hospice physician to take over. While we concur with CMS' statement in the Preamble that attending physicians often have long relationships with patients, and that their input can be "invaluable" (70 Fed. Reg. at 30847), not all patients have attending physicians, nor do all attending physicians have the expertise effectively to manage symptoms at the end of life.

CMS Proposal: Section 418.58 – Quality Assessment and Performance Improvement (QAPI)

The proposed rule would require the hospice to "develop, implement, and maintain an effective, ongoing, hospice-wide data-driven quality assessment and performance improvement program." In particular, the hospice's governing body would have to ensure that the program: reflected the complexity of its organization and services; involved all hospice services; focused on indicators related to improved palliative outcomes; focused on the end-of-life support services provided; and took actions to demonstrate improvement in hospice performance. Further, the rule would require that the hospice "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." The rule would place overall responsibility for QAPI on the hospice's governing body.

VITAS Comment

We commend CMS for its recognition that an individual hospice must have the flexibility to "drive its own quality improvement activities and improve its provision of services" (Preamble, 70 Fed. Reg. at 30848). Hospices must necessarily conduct their own quality assessments on an ongoing basis and take whatever unique actions are necessary to implement improvements; hence, the absence of prescriptive, detailed requirements in this section is highly appropriate.

We suggest clarification of a few specific requirements. First, we are unclear as to what CMS believes to constitute an "adverse patient event" under subsection (a)(2). The meaning of this term is different in the context of hospices than other providers, and, while CMS in the Preamble characterizes such events as "occurrences that are harmful or

contrary to the targeted outcomes" (70 Fed. Reg. at 30848), we believe the regulation itself should be clarified.

Second, in subsection (e), we believe that the interdisciplinary group and not the hospice's governing body should be responsible for defining, implementing, and maintaining the QAPI. The governing body should oversee the plan.

CMS Proposal: Section 418.60 – Infection Control

The proposed rule would require the hospice to "maintain and document an effective infection control program that protects patients, families and hospice personnel by preventing and controlling infections and communicable diseases." The rule would further require the hospice to provide infection control education to staff, patients, and family members or other caregivers.

VITAS Comment

Again, we commend CMS for its recognition that hospices must be afforded flexibility in developing infection control plans, recognizing that a hospice cannot reasonably be expected to be directly responsible for maintaining an infection-free environment in a patient's home or inpatient setting. However, we believe that setting standards for education about infection control generally would be unrealistic. We therefore urge CMS to limit this potentially expansive proposed requirement to educating staff, patients, and family members on "significant" and potentially threatening infections only, i.e., we should not have to inform patients and family members of the remote risks of anthrax, SARS, etc.

CMS Proposal: Section 418.64 – Core Services

The proposed rule would require a hospice routinely to provide substantially all core services directly by hospice employees. The rule would only allow a hospice to contract with another Medicare certified hospice under "extraordinary or non-routine circumstances," or with "highly specialized nursing services" that are "provided so infrequently that…[their] provision …by direct hospice employees would be impracticable and prohibitively expensive…." The rule would provide that such emergency circumstances 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. Outside contracting for continuous care would be prohibited. The proposed rule also would require that a social worker providing medical social services complete a psychological assessment of the patient.

VITAS Comment

While we again commend CMS' effort to allow hospices additional contracting flexibility, VITAS has significant concerns with CMS' proposal to preclude hospices from contracting for continuous care services.

Section 946 of the Medicare Modernization Act did not provide an exhaustive list of the circumstances under which contracting would and would not be appropriate. Rather, it contained the general statement that outside contracting is appropriate in "extraordinary, exigent, or other non-routine circumstances...." It then listed several examples of such circumstances ("such as unanticipated periods of high patient loads, staffing shortages due to illness or other events, or temporary travel of a patient outside a hospice program's service area..."), but this list clearly was not meant to identify the only extraordinary or non-routine circumstances under which contracting world be appropriate. Stated differently, we submit that CMS should not read into the MMA's examples a directive to prohibit arrangements not specifically referenced. Indeed, this provision was included in Title IX of the MMA, and entitled "Administrative Improvements, Regulatory Reduction, and Contracting Reform." Congress clearly intended to provide hospices with additional flexibility.

