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July 20, 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: File Code CMS-3844-P

Dear Sir or Madam:

This letter offers comments on the proposed rule to revise the existing conditions of participation that hospices must meet to participate in the Medicare and Medicaid programs.

418.52 Patient's rights.

Section (a)(1) The requirement to provide every patient with a written notice of the patient's rights and responsibilities will prove burdensome to a hospice serving an area in which many languages are spoken. (For example, at least 24 languages are spoken in Newark, N. J. alone.) **A patient's right to access hospice services should not be denied for lack of a written notice of rights in an obscure language.** The hospice might be required, instead, to provide written notice if a particular language is spoken by more than X% of residents in its service area.

Section (a)(3) The requirement to inform the patient and family of the hospice's drug policies at the time of admission may discourage some patients from electing hospice care. The hospice might instead be required to leave an explanation of the drug policies in the admission packet for later review with the family.

Section (a)(4) The patient's mere understanding of his/her rights is inadequate. The patient should be required to demonstrate his/her willingness **to comply** with the plan of care.

418.54 Comprehensive assessment of the patient.

Overall – As is, this proposed condition would improperly move hospice closer to the medical model, rather than the interdisciplinary decision-making model on which hospice's 30 years of growth and success have been based. So often, it is the social factors that are paramount in the initial assessment and development of the plan of care.

Section (a) The requirement to make an initial assessment visit within 24 hours should be liberalized. Hospices are often hard pressed to even get the first admission order from a physician – how likely are we to secure a second order (after the 24 hours expire) if no one with Power of Attorney is available to authorize election within 24 hours, or family members say on Friday that it would be easier (or better) to do this on Monday?

Section (b) The requirement to complete the comprehensive assessment within four days after election should be liberalized to seven days. The comprehensive assessment is likely to include visits by several members of the hospice team; crowding those visits into four days, particularly as a family is only starting to adjust to the prognosis, is inappropriate.

In neither case (a or b) should the brevity of current length of stay be used as justification of conditions that are likely to be in place for up to two decades.

Section (d) Up to 15 days should be allowed for plan of care updates, for those agencies that want to jibe benefit periods (which are divisible by 15) with plan of care updates.

418.56 Interdisciplinary group care planning and coordination of services.

Section (a)(2) This section should reflect current hospice practice, in which an administrative team is typically responsible for development of policies. Where several interdisciplinary teams exist within one hospice, it would be inappropriate for one to be designated for establishment of policy.

Section (d) This section also should allow up for review of the care plan at intervals of up to 15 days.

418.76 Home health aide and homemaker services.

Section (h)(i.) Our understanding of the intent of this standard is that it discusses supervision of the aide, not supervision of provision of care to every patient. Therefore, the first sentence should read, "A registered nurse or qualified therapist must make an onsite visit to **a** patient's home." (rather than to **the** patient's home).

Section (h)(ii.)(iii) This section is unnecessary. The hospice is already required [in Sections (b) and (c)] to assure aide competency in all tasks "that the hospice may choose to have an aide perform."

418.102 Medical director.

Section (c) It is inappropriate to require the medical director or physician designee to direct the hospice's quality assessment and performance improvement program. Some physicians are not trained or competent to do so. To be sure, the physician must be **involved** in the QA&PI program, but the interdisciplinary team as a whole should be responsible for it. **This is indicative of the troublesome tone of these proposed rules to move toward a medical model for hospice. Many of the most important aspects of hospice care are non-medical, and these must be given full due in management and assessment of services.**

418.104 Clinical records.

Section (b) This section unfairly burdens hospice agencies. Neither nursing facilities nor home care agencies are held to a standard by which the provider must be able to authenticate physician signatures. Further, the phrase "primary author" is undefined.

Section (e) This section should be deleted as additional burden. The discharge summery is sufficiently comprehensive to assure continuity of care. Duplication of the entire clinical record – which could run into the hundreds of pages – is wasteful and unlikely to even be read by the new provider.

418.106 Drugs, controlled drugs and biologicals, medical supplies, and durable medical equipment.

Section (b) As per our comments on 418.52(a)(3), discussing drug policy during the initial assessment would confuse many families and sometimes delay admission.

Further, the phrase "potential dangers" is unnecessarily harsh and should be removed.

418.108 Short-term inpatient care.

This section should be changed to allow short-term inpatient care for crises of a psychosocial/family nature.

Further, hospices should be required to explain to families that there is a plan and/or goal to discharge the patient from inpatient care.

Section (a) This section should require 24 hour RN nursing services only for the general inpatient level of care, not for the respite level of care.

418.110 Hospices that provide inpatient care directly.

Section (o) Overall This section should be removed completely as inappropriate for the nature of hospice care. In those cases where hospices use physical and/or drug restraint, it is being done for **symptom management** caused by the terminal illness (e.g., terminal agitation), not as a means of behavioral management of, say, mental health or dementia patients. Drugs such as Haldol and Atavan are appropriately used by hospice for management of symptoms.

Section (o) (3) (ii) (c) The requirement that the hospice medical director or physician designee must see the patient to evaluate the need for restraint within one hour after its initiation will often prove unworkable (e.g, overnight).

Section (o)(7) The word "unexpected" should be placed before "death."

418.112 Hospices that provide hospice care to residents of a SNF/NF, ICF/MR, or other facilities.

Section (d) This standard is another example of how this proposal would move hospice closer to the medical model of care. The overall coordination of care for a facility patient should be done by the entire hospice interdisciplinary group and appropriate facility staff, not merely by physicians. The section should be changed accordingly.

Section (e)(4)(iii) This section should be removed. It is adequately covered under points (i), (ii) and (iv).

Section (f)(3) The 14-day requirement should be changed to 15-day to provide the flexibility discussed in our comments under 418.54(d).

Section (f)(4) Clarification is needed on the phrase "all caregivers." We believe the intent is to specify the Hospice IDG and the facility staff, and the wording should reflect that intent.

Section (h) Hospice is not in a position to require that patients be retained in an SNF, NF, ICF/MR or other facility after they have been discharged from hospice. These requirements are better placed in the conditions of participation governing the facilities specified.

418.114 Personnel qualifications for licensed professionals.

Section (c)(7) Generally, we believe that the needs of hospice patients and families justify the requirement that hospice services be furnished by an MSW. Indeed, New Jersey has such a requirement (plus requiring a year's employment experience in a non-hospice healthcare setting). We recognize, however, that the dearth of MSWs across much of the nation would make an MSW requirement very burdensome to many agencies, particularly those in rural areas -- and therefore urge CMS to keep the wording of Section 7 as is, requiring merely a baccalaureate from an accredited school of social work.

Section (d) This section should be reworded to clarify that the hospice need not obtain a criminal background check on employees of **contracted** agencies. It is possible that such a requirement could be expanded to an unworkable degree (e.g., DME delivery persons).

* * *

The Board of Trustees and the 39 licensed hospices that comprise the New Jersey Hospice and Palliative Care Organization appreciate consideration of these comments by CMS.

Sincerely,

Donald L. Pendley, M.A., CAE, APR
President

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July 19, 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: Comments on the Proposed Rule for Hospice Conditions of Participation

To whom it may concern,

Enclosed please find one original set of comments and two copies regarding the Centers for Medicare & Medicaid Services' proposed rule on Hospice Conditions of Participation.

These comments are submitted by the Center for Medicare Advocacy (Center). The Center is a national, non-partisan education and advocacy organization that identifies and promotes policy and advocacy solutions to ensure that elders and people with disabilities have access to Medicare and quality health care. Any questions regarding our comments should be addressed to Mary T. Berthelot. She can be reached by telephone at 860.456.7790 or by email at tberthel@medicareadvocacy.org.

Sincerely,

MT Berthelot

Mary T. Berthelot
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Judith A. Stein
Executive Director

Center for Medicare Advocacy
Comments on Proposed Rule for Hospice Conditions of Participation
42 CFR § 418

Section Number	Proposed Rule	Center's Suggestion	Comment
Definitions **§ 418.3**		A social worker is a professional who holds an MSW from an institution of higher learning accredited by the Council on Social Work Education.	The term "social worker" is not defined in the proposed definition section, but instead in the personnel requirements. This term should be defined, as there is a great deal of confusion among the general public as to who should be described as a social worker.
§ 418.3 Definitions		A plan of care is a written document which specifies the hospice care and services necessary to meet the patient and family-specific needs initially identified in the comprehensive assessment. *The plan of care is updated as appropriate based on the hospice's ongoing assessments.*	"Plan of Care" is not defined in the proposed definitions. As eight of the top deficiencies cited by surveyors have to do with the plan of care, it is especially important to define this concept. The suggested language comes from § 418.56.
		Family is a unit of care. It does not refer to kinship but to individuals with whom the patient has a significant relationship and who are part of the plan of care.	As the term "family" is frequently used in the proposed regulations (for example, see § 418.56), and is used in a non-traditional sense of the word that is not limited to kinship, it should be defined.
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Section Number	Proposed Rule	Center's Suggestion	Comment
§ 418.3 Definitions	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.	A representative is an individual authorized under State or other applicable law to act on behalf of a beneficiary.	The suggested language is from 42 C.F.R. § 405.902. The proposed language is unhelpful as it fails to acknowledge the State's case law.
	"Bereavement counseling" is defined as "emotional, psychosocial, and spiritual support and services provided after the death of a patient."	Bereavement counseling is emotional, psychosocial, and spiritual support and services provided *before and* after the death of the patient to assist with issues related to grief, loss, and adjusting.	Good bereavement counseling begins before the patient has died. Moreover, the requirements direct hospices to administer a bereavement assessment as part of the comprehensive assessment which must be completed within four calendar days of a hospice election. (§ 418.54(c)(3)(i)) . This practice and direction should be reflected in the definition.
			Continue to next page

Section Number	Proposed Rule	Center’s Suggestion	Comment
§ 418.3 Definitions	“Clinical note” is defined as 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.”	…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, emotional, *psychosocial, or spiritual condition.*	As hospice care is comprehensive, this definition should be changed such that the last clause reads, “physical, emotional, psychosocial, or spiritual condition.”
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Section Number	Proposed Rule	Center's Suggestion	Comment
§ 418.3 Definitions		Routine hospice care is care rendered in accordance with the plan of care on an intermittent basis in the patient's home. Continuous home care is at least eight hours of continuous care, of which at least half is provided by a skilled nurse, in accordance with the plan of care, provided in the patient's home during a period of physical or psychosocial crisis. General inpatient care is care provided in an inpatient facility which provides 24 hour nursing services, for the purpose of resolving either physical or psychosocial crisis that cannot be managed in the home. Respite care is care provided in an inpatient facility for periods of up to five days for the sole purpose of providing a period of relief from the burdens of care-giving for the patient's family.	The four levels of care should be defined in the definitions.
			Homemaker services should be defined. Continue to next page

Section Number	Proposed Rule	Center's Suggestion	Comment
Patient's Rights **§ 418.52**			
§ 418.52(a)(1)	The hospice must provide the patient 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.	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 *or representative* understands during the initial evaluation visit in advance of furnishing care.	As written, this proposed regulation may have the unintended consequence of barring access to hospice care for individuals who do not speak English or other languages commonly used in the United States. Therefore this rule should be re-drafted so that it is reasonably flexible. For example, if a hospice cannot obtain a written notice of the patient's rights and responsibilities in a language and manner that the patient or representative understands, but is able to obtain a translator who is able to explain the meaning of the written document to the beneficiary, the hospice should be considered to be in compliance with the intent of the rule.
§ 418.52(a)(2)	The hospice must inform and distribute written information to the patient concerning its policies on advance directives, including a description of applicable State Law.	The hospice must inform and distribute written information to the patient *or representative* concerning its policies on advance directives, *in a language and manner that the patient or representative understands,* including a description of applicable State Law.	Advance directives are as important as rights and responsibilities and should therefore be provided by the hospice in a language and manner that the patient or representative understands. If a hospice cannot obtain a written copy of its policy regarding advance directives, including a description of applicable State law, in a language and manner that the patient or representative understands, but is able to obtain a translator who is able to explain the meaning of the written document to the beneficiary, the hospice should be considered to be in compliance with the intent of the rule. Continue to next page.