Outside contracting for continuous care services should be equally justified during periods of high patient loads and during staffing shortages – exigencies which, contrary to CMS' statements in the Preamble, cannot be predicted on a routine basis. We submit that there is no legitimate basis to distinguish these different types of outside contracting needs, and urge that continuous care not be excluded from permissible contracting. We are very concerned that the proposed limitation, given the increasing nursing shortages, could result in continuous care becoming obsolete. This would be a sad consequence considering the fact that most patients would prefer to remain home for their final days even when their care needs are acute. Continuous care frequently is less expensive than a General Inpatient day, as the average number of hours billed each day is between 13 and 17 hours. At VITAS, the primary registered nurse case manager – a VITAS employee -- always retains full management of the case, regardless of the level of care received by the patient. Continuous care, therefore, should be viewed no differently than the General Inpatient level of care. Both are for acute intervention. It would make little sense to permit contracting for supplemental nursing care with General Inpatient care and not at all for continuous care, because in neither case would we abdicate professional management to the contracted staff.

Further, we have concerns that CMS' proposed provision in subsection (a) that "all physician employees and those under contract, must function under the supervision of the hospice medical director." We assume that this provision should not be interpreted to mean that the hospice medical director needs to be involved with every patient's medical care, but we recommend that this be clarified in the final regulations. Specifically, we submit that this section should be amended to read as follows: "all physician employees and those under contract, must function under the general

supervision of the hospice medical director, who shall furnish overall direction for the physician services provided but who shall not be required personally to provide direct physician services to every patient" (suggested new language underscored).

CMS Proposal: Section 418.66 – Statutory Nursing Waiver

The proposed rule would allow a waiver to the requirement that a hospice provide nursing services directly if, among other statutory requirements, the hospice is located in a nonurbanized area.

VITAS Comment

While we appreciate that there can exist differing economic characteristics between urban and nonurban areas, we are concerned that the proposed rule fails to recognize that there currently exists a *national* nursing shortage, and that shortages frequently are the most extensive in large urban areas like Los Angeles, San Francisco and Philadelphia. It is VITAS' experience that nurse recruitment can be just as difficult in these urban areas as in nonurban ones, and we submit that the waiver should apply nationwide. Indeed, the cost to recruit nurses in urban areas has far outstripped the fixed hospice reimbursement rates.

CMS Proposal: Section 418.76 – Home Health Aide and Homemaker Services

The proposed rule enumerates extensive requirements for hospices that provide "home health aide services" and "homemaker services," including provisions relating to aide training, and to supervision and evaluation of aide services.

VITAS Comment

We submit that the proposed requirement of subsection (g)(2) that home health aide services be "ordered by the physician or nurse practitioner" is wholly inconsistent with current practice and with section 418.56(c)(2) of the proposed rule itself. We believe that the interdisciplinary group, and not the physician or nurse practitioner alone, should determine the frequency and scope of services necessary to meet the needs of the patient and family, including home health aide and homemaker services. We request that this section be modified accordingly, and generally urge that CMS permit hospices to be flexible in adapting the scope and frequency of care to respond to patient and family needs. Specifically, we want to make sure that the section allows volunteers to do homemaker chores without having to be certified as aides.

We further urge CMS to eliminate the proposed requirement that "a registered nurse or qualified therapist" make onsite visits to the location where the patient is receiving care, in order to observe and assess each aide while he or she is performing care. At VITAS, we provide extensive orientation and training for our home health aides, including ascertaining their aide skills and competency upon orientation and at least

annually, but more frequently upon request by a member of the interdisciplinary group or, of course, the patient or family. We believe many hospices have the same internal requirements, and we request that CMS not impose arbitrary requirements in this regard.

Finally, we request that language be added to subsection (h) recognizing that information regarding the assessment of a home health aide's competency must be appropriately maintained in the aide's personnel record, rather than the clinical record.

CMS Proposal: Section 418.78(e)

The proposed rule states at subsection (e) that "[v]olunteers 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."

VITAS Comment:

We submit that this standard should be revised to specify that calculation of the required 5 percent minimum volunteer hours be based on *routine* home care hours, as opposed to *total* patient hours. With more hospices providing inpatient care directly in hospice facilities having round-the-clock, 24/7 staffing requirements, the total patient care hours provided by paid staff – effectively, the proposed denominator of the volunteer hours calculation -- has increased exponentially. As written, CMS' proposed requirement would provide a disincentive to hospices to provide inpatient care directly.

We also request that CMS clarify what types of volunteer hours appropriately can be included in calculating the 5 percent volunteer requirement. There continues to be confusion in the field about the issue, and the question has been raised in several CMS Open Door Forum calls.