Section Number	Proposed Rule	Center's Suggestion	Comment
§ 418.52(a)(3) Patient Rights	The hospice must inform the patient and family of the hospice's drug polices and procedures…	The hospice must inform the patient or *representative and relevant family members in a language and manner that the individual understands*, of the hospice's drug polices and procedures…	
§ 418.52(b)(1)	The patient has the right	The patient *and family* has the right	
§ 418.52(b)(1)(i)	To exercise his or her rights as a patient of the hospice.	To exercise his or her rights as a patient of the hospice *or family member of a patient of the hospice.*	
§ 418.52(b)			This section should address the fact that patients who refuse Do Not Resuscitate status cannot be denied hospice care based on that decision. This section should address the fact that patients should not be denied hospice care based on the cost of their reasonable and necessary palliative care. This section should also indicate that patients have a right to refuse treatment and to formulate advance directives.
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Section Number	Proposed Rule	Center's Suggestion	Comment
§ 418.52(e)	Before care is initiated, the patient or representative 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.	Before care is initiated, the patient or representative 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. *This will include information regarding payment of room and board should the individual reside in a SNF or NF.*	As written, this proposed regulation may have the unintended consequence of barring access to hospice care for individuals who do not speak English or other languages commonly used in the United States. Therefore this rule should be re-drafted so that it is reasonably flexible. For example, if the hospice cannot produce a written copy of the financial liabilities in a language and manner that the patient or representative understands, but is able to obtain a translator who is able to explain the meaning of the written document to the beneficiary, the hospice should be considered to be in compliance with the intent of the rule.
Comprehensive Assessment **§ 418.54**			
§ 418.54(c)(3)(ii)	A review of the patient's prescription and over the counter drug profile…	A review of the patient's prescription and over the counter drug profile, *including herbal remedies and other alternative treatments. This review should include all medications that the beneficiary is taking, regardless of their relationship to the terminal illness, also including…*	Concern for safety mandates that the review of the patient's medications be comprehensive.
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Section Number	Proposed Rule	Center's Suggestion	Comment
Interdisciplinary Group Care Planning and Coordination of Services **§ 418.56**	The IDG, 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.	The IDG must work with the patient's attending physician to prepare a written plan of care for each patient. A plan of care is a written document which specifies the hospice care and services necessary to meet the patient and family-specific needs initially identified in the comprehensive assessment. *The plan of care is updated as appropriate based on the hospice's ongoing assessments.*	The proposed rule states that the IDG, "*in consultation* with the patient's attending physician, must prepare a written plan of care for each patient." This statement misrepresents the role that attending physicians play in conjunction with hospice care. They do not consult with the hospice IDG but give orders to the IDG which are incorporated into the written plan of care. Thus the "in consultation" language should be removed from the rule and replaced with language that indicates that even after a beneficiary elects hospice care, the beneficiary's attending physician continues to maintain medical responsibility for the beneficiary's care. In the proposed rule, the meaning of "as it relates to the terminal illness" is unclear.
§ 418.56(a)(1)	The hospice…to meet the physical, medical, emotional, and spiritual needs..	The hospice…to meet the physical, medical, *psychosocial*, emotional, and spiritual needs..	
§ 418.56(a)(1)	The hospice must designate a qualified health care professional…to provide coordination of care…	The hospice must designate a qualified health care professional…to provide coordination of care…*This person shall be referred to as the interdisciplinary group coordinator.*	
			Continue to next page

Section Number	Proposed Rule	Center's Suggestion	Comment
§ 418.56(a)(1)(i) IDG	A doctor of medicine or osteopathy (who is not the patient's attending physician) who is	A doctor of medicine or osteopathy who is an employee of the hospice or is contracted by the hospice as specified in § 418.84(a).	Attending physicians may be and often are the physician member of the IDG.
§ 418.56(c)(6)	The IDG's documentation of patient and family understanding, involvement, and agreement with the plan of care.	The IDG's documentation *regarding the level of* patient and family understanding, involvement, and agreement with the plan of care.	Given that there can be many members in the hospice care unit, including the hospice patient and his or her family, there may be many levels of understanding, involvement, and agreement with the plan of care.
§ 418.56(d)	The medical director or physician designee, and the hospice interdisciplinary team must …	*The hospice interdisciplinary group must review,* revise and document the plan as necessary at intervals specified in the plan…	The medical director or physician designee is a member of the IDG and thus it is redundant and possibly confusing to refer to the medical director or physician designee *and* the IDG. Also of note, for the sake of consistency the group referred to in this proposed regulation should be called the interdisciplinary group rather than team, as that is how it was referred to in earlier regulations.
Core Services **§ 418.64**			
§ 418.64(b)(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.	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. *The contract need not be with another Medicare certified hospice program.*	Since it is not the intent to require that hospices contract with other hospices for the provision of highly specialized nursing care, the regulations should explicitly state this to be the case, as the general rule is that hospices can only contract with other hospices for the provision of core services, which include nursing services. Continue to next page

Section Number	Proposed Rule	Center's Suggestion	Comment
§ 418.64(c) Core Services	Medical social services must be provided by a qualified social worker, under the direction of a physician.	Medical social services *must be provided by a qualified social worker, with an MSW from an institution of higher learning that is accredited by the Council on Social Work Education.*	
§ 418.64(d)(1)(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.	Have an organized program for the provision of bereavement services furnished under the supervision of a qualified professional with experience *or education* in grief/loss counseling.	
§ 418.64(d)(3)(iii)	The hospice must 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 efforts to do so.	The hospice must *make all reasonable efforts to* facilitate visits by local clergy, pastoral counselors, or other individuals who can support the patient's spiritual needs.	As written, the proposed rule makes it sound as if compliance with this requirement is not terribly important.
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Section Number	Proposed Rule	Center's Suggestion	Comment
Nursing Services – Waiver of requirement that all nursing services be routinely provided directly by a hospice. **§ 418.66**			This waiver should not be available for for-profit hospices. Under the current regulations, for-profit hospice programs have been the fastest growing sector of the hospice industry. There is thus no evidence that they need this waiver.
§ 418.66(d)			Is it the intent of CMS to limit the use of the waiver for individual hospice programs to only three years? The language of the proposed regulations indicates that a hospice program would only be eligible for the waiver program for three consecutive years
Physical therapy, occupational therapy, speech language pathology, and dietary counseling. **§ 418.74**			This waiver should not be available for for-profit hospices. Under the current regulations, for-profit hospice programs have been the fastest growing sector of the hospice industry. There is thus no evidence that they need this waiver.
§ 418.74(d)			Is it the intent of CMS to limit the use of the waiver for individual hospice programs to only three years? The language of the proposed regulations indicates that a hospice program would only be eligible for the waiver program for three consecutive years. Continue to next page

Section Number	Proposed Rule	Center's Suggestion	Comment
Home Health Aide and Homemaker Services **§ 418.76**			
§ 418.76(i)			This section should indicate that it is the responsibility of the hospice program to coordinate the services of the Medicaid personal care benefit and the services of the hospice benefit to assure that the patient receives all of the services that he or she requires and is entitled to. Moreover, as it is never said clearly anywhere else, this section should indicate that services available under the Medicaid personal care benefit may be *utilized to the extent that the hospice would routinely utilize the services of a hospice resident's family in implementing the care plan.* (Language from § 418.112(e)(8)).
Organization and Administration of Services **§ 418.100**			
§ 418.100(d)	A hospice may not discontinue or reduce care provided to a Medicare or Medicaid beneficiary because of the beneficiary's inability to pay.		Added to this section should be requirements regarding the issuance of Advance Beneficiary Notices (when the beneficiary faces the possibility of responsibility for payment) and Expedited Determination Notices (notice given to eligible beneficiaries regarding their right to expedited determinations).
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Section Number	Proposed Rule	Center's Suggestion	Comment
Medical Director **§ 418.102**			
§ 418.102(b)(2)	The patient's and family's expectations and wishes for the continuation of hospice care.		This section addresses a beneficiary's terminally ill status. Whether the patient or family wishes to continue hospice care is not material to this question and therefore there is no reason for the medical director to assess this particular issue prior to recertifying an individual as terminally ill. Instead, the patient's and family's wish for continuation of hospice care should be an ongoing assessment by the IDG.
Clinical Records **§ 418.104**			
§ 418.104(a)(2)	Informed consent, authorization, and election forms.		It is not clear in the proposed rule what authorization is being referred to.
§ 418.104(d)	Patient clinical records must be retained for 5 years…		This standard should be consistent with HIPAA.
§ 418.104(e)	…the hospice must forward a copy of the patient's clinical record and the hospice discharge summary to the facility.	…the hospice must forward a copy of the hospice discharge summary to the facility.	As a hospice clinical record will include information about the beneficiary's family, it would be inappropriate and violate confidentiality to forward the entire record to another facility. Moreover, the facility will not need the entire clinical record to render appropriate care to the patient, but only the summary of that information, which would be the discharge summary.
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Section Number	Proposed Rule	Center's Suggestion	Comment
Drugs, Controlled Drugs and Biologicals, Medical Supplies, and Durable Medical Equipment **§ 418.106**			
§ 418.106(b)	The hospice nurse must document that the policy was discussed with the patient and family.	The hospice nurse must document that the policy was discussed with the patient *or representative* and family *in a language and manner that they can understand,*	
Short-term Inpatient Care Proposed § 418.108	Short-term inpatient care must be available for pain control, symptom management and respite purposes…	Short-term inpatient care must be available for pain control, *physical and psychosocial* symptom management and respite purposes…	
§ 418.108(a)	Inpatient care for pain control and symptom management must be provided in one of the following…	Inpatient care for pain control and *physical or psychosocial symptom management* must be provided in one of the following…	
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Section Number	Proposed Rule	Center’s Suggestion	Comment
§ 418.108(a)(2) Short-term inpatient care	A Medicare-participating hospital or skilled nursing facility that also meets the standards specified in § 418.110(b) and (f)…	A Medicare participating hospital or skilled nursing facility that *(i) Provides 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.* *(ii) When patients are receiving general inpatient care for management of acute physical symptoms, each shift must include a registered nurse who provides direct patient care.* *(iii) Meets the standards specified in § 418.110(f) regarding patient areas.*	When patients are receiving general inpatient care for acute symptom management, registered nurses must be available on every shift. The Center’s suggested language is from the current requirements. That a registered nurse be available on every shift is not necessarily required when a beneficiary is receiving short-term inpatient care for psychosocial symptom management or for respite purposes.
§ 418.108(b)(2)	A Medicare/ Medicaid approved nursing facility…	A Medicare/Medicaid *certified* nursing facility…	
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Section number	Proposed Rule	Center's Suggestion	Comment
Hospices that Provide Inpatient Care Directly. **§ 418.110**			
§ 418.110(b)	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.	(i) 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. *(ii) When patients are at a general inpatient level of care for management of acute physical symptoms, each shift must include a registered nurse who provides direct patient care.*	When patients are receiving general inpatient care for acute symptom management, registered nurses must be available on every shift. The Center's suggested language is from the current requirements. That a registered nurse be available on every shift is not necessarily required when a beneficiary is receiving short-term inpatient care for psychosocial symptom management or for respite purposes.
§ 418.110(m) Standard: Pharmaceutical Services			This section needs to address the interface of the hospice inpatient facility with Medicare Part D for the provision of medications not related to the terminal illness.
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Section Number	Proposed Rule	Center's Suggestion	Comment
Hospices that provide hospice care to residents of a SNF/NF, ICF/MR or other facility **§ 418.112**			The term other facility is too vague. It should be either dropped entirely or modified such that it reads "other Medicare/Medicaid certified facility" Otherwise, the regulation appears to apply to hospices that provide hospice care to residents living in assisted living facilities or other unregulated entities.
§ 418.112(a)	Medicare patients receiving hospice services in SNF, NF or other facility…	Medicare patients receiving hospice services in *SNF, NF, ICF/MR or other Medicare/Medicaid certified facility* must meet…	
§ 418.112(b)	The hospice must assume full responsibility for professional management of the resident's hospice care…		This requirement must be mirrored in the requirements for all Medicare/Medicaid certified facilities in which Medicare beneficiaries reside. Moreover, requirements for the certified residential facilities should require that those facilities notify potential residents about hospice care and whether or not hospice care is available within the facility.
			Continue to next page

Section Number	Proposed Rule	Center's Suggestion	Comment
§ 418.112(e) Provision of hospice to residents of certified facilities	The hospice and the facility must have a written agreement that specifies…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.	The hospice and the *Medicare certified* facility must have a written agreement that specifies…The written agreement must include at least the following: (1) A statement of understanding that it is the hospice's responsibility to obtain a signature on the hospice election form from either the patient or representative.	The proposed rule makes no sense. A particular beneficiary's hospice election is not part of the contract between the hospice and the facility.
§ 418.112(e)(5)	An agreement that it is the facility's primary responsibility to furnish room and board.	An agreement indicating: (i) It is the facility's primary responsibility to furnish room and board. (ii) *It is the hospice's responsibility to notify the patient or representative in writing that Medicare does not pay for room and board when the patient is receiving hospice care at the routine level of care.*	
§ 418.112(g)	The hospice must designate a member of its IDG to coordinate the implementation of the plan of care with the representatives of the facility.	*The interdisciplinary group coordinator* must coordinate the implementation of the plan of care with the representatives of the *Medicare certified* facility.	Continue to next page

Section Number	Proposed Rule	Center's Suggestion	Comment
Personnel Qualifications for Licensed Professionals **§ 418.114**			
§ 418.114(c)(7)	Social worker. A person who has a baccalaureate degree from a school of social work accredited by the Council on Social Work Education.	Social worker. A person who has an *MSW* from a school of social work accredited by the Council on Social Work Education.	An MSW is required to meet the complex needs of hospice patients and their families as they confront death and dying. Therefore, regardless of state licensing, social workers providing hospice care should have at least an MSW.

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NEWHOPE™
HOSPICE

June 7, 2005

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

Attention: CMS 38-44-P

Please consider this letter to be in response to above numbered file code, CMS-3844. Covenant Hospice desires the comments included in this letter be considered for review with the proposed Conditions of Participation for Hospice's certified for the Medicare Hospice Program.

Please review the proposed rule 418.116, Standard, Multiple Locations. In order to better serve hospice patients, many hospices have chosen to open and operate satellite offices. This allows the hospice staff to reach the patients faster when there is a critical need, especially in the rural areas. In order for quality hospice care to be provided, especially in rural areas, many hospices have chosen to open satellite offices.

Eliminating satellite offices would harm the rural communities they serve. We serve a great deal of the rural area of Indiana. Our current and future satellite offices would allow us to work out of a rural area that would not be possible to do so if we had to license as a separate hospice, and build the administrative staff accordingly. This would limit access in rural locations.

Satellite offices are surveyed along with the licensed main office of each hospice and are required to adhere to the same regulations as the main office. There seems to be no benefit from a regulatory point of view for the proposed rule. The risk to hospices operating satellite offices is far too great to not enforce regulatory compliance at each satellite office. But limiting the offices to separate certified hospice programs would again seem to limit access to the hospice benefit, because of the cost involved. In opening and operating a separate certified program the costs would increase dramatically by having to provide duplicative administrative personnel, without improving on the quality of care. More Medicare funds would be spent on Administrative tasks, leaving less money available for patient care.

Prior approval from Medicare in order to operate a satellite office seems unnecessary and would negatively affect the patient's accessibility to hospice, and could delay or prevent the rural patient from getting needed services. If the hospices operating satellite offices are willing/able to open additional offices and operate under the state and federal regulations that are mandated, they should be able to take that risk.

If, however, this rule does move forward, we believe that any existing satellite offices opened prior to this rule should be allowed to continue operations as before.

Thank you for your time and consideration to our response to the proposed regulation 418.116 of the Medicare Conditions of Participation for the Hospice Medicare Benefit.

Sincerely,

Chris Ice

Chris Ice
Chief Operating Officer

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Covenant™
HOSPICE

June 7, 2005

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

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2464 Fortune Drive Ste 130
Lexington KY 40509
Phone (859) 273-1225
Fax (859) 273-9225

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Thank you for your time and consideration to our response to the proposed regulation 418.116 of the Medicare Conditions of Participation for the Hospice Medicare Benefit.

Sincerely,

Greg Patterson
President
Covenant Hospice

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Avera Health

Sponsored by the
Benedictine and
Presentation Sisters

3900 West Avera Drive
Sioux Falls, South Dakota 57108-5721
(605) 322-4700
Fax: (605) 322-4799
www.avera.org

July 19, 2005

To Whom It May Concern:

Attached are comments regarding the proposed Hospice Conditions of Participation (file code CMS-3844-P). We encourage you to seriously consider the recommendations and be mindful of the issues discussed in this document as the revisions are finalized. Balancing the proposed revisions and the impact on hospice care in rural areas is critical.

Thank you for your consideration.

Sincerely,

Carol J DeSchepper

Carol J. DeSchepper
Vice President for Quality Integration
Avera Health
3900 West Avera Drive
Suite 200
Sioux Falls, SD 57108

cc: Deb Fischer-Clemens, Director of the Avera Center for Public Policy

We're Caring for Life

Avera

In response to the call by NHPCO, Avera Health offers the following comments on the proposed hospice conditions of participation (COPs). Avera Health is a Catholic Health System based in rural South Dakota, SW Minnesota, NW Iowa and North Central Nebraska.

In many instances, Avera hospices agreed with the NHPCO comments already provided in its 'Request for Comments Version 2 document.' However, in some instances, we felt we needed to comment on other sections or further elaborate on comments provided by NHPCO to ensure that the rural hospice perspective is represented. These comments are outlined below:

2005 CMS PROPOSED COPS	Avera COMMENTS
§ 418.3 Definitions For the purposes of this part, *Attending physicians* means a (1) (i) Doctor of medicine of 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.	• We are requesting that Physician Assistants be among the providers fit the definition of *Attending Physician.* There are rural communities where there are limited numbers of physicians, perhaps no nurse practitioners, but physician assistants may be part of the healthcare delivery team. While their basic training is not equal to that of a nurse practitioner, they are a key provider in many states and communities.

Nursing Services	• It would be helpful to have a definition of *Nursing Services*, so it is interpreted consistently throughout the document by providers and surveyors alike. A definition consistent with the current COPs would clarify the requirement of the standards.
§ 418.52 Patient's Rights (a) (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.	• We are concerned, especially in rural areas, with how the hospice will be able to find an interpreter. Not only will it be difficult to find an interpreter in rural areas, but nearly impossible to do so in the middle of the night. Also, a requirement to have written materials in multiple languages and dialects would be especially burdensome, if not impossible. Avera recognizes that interpreter services are important, but CMS needs to find a balance. Allowing a family member to translate would be helpful.
(a) (3) The hospice must inform the patient and the family of the hospice's drug policies and procedures, including the policies and procedures regarding the tracking and disposing of controlled substances.	• Avera overwhelmingly agrees with NHPCOs comment that providing information on hospice drug policies and procedures at the time of admission will further overwhelm the patient and family. It also may cause families to panic and disallow the use of any controlled substances, which could ultimately disadvantage the patient. Avera also has concerns regarding the definition of terms in (3). What are the requirements for drug tracking and disposal? What does CMS consider a controlled substance, Schedule II or all drugs?
(a) (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 his understanding of rights.	• Avera has concerns regarding the use of the word 'demonstrated' throughout the proposed COPs, without a definition. "Demonstrated" undefined enables broad interpretation and extensive discretion to surveyors that will lead to inconsistencies in application.