We recommend amending this section as follows:

> (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~~ routine home care 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. The volunteer hours that may be used in the calculation of the 5 percent rule may include volunteer travel time, actual time worked as a volunteer, and time spent documenting services provided; however, volunteer training and orientation time may not be included in the calculation.(suggested new language underscored)

CMS Proposal: Section 418.100 – Organization and Administration of Services

The proposed rule would require the hospice to "ensure" that each patient receives hospice care that is "consistent with patient and family needs and desires." It discusses the role of the governing body and the assumption of professional management responsibility. Among other proposed requirements, subsection (e) would require the hospice to be responsible for "supervision of staff and services for all arranged services, to ensure the provision of quality care." Finally, the proposed rule would address satellite locations, stating in subsection (f) that "all hospice satellite locations must be approved by CMS before providing hospice care and services to Medicare patients."

VITAS Comment

As noted, VITAS strives in every case to involve the family and the patient jointly in making care decisions. While we certainly wish to ensure that patients experience hospice care that is consistent with the patient and his or her family's needs and desires, we must acknowledge the reality that families and patients do not always agree on either the needs or "desires" of a patient. We urge CMS to revise the language of subsection (a)(2) to provide that the hospice must "seek to promote hospice care that is consistent with patient and family needs." Thus, we request that CMS replace the word "ensure" with the word "promote" with respect to the patient's and family's needs, and we further request that the word "desires" be eliminated from this proposed subsection.

In addition, we urge CMS to remove the reference in subsection (e) to "supervision of staff" of an agency with which the hospice has a contract. As a technical matter, we supervise service delivery, not the staff itself. Further, we urge eliminating the proposed requirement in subsection (e)(2) that contracted staff have "at least the same qualifications as hospice employees." We submit that this requirement would be difficult to administer at best, and at worst, it may be impossible to meet in certain geographic regions. An example of
this would be the provision of hospice care to a patient who resides in a nursing facility (NF). While the NF aide may bathe the patient once a week and the hospice aide twice a week, the NF aide would be certified as a nursing assistant, whereas the hospice aide would be a certified home health aide. This is due to the different licensing and certification requirements for a NF versus a hospice.

Finally, we appreciate CMS' concern that hospice satellite locations be approved by CMS before they commence hospice care. At the same time, as a practical matter, we would call to CMS' attention the length of time (two years or more) that it is taking satellite locations in some areas, such as California, to receive approval. We urge CMS to take steps to ensure prompt approval of satellite locations, to ensure service to patients located in outlying areas.

CMS Proposal: Section 418.102 – Medical Director

The proposed rule would require that the hospice designate a physician to serve as medical director who would coordinate with other physicians and health care professionals to "ensure that each patient experiences medical care that reflects hospice policy." The rule would further require that before the recertification period for each patient, the medical director or physician designee must review both the patient's clinical information and "the patient's and family's expectations and wishes for the continuation of hospice care." Proposed subsection (c) states that, while the medical director (or designee) and interdisciplinary group are jointly responsible for the coordination of care, the medical director alone is responsible for the hospice's quality assessment and performance improvement.

VITAS Comment

We believe that designating the medical director as responsible for the quality assessment and performance improvement would not be reflective of hospice's interdisciplinary model of care. Often, quite candidly, medical directors do not have the background for such supervision. We urge that the QAPI function be supervised by the specifically designated interdisciplinary group or appropriately qualified individual.

In addition, we request that the phrase "and wishes" be stricken from subsection (b)(2), for reasons discussed earlier on fractured family decisionmaking.

CMS Proposal: Section 418.104 – Clinical Records

The proposed rule would set forth a variety of requirements relating to the maintenance and content of patient clinical records. Subsection (e) would require that, where a patient was transferred to another Medicare/Medicaid approved facility or otherwise discharged (including revoking the hospice election), the hospice would have to forward a copy of the patient's clinical record as well as the hospice discharge summary to that facility or attending physician.