(b) (1) The patient has a right to __ (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	• Avera believes that this clause should be amended to include the patient's right to refuse treatment. This would be consistent with patient rights requirements by other accrediting bodies and in other parts of the continuum.
(b)(4) The hospice must—(i)-(iv)	• Avera is concerned that the proposed complaint policy is too aligned with the nursing facility industry. Hospice care is more congruent with home health care and home health has a more consistent policy. Avera recommends that the proposed COPs incorporate the home health complaint policy, rather than the nursing facility. An example of a hospice's complaint procedure includes: 1. Report complaint to director 2. Director follows up by documenting complaint, discussion, and resolution 3. File a dependent adult abuse report if appropriate 4. Encourage a patient to file police report if appropriate 5. 5. Conduct internal investigation
(e) Patient Liability.	• Avera hospice providers feel an ABN is not necessary for hospices in all cases. For the most part, hospice services including medicine and equipment are covered. The only grey areas that may exist surround drugs and those instances are too difficult to foresee at the time of admission. Prior to admission, it would be best to only review hospice fees. To ask the question another way, how does this requirement relate to or differ from the current ABN requirements?
§418.54 Comprehensive assessment of the patient	
(a) Initial assessment.	• There is confusion regarding the initial assessment, especially since there was no definition of initial assessment or physician's admission order for care. We feel this standard should read that an initial contact, rather than a

	completed assessment, be conducted within the 24-hour time frame. There is also some confusion as to when the time clock begins; is it after the physician's order is received or after the patient elected the benefit? There are many instances where the patient and/or family members request the initial visit and assessment on a specific timeframe, which may exceed the 24 hour period. At minimum a hospice should be offered the flexibility to honor the family's wishes and conduct the assessment 'on the timeframe requested by the family'. Avera also recommends that a 'licensed professional' replace 'registered nurse.' This will help alleviate pressures caused by the nursing shortage; provide individual hospices with the flexibility to work with their own staffing abilities; and reinforce the interdisciplinary team focus and strength of hospice care.
(b) Timeframe for completion of the comprehensive assessment.	• Rural hospices feel the four (4) day time frame for completion of the comprehensive assessment is very problematic. Many rural hospices utilize part time disciplines like social workers or chaplains making the completion of an assessment within 4 days often not feasible, especially with a weekend admit. Seven (7) days would be preferable, definitely no less than five (5) days. Avera providers acknowledge this assessment will be done much earlier than 5-7 days if the patient is in crisis.
(c) Content of the comprehensive assessment.	• Avera recommends that CMS insert new language into this COP standard. First, (c) should be amended as follows: 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 and family's wellbeing, comfort, and dignity throughout the dying process. Second, more factors should be included in (c) (3) because hospices provide more services than bereavement and drug therapy. Two factors that should be among those included are (1) pain and symptom

	management and (2) emotional and spiritual support. Another important issue regarding the comprehensive assessment is that there should be an additional, more limited standard for short stay assessments. Having a short stay standard would benefit the patient and family, allowing them to receive services in the last day without overwhelming them with the rest of the information.
(d) Update of the comprehensive assessment.	• We wonder if the update should apply to the plan of care, not the comprehensive assessment. The way the proposed standard reads, we are concerned that due to the terminology, we would need to update two documents: comprehensive assessment and plans of care. Rather the comprehensive assessment should be completed, and then the plan of care should be updated every two weeks. Avera hospices are also concerned about the 14-day requirement in relation to holidays. Language allowing some flexibility in these holiday circumstances would allow hospices to meet this standard.
(e) Patient outcome measures.	• Data collection related to patient outcomes by Avera hospices, and hospices in general, is not as fully developed as it needs to be. Avera, as an organization, recognizes the importance of data collection; however, many of our smaller hospices have difficulty finding the value and ROI for extensive PI programs, when faced with finite resources (time, people, and money). In addition, when a hospice has an average daily census of 1-4 patients, the data collected is not statistically significant. Therefore the hospice arguably doesn't see the value in data collection since it does not have a large enough patient base to enable meaningful data analysis. Each case can quickly be examined on its own merits and distinguished from others.

	Thirdly, there are limited choices of software programs and tools targeted specifically for hospices to simplify data collection. To compound the lack of choice and access to vendors, the initial expense of the software and upgrades and support is often prohibitive. When all of these factors are combined, rural hospices place a higher priority on patient care than data collection and measurement of patient outcomes. We believe this standard as currently written will be burdensome, may result in time being taken away from patient care, and will result in data that is of limited or no significance/value.
§ 418.56 Interdisciplinary group care planning and coordination of services. (a) Approach to service delivery.	• Avera hospices had serious concerns regarding (a) (1) (i) that prohibits the doctor on the IDG from being the patient's attending physician. In rural communities, this prohibition is not realistic. In our rural communities in the four state region, the medical director for hospice almost always has his/her own practice in town, with their own patients. To prohibit the medical director from sitting on the IDG when he/she is the attending will practically eliminate Doctors from wanting to serve as medical directors for hospice. There are not enough providers in rural communities to comply with this prohibition.
(b) (6) The IDG's documentation of patient and family understanding, involvement, and agreement with the plan of care. . .	• We are concerned about the problems this standard creates and feel compliance with this standard will be difficult. How would this be documented? By an attestation of agreement? A hospice cannot attest that the patient and or family were in agreement on every change in care. Further, what about instances when the patient and family disagree, but the change is clearly in the best interest of the patient's comfort and outcome? We believe that the term 'agreement' should come out in the standard.

(d) Review of the plan of care.	• Avera has significant concerns regarding the separation of the medical director from the IDG in these proposed COPs (in this proposed standard, as well as others). CMS should retain the IDG framework for hospice, including no separation between the IDG and the Doctor. The IDG is a cornerstone of what makes hospice care distinctive— it is patient-centered, collaborative treatment for patients at the end of life.
§418.64 Core Services	
(a) Physician service	• Again, Avera hospices have significant concerns regarding the separation of the medical director from the IDG in these proposed COPs. See previous comments above.
(c) Medical social services	• This is another instance of CMS separating the physician from the IDG. We believe the social worker should remain under the direction of the IDG, rather than the physician, as proposed in the COPs.
(d) (1) (ii) Bereavement Counseling	• Avera disagrees with CMS regarding the requirement to provide nursing facility staff with bereavement services. Nursing facility should be equipped to provide this service to its own staff. For a hospice with a significant number of clients requiring nursing facility placement, this requirement would be burdensome. It seems inappropriate to require bereavement counseling to another group of health professionals and/or to residents with whom the hospice has no relationship.
§ 418.76 Home Health Aide and Homemaker services.	• We would advocate for a definition of home health aide and homemaker services. In the proposed standards if appears that a homemaker actually must meet the training and continuing education requirements of for a home health aide. This is a major shift and an additional burden to a hospice organization.
(h) Supervision of home health aides.	• We are requesting clarification of whether the supervision visit needs to be done per each patient or per each aide.

	Avera hospices feel the supervision requirements are too restrictive and they do not understand the rationale for such additional scrutiny being placed on home health aides, especially since aides are already required to have competency training. We recommend that the supervision be left as it is or, at a minimum, it reflects the current home care regulations. This would relieve rural providers that often provide both home care and hospice of the burden of having to track and comply with potentially conflicting regulations. Also, if CMS decides to move forward in this direction, it would at least be helpful to provide hospice providers with flexibility by incorporating every two weeks and monthly, instead of the specific day requirements.
§418.100 Organization and administration of services.	
(a) (2) That each patient experience hospice care that is consistent with patient and family needs and desires.	• Avera recommends striking 'and desires' from this condition because it is too subjective.
(e) Professional management responsibility.	• Avera strongly suggests the removal of 'staff' from this condition because it is unclear how hospices can become supervisors of nursing facility staff. However, we concur that it is clearly (and appropriately) the responsibility of the hospice to provide oversight and direction to the services provided.
§ 418.102 (c) Coordination of medical care.	• Avera feels that placing the hospice's quality assessment and performance improvement program under the responsibility of the medical director, rather than the IDG is a major concern. First, this responsibility is too burdensome for a volunteer medical director (which many are in our communities). In rural communities, medical directors also maintain their own practice. This additional responsibility may cause many physicians to

	choose not to serve as medical director, creating huge problems for rural hospices and potential access issues for patients. A suggestion is to place the QA/PI program under the responsibility of the IDG, with the medical director reviewing. This places the responsibility for QA/PI with the IDG where it belongs, since all members of the team contribute to the quality of the patient experience. The hospice experience is not a *medical* experience, it is an experience based on collaboration and the contributions of many professionals. The quality program should be reflective of that fact.
§ 418.104 Clinical Records (b) Authentication.	• Avera hospices recommend this condition track more closely with home care. Specifically, removing the signature requirement so that software can comply with both hospice and home care. Electronic medical records already have multiple protections in place making the signature requirement duplicative and unnecessary (exp. passwords, etc.)
(e) Discharge or transfer of care.	• Avera hospices feel that sending the entire clinical record at discharge is not feasible. Discharge summary and other documents required to support ongoing care are sufficient. In no other part of the continuum is it a requirement to send an entire copy of the patient's medical record. This requirement seems costly and excessive. We believe that continuity of care can be achieved through the discharge summary and perhaps, select other documents being provided.
§ 418.108 Short-term inpatient care. Inpatient care must be available for pain control, symptom management, and respite purposed, and must be provided in the participating Medicare or Medicaid facility.	• This standard should be expanded to include admission for a crisis of psychosocial or family nature. In the experience of our hospices, the family or patient in crisis is often a time when alternatives to home care must be considered, if even for short term inpatient care.

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Baystate Visiting Nurse Association & Hospice
A Member of Baystate Health System

July 21, 2005

Center for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS – 3844-P
PO Box 8010
Baltimore, MD 21244-8010

Dear Sir/Madam:

Thank you for this opportunity to comment on the Medicare and Medicaid Programs: Hospice Conditions of Participation; Proposed Rule which appeared in the Federal Register on May 27, 2005. Baystate Visiting Nurse Association & Hospice is a not for profit organization which has provided Hospice services since 1988.

We are very pleased that the proposed standards are based on assuring patient quality of care. The new organization of the proposed CoPs are very helpful and more user friendly as well as consistent with the hospice's interest in assuring quality and uniformity among hospice programs. I will provide comment on those standards which I believe need further clarification or where the standards may pose implementation problems for our hospice.

General Comments

- Well-organized with new structure, patient care followed by Administrative Standards.
- The greater flexibility to choose appropriate practices is appreciated.
- The impact analyses appear unrealistic in terms of time and cost.
- Palliative Care requires additional focus and clarification in order to meet the current practice trends.

418.3 Definitions

Satellite location – needs further clarification. Medicare should be clear about what criteria a "satellite" must meet if it is to use a single provider number to establish other hospice programs. Criteria might include shared staffing, level of administration, and distance of service area from main office. Clarification on the survey process/time frame for the approval process is also requested.

418.52 Patient's rights

(a) *Notice of rights*

(1) Translation – requirement of written translation could provide problems for hospices in urban areas with significant multi-cultural populations.

(2) Information about tracking and disposal of controlled substances – Informing families about drug policies at the time of admission will be confusing and potentially terrifying to families already concerned about having controlled substance in the home. Patients and families are overwhelmed by the amount of information and forms to be signed at admission. Explanations in a patient handbook should suffice, with conversations by the clinician given as appropriate.

(b) *Patient liability* – Use of ABN form for hospice is still confusing.

418.53 Comprehensive assessment of the patient

(a) Initial assessment – requirement for assessment within 24 hours is not practical. Many referrals come from non-physician referral and are not subject to an attending physician's order. Even with a physician referral, the first physician order may be for a consult, not an admission. What ever the source of the referral, the patient/family controls when the admission takes place as the patient must elect the benefit. Language might be revised to "make available to the family a visit within 24 hours" or as otherwise requested by the family", or "contact" rather than "visit".

418.56 Interdisciplinary group care planning

(c) Content of the plan of care – There should be no requirement that the family agree with the PoC as the patient's wishes should prevail. Further clarification is needed if the patient is not competent and there is disagreement among family members. In Massachusetts, the patient's appointed health care proxy would make the health care decisions.

(d) Review of the PoC – The requirement for the Hospice Medical Director to collaborate with the attending physician is desirable but not always practical given time, interest of the attending and the resources of the hospice program. "To the extent possible" is acceptable language

418.76 Home Health Aide and homemaker services.

(h) Supervision of HHA – the purpose of this standard needs clarification. Is the supervision of the aide or of the patient's care? If the supervision is for the patient's care, this would pose a substantial coordination and operational challenge since there may be more than one HHA caring for the patient, covering various shifts.

418.100 Organization and administration of services

(c) Professional management responsibility – The hospice should have professional responsibility for the services provided, but not the staff. That responsibility belongs to the SNF.

418.102 Medical Director
(c) Coordination of medical care – It is neither realistic or appropriate for a medical director to be responsible for directing the hospice's QA/PI program. The medical director has neither the time nor the training to administer such a program. Our medical director is part-time, as is the case in most hospice programs.

418.54 – The Medical director or physician designee appointed by the medical director, must either be a hospice employee or under contract with the hospice. Clarification is needed on the condition that a contractual arrangement with another agency or organization is not permitted. Hospice programs that are part of a large health system may need to contract with an agency or practice that is under their system, but considered a separate organization. Can the hospice contract with a physician group to provide Medical Director Service's?

Thank you for your acceptance of these comments.

Sincerely,

Patricia Hanson, Director
Baystate VNA & Hospice

VNA & HOSPICE OF COOLEY DICKINSON
DARTMOUTH-HITCHCOCK ALLIANCE

July 19, 2005

Department of Health and Human Services
Attention: CMS – 3844-P
P.O. Box 8010
Baltimore, MD 21244-8010

Delivered via US mail and via email at http://cms.hhs.gov/regulations/ecomments

Dear CMS:

Thank you for publishing the long awaited Medicare Hospice Conditions of Participation in draft form last month. By and large, they show thoughtful work on moving hospice into the current medical age of performance improvement using data measurement driving process change. This will have a beneficial impact on care to beneficiaries. There remains a great deal of flexibility in the regulations which would allow programs to customize services to their individual communities. I agree with the comments submitted by the Hospice Association of America. I did, however, want to comment directly on a few areas of concern to me as a provider of hospice services.

418.3 Definitions

Clinical Note - Spiritual care is not listed as a component of that note. It should be. The spiritual care is part of the interdisciplinary team and is as important as the medical and emotional care provided our patients.

Drug Restraint – Our program has concern that many drugs that might be used for the purpose of restraint in another setting are standard practice in hospice for terminal restlessness and pain management. We strongly suggest the definition be amended to add "not a standard treatment for a medical or psychiatric condition within a hospice program". If not, we can see a surveyor in hospice, who spends the majority of their time in the nursing home survey processes, citing hospice programs for what is effective symptom management thus potentially taking a step backwards in the appropriate treatment of hospice patients at the very end of life.

Hospice care – Should include that "hospice means a comprehensive set of services provided in the home, in the community and in facilities, identified and coordinated by an interdisciplinary team...." Despite memos from CMS, to the contrary, some facilities are becoming licensed as hospice programs with no intention of caring for other than their own residents. This dilutes the foundation's hospice philosophy of providing care across all settings, wherever the patient's home may be, and is a risk for potential fraud and abuse. I agree with this section submitted by the Hospice and Palliative Care Federation of Massachusetts.

418.52 Condition – Patient's Rights
(a) (1) – Provide the patient or representative with verbal and written notice . . . in a language and manner that the patient understands. While we all agree that the rights and responsibilities must be provided to the patient in a way that they understand, this seems to suggest that hospices must have all documents converted to all possible languages that our patients may speak. Today, we have our documents translated only for those languages in which we primarily see in patients in our area. For example, I may only admit one patient a year who speaks Kumar. Do I need all of my forms in that language versus using the interpreter service? This would be costly and burdensome to do and an impossible task at best.

418.54 Condition – Comprehensive Assessment of Patient
(a) Initial Assessment – Although most of the regulations tend to move away from a very prescriptive approach, this section has become more prescriptive. It appears to drop the patients' requests out for the decision by 'making an initial assessment visit within 24 hours after the hospice receives the order'. We often set the admit date based on patient's desire for admission – for example, when their daughter will be at home from out of town and the patient will request to have the admit done in a week and not the day we receive the order. Patient choice is paramount in hospice and this should read 'within 24 hours of admission or at patients' request'. It seems to me that this time frame is aimed at making sure hospice programs do not delay in admit for staffing or other reasons yet the proposed solution does not take care of that issue.

Also, only the Nurse is allowed to make an initial assessment. From a clinical perspective, there are times in which the main issue is spiritual or psychosocial and the pastoral care person or the social worker would be most appropriate for the admitting clinician. Often times, the admit process is long, and will be longer with these regulations regarding teaching medication use and disposal, and tires the patient. In this situation, they would need to go through the RN assessment and admit and then have a visit from the social worker. That does not seem to meet their needs.

418.56 Interdisciplinary group care planning and coordination of services
(a) – the medical director cannot be the attending physician as this is written. There are times when the medical director is also the patients attending physician, therefore, would the patient be forced at this time in their life to change doctors? This section should include a statement that the hospice medical director may also be a patient's primary physician.

(d) Review of the plan of care – I wonder why the hospice medical director, who is part of the IDG, is separated from the group in this language – 'the medical director or physician designee, and the hospice interdisciplinary team'. I would suggest – 'and the hospice interdisciplinary team which includes the medical director or physician designee,...'.

418.64 Core Services
(2) Nutritional counseling – this is wonderful language. Very appropriate for hospice care.

418.76 – home health aide and homemaker services. I am not clear on the intent of this change. In reading it with several other people, there were several very different conclusions drawn from my group. Therefore, the language is not understandable and needs to be rewritten. Does each aide on each case require a supervisory visit every 14 days? That would be impossible and trip multiple extra RN visits only for aide supervision. For example, there are 7 days a week aide care. Two aides take the weekdays and one aide each weekend in an every 4 week rotation and the patient requires 1 RN visit / week. Now we are making 2 additional visits to see the other aides. This is an intrusion into the patient and family time and a costly burden for the program not accounted for in the regulations.

If, this is trying to say that each aide requires supervision as part of their competency every 14 days, I respectfully disagree that the aides require that level of review. It would be overly burdensome to the aide and to the agency and should be deleted. HHA's are required a competency assessment in the home health conditions of participation. These regulations should mirror those regulations

(j) Standard: Homemaker Qualifications – I am unclear, after looking at 418.76 and 418.202 G if volunteers can be homemakers, or if only home health aides can be homemakers. We use volunteers with standard volunteer training as homemakers and would not want to lose that ability.

418.102 Medical Director
C. Coordination of Medical Care – This puts the hospice medical director responsible for directing the performance improvement program. This would be overly burdensome to some hospice medical directors who are volunteers. It assumes that all doctors are proficient in performance improvement which is not the case. I believe the hospice program must be responsible for PI.

418.104 Medical records – (e) discharge and transfer of care
1 – For transfer, 2 – for revoke, 3 – for discharge
Each of these 3 sections requires the hospice to send a copy of the medical record and a discharge summary. The discharge summary is inclusive of the information required at each receiving point (facility or MD). The burden of sending all of the pages of a record is great both on the cost of producing and mailing as well as the costs of storing at the other end. Many of our programs have computerized records which, when printed, prints all of the data points and not just those with information filled in. The down side of an electronic record is the cumbersome and excessively long nature of a printed copy. No physician I have spoken with in the last few weeks wants a copy of that for their records, only the summary. We suggest that this section be changed to summary only with a copy available and provided at request.

418.106 – this section on drugs demonstrates safe practice. I want to make sure that there is no requirement to 'collect' the drugs when the family / patient refuse to relinquish them. They are owned by the patient and they do have a right, after they receive their education, to make a decision. The hospice would then document their refusal.

418.108 short term inpatient care
You should add the current language that allows for this level of care for psychosocial and family crisis. Also, this section and section 418.110, should require an RN on duty whenever the patient is in the facility for general inpatient care, not for respite care or for residential care.

(0) Seclusion and restraint – again, refer to above definition of restraint with use of drugs customarily used for treatment in hospice.

418.112 – hospices that provide hospice care to residents of a SNF/NF, ICF/MR, or other facilities- standard – (d) Medical director. This section is most problematic and will become a barrier for admission of hospice patients in such facilities. The medical director of the facility is not always the patients' primary care physician. Why would the person who knows nothing about the patient be required to talk with the hospice medical director on a monthly basis? That is not respectful of either physician's time, and does not improve the patients care. I have spoken with 3 SNF medical directors on what the benefits of this regulation would be to them in their role, and there is no benefit, only burden.

Again, I want to thank CMS for its work in producing these regulations and allowing me to comment. We look forward to the final version.

Sincerely,

Carla Braveman

Carla Braveman, BSN, RN, M.Ed, CHCE
Executive Director

47
1 of 55

ILLINOIS
HOSPICE &
PALLIATIVE CARE
ORGANIZATION

Comments on Proposed COP's

Please print/write legibly. Use one sheet for each comment.

Subpart: C+D

Condition Title: all

Standard Title: all

Citation Reference: 418.____ Standard #________ Item #________

Concern/Issue:
use of the word "Drugs".

Potential Impact:
Negative connotation

Suggested Correction:
Replace the word Drugs with medication throughout the regulation.

Name Rebecca Wisdom Title CEO/President
Organization Hospice of Southern Illinois
Phone 800/233-1708 E-mail See below
Fax 618/235-3130

Please return to the IL-HPCO organization office by June 27th by either e-mail (hconnor@il-hpco.org) or fax (888-844-7697). This form is on the IL-HPCO website (www.il-hpco.org) in the events section.

Contacts who worked on these comments:
Rebecca Wisdom CEO/Pres rwisdom@hospice.org
Colette Hoffarth Director choffarth@hospice.org
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HOMECARE & HOSPICE

NATIONAL ASSOCIATION FOR HOME CARE & HOSPICE
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Ruth L. Constant, EdD
Chairman of the Board

Val J. Halamandaris, JD
President

July 26, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 445-G
Washington, DC 20201

Attention: CMS-3844-P – Comments on the Proposed Medicare Hospice Benefit Conditions of Participation

Dear Administrator McClellan:

The Hospice Association of America (HAA) and its affiliated National Association for Home Care & Hospice (NAHC) is the largest national trade association representing hospices, home care agencies and their caregivers from across the country. HAA/NAHC supports the efforts of the Centers for Medicare & Medicaid Services (CMS) to update the conditions of participation (CoP) for providers of the Medicare Hospice Benefit.

In general, we believe the proposed Hospice CoP will foster improvement in hospice performance, patient outcomes and patient and family satisfaction. We support CMS's efforts toward quality assessment and performance improvement. However, it is essential that CMS recognize the cost of implementing these new requirements. It is especially critical that CMS adequately train surveyors in the proposed regulations and in the use of techniques appropriate for outcome focused surveys.

After careful analysis of the proposed regulations and in accordance with HAA/NAHC's 2005 Regulatory Blueprint for Action, and verbal and written concerns from members of the association, we offer the attached comments.

Thank you for this historic opportunity to comment on these critically important proposed changes in Medicare Hospice Benefit regulations. If there are any questions, please feel free to contact us.

Sincerely,

Val J Halamandaris
Val J. Halamandaris
President, NAHC

Janet E Neigh
Janet E. Neigh
Director, HAA

Representing the Nation's Home Health Agencies, Home Care Aide Organizations and Hospices

418.3 - Definitions

Attending physician

(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.

Recommendation: A (3) should be added to allow the hospice medical director or nurse practitioner to serve as the attending physician.