VITAS Comment

VITAS appreciates the concern that a patient's new hospice (or, in the case of a discharge or revocation, attending physician) possess the necessary information to provide effective care. Nevertheless, we submit that the requirement to forward a copy of the entire clinical record along with the discharge summary would be onerous, and may not be operationally feasible, especially for patients who have been on service for some period of time. Furthermore, such a requirement is not likely to contribute to improved quality of care, since the most relevant information would already be contained in the prescribed elements of the discharge summary: a summary of the patient's treatments, symptoms, and pain management; the current plan of care; the physician's order; and "any other documentation that will assist in post-discharge continuity of care." CMS

states in the Preamble its interest in ensuring that attending physicians and new hospices have "the most current clinical information" (70 Fed. Reg. at 30855), and we submit that this information will be contained in the discharge summary alone. Moreover, the clinical record typically contains information regarding the patient's family that we consider to be confidential.

CMS Proposal: Section 418.106 – Drugs, Supplies, and DME

The proposed rule would require that the interdisciplinary group determine the ability of the patient and family to administer medications as a part of the 14-day review of the plan of care that would be required by proposed section 418.54(d). The proposed rule would further require that the hospice have a written policy for tracking, collecting, and disposing of controlled drugs maintained in the patient's home. In addition, during the initial hospice assessment, the rule would require that the use and disposal of controlled substances be discussed with the patient and family to ensure the patient and family are educated regarding the uses and "potential dangers" of controlled substances, with the hospice required to document such discussion. The proposed rule also would require that the hospice ensure that the patient and family receive instruction in the safe use of durable medical equipment (DME) and supplies. Finally, the proposed rule would require that the hospice develop in writing its own repair and routine maintenance policy with respect to DME where there is no manufacturer recommendation for a piece of equipment.

VITAS Comment

As noted in our discussion of proposed section 418.54, we believe that an arbitrary 14-day requirement for the review of the plan of care would be impractical and unnecessary. We submit that the time frame for such review should reflect the patient's personal situation, occurring as often as necessary to meet the needs of the patient and family.

We have a number of comments regarding subsection (b), relating to controlled drugs in the home. First, as noted previously, we do not believe that hospices should be required to discuss drug disposal and the like at the time of admission, but only if or when it is determined that narcotics in fact will be used with a particular patient. We do not use narcotics on every patient, and this conversation has the potential to instill unnecessary fear in patients. Further, we question inclusion of the broad requirement to explain the "potential dangers" of controlled substances, for fear that it would scare our patients. As noted, the hospice industry has worked for years to dispel myths associated with narcotic use with terminally ill patients, and such phrases impede our progress. We do not believe that hospices should be required to document that they have discussed the use and disposal of controlled substances with the patient and family, but, rather, should have a policy that directs staff in the disposal of narcotics within the home. We also request that the word "collecting" be eliminated from subsection (b). "Collecting" implies removal and transporting of narcotics, which could pose safety problems to staff.

Further, the word "tracking" should be replaced with "monitoring" as it is more in line with the industry's practice in the patient's home.

We submit that the word "supplies" in subsection (c)(2) ("use and maintenance of equipment and supplies") is superfluous and should be eliminated. In addition, regarding DME, we submit that it should not be the hospice's responsibility to formulate a repair and routine maintenance policy for a piece of equipment, but rather the vendor's responsibility. Consequently, we request that CMS replace the third sentence of subsection (c)(1) with the phrase "when using an outside vendor for durable medical equipment, the vendor is responsible for obtaining and adhering to manufacturer repair recommendations and maintenance requirements."

CMS Proposal – 418.108 – Short-term Inpatient Care

The proposed rule would require that inpatient care be available for pain control, symptom management, and respite purposes, and be provided in a participating Medicare or Medicaid facility. The rule would eliminate a previous requirement that a registered nurse be available on a 24-hour basis.

VITAS Comment

While we appreciate CMS' concern for providing hospices with staffing flexibility, we believe that registered nurses should in fact be required for all patients receiving the General Inpatient level of care. Such a requirement would not need to apply, however, to patients receiving the Respite level of care. It is an important quality measure to have a registered nurse on site 24-hours per day to meet the potential needs of patients and families. Thus, we request that language be added to subsection (a)(2) that requires the availability of a registered nurse 24 hours per day for General Inpatient stays. In addition, we request that the phrase "crises of a psychosocial/family nature" be added to the first sentence describing the purposes for which inpatient care must be available. Finally, we request that subsection (a)(1) be changed from "A Medicare-approved hospice" to "A Medicare certified hospice."

VITAS requests that CMS clarify that a freestanding hospice inpatient facility operated by a Medicare certified hospice will qualify as a "participating Medicare or Medicaid facility" in this condition.

CMS Proposal – 418.110 – Hospices That Provide Inpatient Care Directly

The proposed rule provides numerous standards with which all hospices furnishing direct inpatient care would have to comply, including adequate staffing, 24-hour nursing services, safe premises, comfortable patient rooms, convenient toilet/bathing facilities, sanitary premises, healthy and appetizing meals, pharmaceutical services, and freedom from restraint/seclusion.

VITAS Comment

We have a variety of miscellaneous comments and recommendations on this section.

First, we request that subsection (c)(1)(ii) provide only that "the hospice must take steps to prevent equipment failure," eliminating the remainder of the sentence requiring the hospice to report such failure to "appropriate State and local bodies."

The patient room space requirements in subsection (f)(3)(iv) should require a patient room to accommodate "no more than two patients and families" (suggested new language underscored), to recognize the important role of ever-present families in the calculation.

We request that CMS add language to subsection (n), specifically to permit a patient to bring previously dispensed drugs into the hospice unit.

Finally, we have several concerns with subsection (o) relating to seclusion and restraint. The subsection as written is inappropriate in light of the fact that hospices use psychotropics in ways that are not "standard treatments" except in the hospice population. In this regard, CMS' references in the Preamble to the Children's Health Act (CHA) as justifying the need for new hospice provisions on seclusion and restraint are inapposite (70 Fed. Reg. at 30857). With respect to patient restraint, we submit that it would be wholly unrealistic to require a physician to evaluate the use of a restraint within the proposed one-hour time frame. In this regard, subsection (o)(3)(ii)(C) should be revised to read "A hospice medical director or physician designee should be consulted to evaluate the continued need for restraint or seclusion in an appropriate timeframe after the initiation of this intervention." We submit that the maximum time frames for seclusion and restraint set forth in proposed subsection (o)(3)(ii)(D), while potentially appropriate for CHA purposes, are wholly inappropriate in a hospice setting; we urge that this subsection be eliminated.

For example, bed rails and Posey vests, which might be considered restraints in other settings, are used in hospice for safety and to assist patients in positioning themselves and maintaining maximum independence. These interventions should be seen in a positive light and not as restrictions imposed on the patient. Finally, we request that subsection (o)(7) be eliminated, as we are already required to report adverse responses, and our patients are expected to die. Furthermore, the requirement to call CMS when a patient dies on, for example, haldol – a drug that might be viewed as restraining in nature, but is frequently used in a hospice setting –would be operationally impossible for both the provider and CMS, and could increase concerns about appropriate drug utilization for the symptom management of hospice patients.

CMS Proposal: Section 418.112 – Residents Residing in a Facility

The proposed rule would provide multiple additional standards with which all hospices that provide hospice care to residents of an SNF/NF, ICF/MR, or other facility must comply, including provisions requiring the medical director to provide overall coordination of the medical care of the hospice resident and further requiring a written agreement that specifies the provision of hospice services in the facility.

VITAS Comment

Our primary and overarching comment is to request that the effective date of this section be delayed until a parallel section is enacted for skilled nursing facilities (SNFs). In our view, this section could not be successfully implemented until the SNF/NF regulations containing a parallel condition conforming these requirements are published. Both entities need to be held to the same requirements at the same time.

To provide some background, we note that, when the Medicare Hospice Benefit was enacted, the primary site of death for Medicare beneficiaries was the hospital. The Hospice Benefit has played an important role in changing that trend, by providing support to terminally ill patients and their families, making it possible for them to die at home in accordance with their wishes. Not only was this a preferable option for many patients/families, it also proved to be cost effective for Medicare.

Today, the demographics have changed, longevity has increased, and people are living longer with multiple chronic illnesses and significant deficits in their ability to perform activities of daily living. As a result, the percentage of Medicare beneficiaries who die while residing in nursing facilities has increased, and VITAS and other hospices have responded by entering into agreements with long-term care facilities to make hospice services available to their residents. Research has indicated that a successful collaboration is beneficial to all concerned: patients, families, and staff of both providers.[1] A study published in the July 13, 2005 issue of the *Journal of the American Medical Association* indicates that simple communication efforts can improve the quality of end-of-life care and increase the use of hospice in nursing homes. A randomized controlled trial evaluated the impact of a "case finding" intervention and found that referrals to hospice were increased and that families' satisfaction ratings with the care their loved ones received at the end of life improved. The study also shows that simple communication interventions about hospice may also decrease the use of acute care resources.[2]

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6 Office of Disability, Aging and Long Term Care Policy, *Use of Medicare's Hospice Benefit by Nursing Facility Residents*,(Washington, D.C., Assistant Secretary for Planning and Evaluation, US DHHS, June 2000).