Rationale: The current hospice CoPs allow the hospice physician or nurse practitioner to serve as an attending physician. If a patient's physician does not wish to continue caring for a patient when the patient elects hospice services, it should be possible for the patient to choose the hospice medical director or nurse practitioner to fill that role. There are also occasions when hospice medical directors or nurse practitioners have private practices with patients who become eligible for and choose to access the Medicare hospice benefit. It would be unreasonable and burdensome for the patient to require that they find another attending physician not employed by the hospice.

Drug restraint– medication used to control behavior or restrict patient's freedom of movement – not a standard treatment for a medical or psychiatric condition.

Recommendation: Add the words "within a hospice program" at the end of the sentence.

Rationale: Some medications used by hospices would be considered in the category of drug restraint in other health care settings.

Subpart C – Patient Care

418.52 Condition – Patient's 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.

Recommendation: The words "both verbally and in writing," should be removed from this Standard. The hospice should provide the patient and family with information on patient's rights via an interpreter if necessary and obtain the patient's or family's signature confirming their receipt of the information.

Rationale: It would be impractical for hospices in some areas of the country to

provide written patient's rights in every language in the community, and could result in a barrier to care if the hospice were required to do so in order to serve the patient and family. The interpretive guidelines should include language stating that a hospice may ensure the patient understands via an interpreter and obtain written confirmation that the information was received.

(3) The hospice must inform the patient and family of the hospice's drug policies and procedures, including the policies and procedures regarding the tracking and disposing of controlled substances.

Recommendation: The Interpretive Guidelines should suggest that a hospice's information on drug policies may be included in the admission packet, explained and left for patients and families to review. The hospice would obtain a signature from the patient/family to confirm receipt of this information.

Rationale: As the drugs become the property of the patient and family, the hospice may explain their policies and procedures for tracking and disposing of drugs but the hospice cannot force the patient and family to comply.

(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.

Recommendation: The words "demonstrated an understanding" should be replaced with "acknowledged receipt."

Rationale: It is hard to determine how a hospice would document that the patient or representative may demonstrate an understanding of the rights but the hospice could document that the patient's rights had been communicated by obtaining a signature.

Standard (b): 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.

Recommendation: Patient's right to refuse treatment was omitted. The following language should be added: (v.) To refuse treatments.

Rationale: Patients should not be denied their right to refuse treatment if they so choose.

Standard (e) Patient liability – Before care is initiated, patient must be informed, verbally and in writing, and in a language they 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.

Recommendation: We suggest the Interpretive Guidelines include language to the effect that the Hospice Interdisciplinary Group, in consultation with the patient/family, execute a comprehensive plan of care including whether and when it is appropriate for the patient to be placed in an inpatient facility. Care (related to the terminal illness) sought by the patient and family outside of the plan of care is the responsibility of the patient and family. This language may be included in the hospice's admission packet, explained and left with the patient/family.

Rationale: There are times when a hospice patient's family panics and calls "911" in a crisis situation rather than contacting the hospice. The patient then ends up in the emergency room and/or hospital receiving treatment inappropriate for a hospice patient. The hospice explains that only the hospice is to be called in relation to care needed for the terminal illness but this is occasionally difficult to remember. If the hospice interpretive guidelines contain the above language, the hospice position would be reinforced and the patient would be more likely to receive only the supportive palliative care appropriate for their condition. Inappropriate rescue care can be very disruptive and painful for the patient and family.

418.54 Condition – Comprehensive assessment of 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.

Recommendation: The words, "but is not limited to" should be removed.

Rationale: The current language could be interpreted to require the hospice to assess care needs beyond their expertise. The hospice benefit is intended to provide care for the terminal illness and related conditions.

Standard (a) 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.

Recommendation: Physicians should be added as another discipline permitted to do the initial assessment. The words "or physician" should be inserted after "registered nurse."

Rationale: Given the nursing shortage, it may be more practical for a hospice physician to do the initial assessment. How will a patient/family request for a specific date of admission be accommodated? Considering the intensity of the situation at this critical time of a patient's life, it would be inappropriate to force a patient to submit to the initial assessment within 24 hours just because it is written inflexibly in a regulation.

Standard (b) 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.

Recommendation: The language should be expanded by adding, "if he/she so desires" after "attending physician." The words " to 7" should be inserted after "4."

Rationale: To avoid creating a barrier to hospice services, we suggest the language should stipulate that the attending physician be included if he/she so desires. Patients now have more complex needs requiring more assessment time. We think this should be expanded to allow up to 7 calendar days.

Standard (c) 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 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.

Recommendation: The words "The comprehensive assessment describes –" should be eliminated. The language from (3) should be moved to be the heading for the listing of assessment content. The words "e.g., individual's functional status and ability to understand and participate in the plan of care" should be inserted at the end of (2). A new (3) should be inserted which reads: "(3) Imminence of death." A new (4) should be inserted which reads, "(4) Severity of symptoms." The current (i) should become (5) and (ii) should become (6) and "Ineffective drug therapy" should be changed to "Effective," in (ii), "Unwanted drug side and toxic effects," should be changed to "Drug side effects." "Drug interactions" should be changed to "Potential drug interactions." The Interpretive Guidelines should specify that the list of current medications is for informational purposes.

The revised Standard (c) would now read (additions underlined): 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.

> **Factors that must be considered in developing individualized care plan interventions, include—**
>
> **(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, <u>e.g. individual's functional status and ability to understand and participate in the plan of care;</u>**
> **(3) <u>Imminence of death;</u>**
> **(4) <u>Severity of symptoms;</u>**
> **(5) 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.**
> **(6) Drug therapy. A review of the patient's prescription and over-the-counter drug profile, including but not limited to identification of the following—**
> **(i) Effective drug therapy;**
> **(ii) Drug side effects; and**
> **(iii) <u>Potential</u> Drug interactions.**
> **(7) The need for referrals and further evaluation by appropriate health professionals.**

Rationale: The care plan is broader than bereavement and drug therapy as stated in the beginning paragraph of this Standard. Reorganization and expansion of

the comprehensive care plan requirements makes the intent of this Standard easier to understand and follow. Hospice is not expected to assume responsibility for providing drugs beyond those required in connection with the terminal illness.

Standard (d) 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; and

(2) At the time of each recertification.

Recommendation: "(2) At the time of each recertification" should be removed from this Standard.

Rationale: If an update is required every 14 days, it is unnecessary to also do one at the time of recertification as a 14-day comprehensive assessment would have occurred within a few days of a recertification date. A hospice may currently obtain a physician's recertification prior to a recertification date. Under the proposed Standard, an update of the comprehensive assessment would have been performed within a maximum of 6 days of the recertification date (6 days for a 90-day recertification period and within 4 days of a 60-day recertification period).

Standard (e) 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.

Recommendation: CMS should work with the hospice industry to develop a reliable set of indicators of quality hospice care before these CoPs become final.

Rationale: There are currently no uniform standards. This will be difficult for many small hospices to meet.

418.56 Condition – Interdisciplinary group care planning and coordination of services.

(1) **Standard (a) Approach to service delivery** - 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.

Recommendation: The flexibility of allowing hospices to designate the coordinator of care is appreciated. For clarification purposes, we suggest that the words "specific hospice care" replace "needs" after "family's" in the sentence "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 specific hospice care and implementation of the interdisciplinary plan of care." In (1)(i), the parenthetical "(who is not the patient's attending physician)" should be removed.

Rationale: The continuing nursing shortage makes it even more important for hospices to judiciously select the tasks that the RN must perform. There are occasions when the hospice IDG physician is also serving as the attending physician upon request of the patient and family.

Standard (c) Content of the plan of care -

(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.

Recommendation: The words "or disagreement" should be inserted after the word "agreement" in (6).

Rationale: Family understanding is important but agreement is not always possible. In particular, there may be disagreement among family members.

Standard (d) – 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.

Recommendation: The words, "medical director or physician designee" should be removed so the sentence would begin with "The hospice interdisciplinary team."

Rationale: The specific reference to "the medical director or physician designee" is unnecessary as the medical director is a member of the IDG which functions as a team to formulate and review the plan of care.

418.58 Condition – Quality assessment and performance improvement –

Standard (a) – Program scope –

Standard (b) – Program data –

Recommendation: CMS should work with the hospice industry to develop a system of care measures specific to providers of the Medicare hospice benefit. Appropriate surveyor training is critical.

Rationale: There are currently no national uniform standards, it would be helpful

for CMS to work with the hospice industry to begin now to develop a system of care measures that hospices may use. Appropriate surveyor training will be the key to meeting this standard.

Standard (c) - 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.

(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.

(2) 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.

Recommendation: CMS should first begin to implement QA/PI processes before moving to collection of adverse event data. These requirements should be phased in, first with the implementation of QA/PI outcomes, then, after a standard system is established, hospices move to begin defining adverse event tracking and reporting. CMS should specify the acceptable data source and benchmark as the outcomes standards are further defined. Appropriate surveyor training is critical to meeting this standard. Hospices should be given a role to help define adverse patient events and preventive actions.

Rationale: Hospices are not prepared to meet this requirement. This approach would allow hospice programs to first install a quality data initiative while benchmarking is being further identified and standardized for the industry.

Standard (d) – 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.

Recommendation: Again, as noted above, this requirement should be phased in. Once this goes into effect, appropriate surveyor training is critical. It should also be stipulated in the Interpretive Guidelines that surveyors are not to use the hospice's own data to cite deficiencies.

Rationale: A phased-in approach will allow CMS the time to gain a greater understanding of hospice quality improvement projects while not placing an undue burden on the agency staff and the delivery of hospice services.

418.64 Condition – Core services – Standard (d) (1) Counseling services – . 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.

Recommendation: Insert the word "may" after "Bereavement counseling" in (1)(ii) so it would read "Bereavement counseling may also extend . . "

Rationale: Counseling services for staff and residents of a facility where a hospice patient has resided for an extended period of time may be appropriate. Adding the word "may" makes it clear that it is an option. A hospice may inquire if counseling is desired and include it in the plan of care.

(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.

HAA/NAHC would like to thank CMS for this inclusion. This is welcome news as it allows the hospice more realistic flexibility to meet the patient's needs.

418.76 Condition – Home health aide and homemaker services – Standard (g)

(2)A home health aide provides services that are:
- (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.

Recommendation: (2)(i) should be deleted.

Rationale: These services must be included in the plan of care; it is a duplication to require a physician or nurse practitioner order.

Standard (d) 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 when 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.

Recommendation: The words, "except one that is excluded by paragraph (f) of this section" should be deleted. Hospices should have the same requirements as home health providers [Section 484.36(b)(2)].

Rationale: Paragraph (f) would exclude hospices from providing in-service training if they have had survey deficiencies within the previous 2 years. This would result in a hospice having to make arrangements with others to provide the in-service training which could be cost prohibitive. Section 484.36(b)(2) of the home health CoPs Interpretive Guidelines states "HHAs that are precluded from conducting their own training and/or competency evaluation programs must still complete their aides' annual performance reviews and in-service training as part of their administrative, personnel and patient care responsibilities."

Standard (h) - 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.

Recommendation: The requirement for a supervisory visit "every 28 days" should be changed to "quarterly."