7 D Casarett, Intervention Increases Hospice Access for Nursing Home Residents and Raises Satisfaction Levels for Patients and Families. *JAMA*, (July 13, 2005).

To the extent that CMS does not delay issuance of these conditions until such time as the SNF conditions are issued, we have the following specific comments in a number of areas:

Title & First Sentence: We suggest revising the title and first sentence of this section to delete an ambiguous reference to "or other facilities." The conditions should apply to hospice services provided "to residents of an SNF/NF or ICF/MR" only – not to services provided in entities that are not subject to federal regulations, such as assisted living facilities. Such entities are regulated at the state level already and, as a practical matter, often do not provide medical services.

(a) Standard: Resident eligibility, election, and duration of benefits: Here too, the phrase "other facility" should be deleted, and a reference to ICF/MR should be added, so that the revised subsection would read:

(a) *Standard: Resident eligibility, election, and duration of benefits.* Medicare patients receiving hospice services and residing in a SNF/~~,~~ NF, or ~~other facility~~ ICF/MR must meet the Medicare hospice eligibility criteria as identified in §418.20 through §418.30.

(b) Standard: Professional management: Proposed section 418.100(e) already requires that hospices assume professional management responsibilities, so we believe this section to be unnecessary and recommend its deletion. We note that the SNF conditions of participation also require the nursing facility to assume professional management responsibility, resulting in occasional conflict between hospice staff (providing palliative care) and nursing staff (providing curative care and rehabilitation services).

(c) Standard: Core services: We also recommend deletion of this subsection, since the content is covered in section 418.64.

(d) Standard: Medical director: We request that subsection (d) reflect that the medical director may not necessarily be the "coordinator of hospice care," and that it therefore may not be appropriate to communicate with the SNF medical director at all. We believe this section might more appropriately be entitled "Physician services," and we believe additional provisions are needed to identify the respective roles of the hospice physician, attending physician, and the facility medical director. We recommend that this section be modified as follows:

(d) *Standard: ~~Medical director~~ Physician services.*

(1) The medical director or~~and~~ physician designee of the hospice must provide clinical guidance in the development of patient care policies and procedures that meet the needs of terminally ill patients~~overall coordination of the medical care of the hospice resident that resides in an SNF, NF, or other facility~~.

(2) The attending physician has primary responsibility for the medical care of an individual patient, in collaboration with the interdisciplinary team.

(3)The medical director or ~~and~~ physician designee must communicate, as appropriate, with the medical director of the SNF/NF or ICF/MR, the patient's attending physician, and other physicians participating in the provision of care for the terminal and related conditions to ensure quality care for the patient and family.

(e) Standard: Written agreement: We have a number of comments on this proposed subsection. First, we do not believe that CMS intended to require the written contract between the hospice and nursing facility to include the written consent of individual patients in its terms; more likely, CMS intended to specify that the hospice must obtain written consent from nursing facility patients. Providing the hospice election form to the facility, however, would satisfy this requirement.

In subsection (e)(2), we believe the respective roles of the hospice and nursing facility can be more clearly delineated, and we have set forth suggested language for two new subsections below. Subsection (e)(4) should be deleted; nursing facilities should not have to notify hospices if patients develop a "life threatening condition," because hospice patients by definition all have life threatening conditions. Subsections (e)(6) and (e)(7) also should be deleted, as these requirements would be covered in our suggested revisions section 418.112 (1) and (2).

In subsection (e)(8), we suggest clarifying that the hospice's ability to use the facility's nursing personnel to provide certain services will be determined by applicable State law, as well as the facility itself, and to note that the hospice patient's plan of care is to be a coordinated plan. The hospice should be able to have the facility's nursing personnel implement the plan of care to the extent that the hospice would be able to utilize the services of a hospice patient's family, if the patient resided at home. As a practical matter, family members and caregivers of hospice patients often perform skilled nursing care, after having been trained and educated by hospice staff. While nursing services admittedly are a core hospice service, we urge that CMS clarify that nursing facility staff can provide certain nursing services to hospice patients residing in the facility, to the extent that the hospice would have relied on the patient's family to do so in other settings, and to enhance patient safety and comfort. A good example would be the hospice patient who needs to be suctioned in the middle of the night. Hospice staff typically trains family members to provide suctioning so that the patient remains comfortable; in the same way, they would train the nursing home staff to do the suctioning until the hospice nurse is able to visit the patient.

Our suggestions on revising this subsection are set forth below:

(e) *Standard: Written agreement.* The hospice and the facility 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 facility before the provision of hospice services. The written agreement must include at least the following:

(1) That the hospice will supply a copy of the written consent of the patient or the patient's representative for each patient stating that hospice services are desired.

~~(2) The services that the hospice will furnish and that the facility will furnish.~~

(2)) Services to be provided by the hospice

(i) A delineation of the hospice's responsibilities, which include, but are not limited to, providing medical direction and management of the patient, nursing, counseling (including spiritual and dietary counseling), social work, bereavement counseling for immediate family members, provision of medical supplies and durable medical equipment, and drugs necessary for the palliation of pain and symptoms associated with the terminal illness, as well as all other hospice services that are necessary for the care of the resident's terminal illness.

(ii) Hospice services would be provided at the same level and to the same extent as would have been provided if the resident were in their own home.

(3) Services to be provided by the nursing facility:

(i) The nursing facility provides 24 hour room and board care, meeting the personal care and nursing needs that would have been provided by a primary caregiver in the home.

(ii) The services provided are at the same level that would have been provided if the resident had not elected to receive hospice services

(4) The manner in which the facility and the hospice are to communicate with each other to ensure that the needs of the patient are addressed and met 24 hours a day.

(5) A provision that the facility immediately notifies the hospice if—

(i) A significant change in the 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 life-threatening condition appears;~~

~~(iv)~~(iii) A need to transfer the patient from the facility and the hospice makes arrangements for, and remains responsible for, any necessary continuous care or inpatient care necessary related to the terminal illness; or

~~(v)~~(iv) The patient dies.

(6) A provision stating that the hospice assumes responsibility for determining the appropriate course of care, including the determination to change the level of services provided.

~~(6) An agreement that it is the facility's primary responsibility to furnish room and board.~~

~~(7) A delineation of the hospice's responsibilities, which include, but are not limited to, providing medical direction and management of the patient, nursing, counseling (including spiritual and dietary counseling), social work, bereavement counseling for immediate family members, provision of medical supplies and durable medical equipment, and drugs necessary for the palliation of pain and symptoms associated with the terminal illness, as well as all other hospice services that are necessary for the care of the resident's terminal illness.~~

(7) A provision that the hospice may use the facility's nursing personnel where permitted by State law and as specified by the facility to assist in the administration of prescribed therapies included in the coordinated plan of care only to the extent that the hospice would routinely utilize the services of a hospice resident's family in implementing the plan of care.

CMS Proposal: Section 418.114 – Personnel Qualifications for Licensed Professionals

The proposed rule would establish the requisite qualifications for all professionals who furnish services directly, under an individual contract, or under arrangements with a hospice; each would be need to acquire the proper license as required by the particular state in order to perform his or her functions. The proposed rule for social workers would require only a baccalaureate degree from a social work school as opposed to a master's degree in social work. Furthermore, the proposed rule would require the hospice to

perform criminal background checks on each hospice employee and contracted employee before employment at the hospice.

VITAS Comment

While VITAS requires a masters of social work degree for our social workers, we would support the requirement in subsection (c)(7) that a social worker need only have a baccalaureate degree from a school of social work rather than a masters of social work. We recognize that a master's degree in social work is not available in all locations, and therefore urge that CMS allow flexibility here. At the same time, we believe that the proposed requirement to conduct criminal background checks on *all* employees and contactors would be too far reaching and would present a significant financial burden. While patient protection from criminal acts is clearly an important goal, hospices should be permitted to limit such background checks to those providing and supervising patient care. We also believe that contracted agency staff should have their background checks conducted by the agency, as specified in the contract; it would be inappropriate for the hospice to conduct background checks on contracted employees. Language in the contract should require it of the vendor.

CMS Impact Analysis

The Impact Analysis discusses the burdens associated with compliance with each of the proposed rules.

VITAS Comment

We submit that CMS has greatly underestimated the costs related to each of the proposed changes. Many of these changes will present a great burden to providers large and small, and suggest that a more realistic estimation of these costs is in order.

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We appreciate the opportunity to submit comments, and would be pleased to answer questions or provide additional background, operational, or other information.

Sincerely,

Peggy Pettit
Executive Vice President
Chief Operating Officer