Rationale: CMS has clarified this observation is for each aide not each aide with every patient. It should not be necessary for every aide to demonstrate competency 12 times a year as they already have a requirement for continuing in-service training, are in frequent communication with the case manager, and the RN or therapist is visiting each patient every 14 days to assess the aide's services. A quarterly supervisory visit while the aide is present should be sufficient.

Subpart D – Organizational Environment

418.100 Condition – Organization and administration of services. Standard (a) – . 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.

Recommendation: The words "and desires" should be removed from (2) of this condition.

Rationale: "Desires" is too open to interpretation and its removal would not affect hospice care. The hospice is required to provide care consistent with patient and family needs as established in the plan of care; the patient and family participate in creating the plan of care.

Standard (e) – 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.

Recommendation: The word "supervision" should be replaced with "oversight." Also, the language "at least the same qualifications as hospice employees" could be problematic and should be replaced with "by qualified personnel."

Rationale: The supervision should be conducted by the actual contracted employer. "Qualified personnel" is more appropriate than "at least the same

qualifications as hospice employees."

Standard (f) – Hospice satellite locations –

Recommendation: This is a welcome addition to the CoPs. CMS clarified that there are no mileage restrictions but that the parent office must exercise control. There should be uniform enforcement of this Standard across the country.

Rationale: There are some regions where satellite offices are being denied based on distance from the parent office.

418.102 Condition – Medical director – The hospice must designate a physician to serve as medical director. The medical director must be a doctor of medicine or osteopathy who is 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.

Recommendation: The words, "the hospice" should replace "the medical director" in the third sentence . . . . "When the medical director is not available, a physician designated by the hospice assumes". . .

Rationale: Most hospices have part time medical directors and it would be more appropriate for the hospice to retain the responsibility of ensuring hospice coverage when the medical director is not available.

Standard (b) Recertification – 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.

Recommendation: The words "desire to continue with" should replace "expectations and wishes for the continuation" in the above sentence.

Rationale: It is not clear what "expectations and wishes" means.

Standard (c) 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.

Recommendation: The words, "in its entirety" should be removed from the first sentence. The words "medical director or physician designee" should be expanded with "or other hospice professional" in the last sentence above.

Rationale: Hospices are responsible for the care related to the terminal illness which is not always the entirety of a patient's medical care. This requirement could be particularly problematic when the patient resides in a nursing facility. Many hospices have part time medical directors who, appropriately, focus their limited time on the patient's medical care, by expanding the language the hospice would have the ability to hire a full time employee to fulfill this responsibility.

Standard (b) – 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.

Recommendation: Authentication of the documentation should be required – not authentication of every signature.

Rationale: This is from the hospital CoPs; the nature of hospice care is broader so this Condition could be misunderstood. As the hospice IDG is responsible for ensuring that the patient receives appropriate, quality care, it is reasonable to require authentication only of the documentation, not every signature such as referring physicians, etc. Clear interpretive guidelines are critical.

Standard (d) – 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.

Recommendation: Retention should be changed to 6 years to mirror the requirement under HIPAA.

Rationale: Many state laws have higher requirements but for those that do not, it is less confusing to make this requirement the same as the HIPAA requirement.

Standard (e) – 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.

Recommendation: The words "if desired" should be added in (1) after "a copy of the patient's clinical record."

Rationale: Other providers will not ordinarily want to be burdened with the complete clinical record which could easily be hundreds of pages. A copy of the discharge summary should be provided with a hospice offer to the receiving

facility or physician to send the clinical record if so desired.

418.106 Condition – Drugs, controlled drugs and biologicals, medical supplies, and durable medical equipment – Standard (b) 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.

Recommendation: The word "collecting" should be removed from the first sentence. The words "potential dangers" should be removed from the second sentence and the word "safe" inserted before the word "uses" in that same sentence. The sentence would now read: "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 safe uses of controlled substances." The interpretive guidelines should allow hospices to include their drug policies in their written materials that are reviewed at the initial assessment and then left with the patient/family for their further review.

Rationale: The word "collecting" is problematic and should be eliminated as the patient "owns" the drugs that are placed in the home. Use of the words, "potential dangers" should be removed as they could influence acceptance of narcotics which may be necessary to make the patient comfortable. There is so much information being presented to the patient and family at the initial hospice assessment that it will be difficult for them to retain it all.

Standard (c) – 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.

Recommendation: This should be rewritten to state that when DME is provided under contract, the vendor is responsible.

Rationale: The hospice has responsibility for ensuring that needed DME is available mostly by contracting with an outside vendor to provide this equipment. The vendor must maintain the equipment as part of their contract with the hospice.

418.108 Condition –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.

Recommendation: This language should be expanded to include "psychosocial/family crises" which also trigger a need for short-term inpatient care.

Rationale: There are many incidences where the need for short term inpatient care is triggered by a breakdown in the family caregiver support system.

Standard (a) – 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.

Recommendation: This standard essentially removes the 24-hour RN on duty requirement from both inpatient respite and general inpatient levels of care. We thank CMS for making our recommended change for inpatient respite care. However, an RN should be required to be on-site 24-hours a day for the general inpatient level of care.

Rationale: Inpatient respite care is provided to allow the family caregiver a respite from their caregiving duties. The need for the general inpatient level of care is generally triggered by a medical crisis, requiring a higher level of patient care than inpatient respite care.

418.110 Condition – Hospices that provide inpatient care directly – Standard (b) – 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.

Recommendation: As stated above, this standard essentially removes the 24-hour RN on duty requirement from the general inpatient level of care. This is appropriate for the inpatient respite care but an RN should be on duty 24-hours a day for general inpatient care.

Standard (l) Meal service and menu planning. The hospice must furnish meals to each patient that are—

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

Recommendation: We applaud this change that CMS has made as it respects

what the patient wants and needs rather than forcing rigid adherence to artificially established meal times.

Standard (o) – 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, 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.

Recommendation: CMS should clarify the definition of drug restraint by adding "within a hospice program" to the end of the last sentence in (1) above"

Rationale: Hospice programs commonly use drugs for treatment of terminal restlessness which are viewed in other settings as chemical restraints.

418.112 Condition – Hospices that provide hospice care to residents of a SNF/NF, ICF/MR, or other facilities – Standard (b) 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 Section 418.100.

Recommendation: The word "hospice" should be inserted before the word "inpatient."

Rationale: Adding the word "hospice" clarifies that the hospice is responsible only for care related to the terminal illness.

Standard (d) – 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.

Recommendation: Given that the focus of hospice care is a team approach and the IDG is responsible for the care, the hospice IDG should be given the option of assigning a hospice nurse or physician to coordinate the patient's hospice care. The current language should be replaced with: "The hospice interdisciplinary group must assign a hospice nurse or physician to provide overall coordination of the medical care of the hospice resident in a SNF/NF, or other facility. The hospice coordinator would also be responsible for communicating with other

physicians participating in the provision of care for the terminal and related conditions to ensure quality care for the patient and family."

Rationale: The current language is very restrictive, increases the burden on the hospice medical director and may create a barrier to access if the SNF medical director must be involved. The current regulations require that a hospice nurse be the coordinator of care.

Standard (e) Written agreement.

(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.

Recommendation: (4)(iii) should be eliminated.

Rationale: As all hospice patients have a life threatening condition and (4)(i) covers all changes in the patient's condition including crisis situations such as a drug interaction.

Standard (f) Hospice plan of care

(4) Any changes in the plan of care must be discussed among all caregivers and must be approved by the hospice before implementation.

Recommendation: Language in (4) should be clarified by replacing "among all caregivers" with "between both providers."

Rationale: The language "among all caregivers" is too broad to address. As the Hospice plan of care (care related to the terminal illness) must be followed by both the hospice and the facility, the discussion must occur between the hospice and facility representatives to ensure that all caregivers are then informed of any changes and that changes must be approved by the hospice.

Standard (g) Coordination of services. 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 24-hour on-call system.
(5) Medication information specific to the patient
(6) Physician orders.

Recommendation: In (1), the word "Hospice" should be inserted before "Plan." A (7) should be added to require a physician's certification and recertification of the patient's terminal illness. The SNF/NF regulations must mirror the Hospice regulations to ensure the proper coordination of services and that the patient receives the highest quality of care. It is important that the surveyor guidelines are very clear on the responsibilities of the hospice and the facility and make allowances for the fact that the SNF/NF regulations may not be updated to match the hospice regulatory requirements when the new Hospice CoPs go into effect.

Rationale: Adding the word "Hospice" to (1) clarifies the requirement. For (7), if the SNF has the physician's certification of terminal illness, the box on their Minimum Data Set for "end stage disease, 6 or fewer months to live" could be checked.

Standard (h) 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.

Recommendation: The second sentence should be removed from the Standard.

Rationale: The hospice is not involved in determining a resident's eligibility status for residing in a facility.

Standard (i) 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.

Recommendation: The words "assure orientation of" should be added after "must" in the first sentence.

Rationale: As there are frequently several hospices contracting with a facility for provision of hospices services for their residents, the intent of this requirement would be met by adding the words "assure orientation" after must and relieve the facility staff of having to receive multiple orientations from several hospices.

418.114 Condition – Personnel qualifications for licensed professionals – Standard (b) Personnel qualifications for physicians, speech-language pathologists, and home health aides.

Recommendation: The words, "social workers" should be inserted before "and." A new (3) should be added: (3) Social workers. A person who has a baccalaureate degree from a school of social work accredited by the Council on Social Work Education."

Rationale: If Social workers are not included in this section, it would be possible in some states for non-degreed persons to qualify as a hospice social worker. Although there is some feeling in the hospice industry that a masters in social work should be required, the lack of MSWs in some parts of the country would make it an impractical requirement and create a barrier to hospice services. It is also strongly believed that the social worker requirement should not be diminished from what is currently required by the Hospice CoPs.

Standard (c) Personnel qualifications when no State licensing certification or registration requirements exist – new for OT, OTA, PT, PTA, RN – graduate of a school of professional nursing, LPN – person who has completed a practical nursing program.

(1) **Social worker** – A person who has a baccalaureate degree from a school of social work accredited by the Council on Social Work Education.

Recommendation: Remove (7) Social worker from this Standard and place it in Standard (b).

Rationale: It is strongly believed that the social worker requirement should not be diminished from what is currently required by the Hospice CoPs.

Standard (d) – Criminal background checks – The hospice must obtain a criminal background check on each hospice employee and contracted employee before employment at the hospice.

Recommendation: This requirement should be delayed until the MMA mandated pilot program to identify the best practices for long term care providers to identify disqualifying backgrounds of unsuitable workers is completed. If CMS chooses to go forward with this requirement, Hospices should only be responsible for background checks on their own direct employees. An entity that contracts with hospices to provide some services would be responsible for their own employee checks.

Rationale: There is no current national system in place to handle a large volume of requests. Many states already have this type of requirement but they are usually limited to a specific state. To ensure a thorough background check, it is necessary to have access to a national data base.

HOMECARE & HOSPICE

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July 26, 2005

Mark B. McClellan, MD, PhD
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Washington, DC 20201

Attention: CMS-3844-P

Dear Dr. McClellan:

The American Association of Homes and Services for the Aging (AAHSA) appreciates the opportunity to comment on the Proposed Rule; Medicare and Medicaid Programs; Hospice Conditions of Participation, published in the Federal Register, May 27, 2005.

The members of the American Association of Homes and Services for the Aging (www.aahsa.org) serve two million people every day through mission-driven, not-for-profit organizations dedicated to providing the services people need, when they need them, in the place they call home. Our members offer the continuum of aging services: adult day services, home health, community services, senior housing, assisted living residences, continuing care retirement communities, and nursing homes. AAHSA's commitment is to create the future of aging services through quality people can trust.

Although AAHSA's membership spans the continuum of long-term care, the majority of our members continue to provide nursing facility (NF) and skilled nursing facility (SNF) care, either alone or in combination with other services.
We consider the ability for hospice and nursing facilities to work together successfully critical to the provision of quality care to those residents who elect the hospice benefit.

AAHSA's comments focus on the proposed Condition of Participation (CoP) 418.112 - Hospices that Provide Hospice Care to Residents of a SNF/NF, ICF/MR or Other Facilities. As instructed, we have organized our response by page number and issue identifier as they occur in the Proposed Rule.

Following are AAHSA's comments:

RESIDENTS RESIDING IN A FACILITY

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418.112 – Hospices that Provide Hospice Care to Residents of a SNF/NF, ICF/MR or Other Facilities

GENERAL COMMENTS:

AAHSA appreciates CMS' recognition that clarification is needed regarding the hospice / nursing facility relationship. We agree that better delineation of provider roles and responsibilities for residents who elect hospice can enhance quality care. However, promulgation of a Condition of Participation for hospice alone, absent conforming changes in the Requirements of Participation (RoPs) for Long Term Care Facilities (SNFs/NFs), will do little to rectify current conflicts or relieve the hesitation of some nursing facilities regarding potential hospice agreements.

The biggest impediments to establishing successful relationships between hospice and nursing facilities are the fundamental incompatibilities and inconsistencies that currently exist within the respective requirements and accompanying interpretive guidance. Embodied in the nursing facility requirements is the underlying principle of ongoing, aggressive, curative treatment. The philosophy of palliative care and/or hospice care is minimally identified and inadequately addressed. Under the current regulatory construct, accountability and liability continue to be the chief concerns of nursing facilities contemplating a relationship with hospice.

The Preamble states that CMS is "...preparing a separate regulatory document to address long-term care facility obligations regarding residents receiving hospice services." We concur that there are obligations on both sides of the provider equation that must be met to assure optimal care to residents. However, specification of only "long-term care facility obligations" is not sufficient. For nursing facilities, the RoPs and Interpretive Guidance must also recognize and integrate the philosophy of hospice care. For example, it must be understood and clearly acknowledged that outcomes resulting from a resident's choice to shift from curative to hospice services can, in fact, constitute the achievement of his/her "highest practicable physical, mental and psychosocial well-being." Absent this type of recognition, there will continue to be a potential for contradictory, inconsistent, and/or fragmented care for nursing facility residents who choose hospice services.

RECOMMENDATION(S):

- This CoP cannot be successfully implemented absent conforming changes to the Requirements of Participation for Long Term Care Facilities.
- Changes to the RoPs and Interpretive Guidance must incorporate not only facility obligations, but also recognition and integration of the philosophy of hospice care for those residents electing these services.
- The effective date of this provision should be deferred pending completion of conforming amendments to the Requirements of Participation for Long Term Care Facilities and the Interpretive Guidance for Surveyors.
- In the interim, and at minimum, the [final] hospice CoP-418.112 should be incorporated by reference into the SNF/NF requirements, with implementation deferred until incorporation is effected.
- Clarification must be provided on how accountability will be determined if a negative [or potentially negative] outcome is identified under survey.

RECOMMENDATION(S):

- Coordination between nursing home and hospice oversight authorities at the Federal and State level is essential to ensure uniform understanding and consistent application of the requirements and related expectations at 418.112.
- Adequate notice and surveyor and provider training, i.e., for both hospice and nursing facilities, must be provided prior to implementation of this proposed standard and when changes to the RoPs are effected.

SPECIFIC COMMENTS

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418.112 – Hospices that Provide Hospice Care to Residents of a SNF/NF, ICF/MR or Other Facilities. AAHSA questions the applicability of these standards to "other facilities" or entities beyond SNF/NFs and ICFs/MR. For facilities where there is no federal oversight authority or jurisdiction, there is also no federal capability to distinguish and/or implement appropriate conforming or parallel regulatory standards (for example, all "other facilities" may not be required to have a medical director).

RECOMMENDATION: Delete the reference to "other facilities" wherever it occurs in the regulation.

(b) Standard: Professional Management. The assignment of full responsibility for professional management of the resident's hospice care has the current potential to interfere with nursing facilities' ability to assure compliance with the Requirements of Participation for Long Term Care Facilities. The RoPs' concentration on ongoing, aggressive, curative treatment, combined with the mandate that all SNF/NF residents meet their "highest practicable...well-being" and the underlying regulatory assumption that the nursing facility remains accountable and responsible for all that occurs within its walls, do not allow facilities to abdicate the function of primary professional management responsibility to the hospice.

RECOMMENDATION(S):

- See AAHSA's recommendations under General Comments regarding needed amendment to the RoPs and Interpretive Guidance, deferred implementation pending incorporation of these changes.

- The RoPs and Interpretive Guidance must clearly allow nursing facilities to relinquish and/or assume secondary professional management responsibility for those residents electing the hospice benefit.

- Clarify how accountability with be determined if a negative [or potentially negative] outcome is identified under survey.

(c) Standard: Core Services. This proposed standard states that a hospice must routinely provide "all" core services, and therefore prohibits any delegation of these services to nursing facility staff. The proposed hospice CoP at 418.64 requires that hospices routinely provide "substantially all core services...

including nursing, medical social services, and counseling...", implying that some delegation may, in fact, be permissible.

It may be both unrealistic and impractical to strictly prohibit assistance with all core services for nursing facility residents electing hospice. For many of these individuals, it can be very difficult to distinguish the components of care that are specifically related to the terminal illness. Nursing facilities with existing hospice agreements have reported that while the hospice does develop the plan of care, some of the actual resident care, e.g., nursing, social services, and/or physician services, inevitably overlaps. Under the current regulatory construct for long-term care facilities, this proposed standard again potentially impedes nursing facilities' ability to maintain compliance with the RoPs.

RECOMMENDATION(S):

- <u>If delegation of core services is prohibited, the RoPs and Interpretive guidance must clearly allow nursing facilities to relinquish responsibility for these services for those residents electing the hospice benefit.</u>

- <u>If delegation of core services is prohibited, the word "substantially" should be deleted from 418.64. As currently written, it implies that some delegation of core services is permissible.</u>

- <u>If assistance with core services may be provided by the SNF/NF, this should be clearly defined in the regulation, e.g., "A hospice must routinely provide all core services. These services include ...; The hospice may involve facility personnel as specified in written agreement between the hospice and the..."</u>

- <u>See AAHSA's recommendations under General Comment regarding needed amendment to the RoPs and Interpretive Guidance, deferred implementation pending incorporation of these changes.</u>

- <u>Clarify how accountability with be determined if a negative [or potentially negative] outcome is identified under survey.</u>

<u>(d) Standard: Medical Director.</u> The requirement that the medical director and physician designee of the hospice provide overall coordination of the medical care for residents who elect hospice again potentially impedes nursing facilities' ability to maintain compliance with the Requirements of Participation for Long

Term Care Facilities. 42 CFR 485.75(i)-Medical Director, charges the SNF/NF medical director with coordination of care in the facility. He/she is responsible for overseeing and assuring the provision of appropriate medical and other designated care to all facility residents.

The proposed standard mandates that the hospice medical director and physician designee communicate with the attending physician(s) participating in the provision of care, but is unclear as to which physician retains primary responsibility for the provision of medical care. Failure to clarify can again result in the delivery of inconsistent or "fragmented" care.

RECOMMENDATION(S):

- <u>See AAHSA's recommendations under General Comments regarding needed amendment to the RoPs and Interpretive Guidance, deferred implementation pending incorporation of these changes.</u>
- <u>The RoPs and Interpretive Guidance must clearly allow the nursing facility medical director to relinquish and/or assume secondary professional responsibility for the coordination of medical care for those residents electing the hospice benefit.</u>
- <u>Define "physician designee"</u>
- <u>Amend to clarify the distinction between coordination of care and primary responsibility for the provision of medical care for those residents electing hospice services.</u>
- <u>Clarify how accountability with be determined if a negative [or potentially negative] outcome is identified under survey.</u>

<u>(e) Standard: Written Agreement; #8.</u> Nursing facilities must use licensed/certified staff to perform nursing-related services such as administering medication and assisting with prescribed therapies in order to comply with the Requirements of Participation for Long Term Care Facilities. Since family caregivers, etc., would not perform these functions in a nursing facility, the hospice's ability to involve nursing facility staff in the implementation of the care plan "only to the extent that the hospice would routinely utilize the services of a hospice patient's family/caregiver..." appears contradictory.

RECOMMENDATION(S):

- See AAHSA's comments above under standard (c) –Core Services.
- See AAHSA's recommendations under General Comments regarding needed amendment to the RoPs and Interpretive Guidance, deferred implementation pending incorporation of these changes.
- Clarify how accountability with be determined if a negative [or potentially negative] outcome is identified under survey.

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(f) Standard: Hospice Plan of Care. It is unclear whether the intent of this proposed standard is to have a single coordinated plan of care or two plans that distinguish palliative goals and are coordinated in these areas.

While responsibility for establishing and maintaining the plan of care lies with the hospice, completion of the Resident Assessment/Minimum Data Set (RAI/MDS), remains under the auspice of the nursing facility. The proposed standard details what is expected, but does not address which entity is to be held accountable if these expectations are not met.

RECOMMENDATION(S):

- Clarify whether expectations are for a single coordinated plan or two plans coordinated in the areas of palliative care.
- If the intent is for a single coordinated plan of care, the RoPs and Interpretive guidance must clearly allow nursing facilities to relinquish primary responsibility and/or share this responsibility for those residents electing the hospice benefit.
- See AAHSA's recommendations under General Comment regarding needed amendment to the RoPs and Interpretive Guidance, deferred implementation pending incorporation of these changes.
- Clarify how accountability with be determined if a negative [or potentially negative] outcome is identified under survey.

(g) Standard: Coordination of Services. (1) Plan of Care. It is again unclear whether the intent of this provision is to have a single coordinated plan of care or two plans that distinguish palliative goals and are coordinated in these areas.

RECOMMENDATION:

- See comments above, under (f) Standard: Hospice Plan of Care.

(i) Standard: Orientation and Training of Staff. To assure the provision of optimal care and services for residents electing hospice, both administrative and direct care staff from hospice and SNF/NFs / ICFs/MR must have an understanding of the other's governing care practices, philosophy and requirements.

RECOMMENDATION(S):

- Amend proposed 418.112(i) and the RoPs for Long Term Care facilities to include that both administrative and direct care SNF/NF / ICF/MR staff must be oriented to the hospice philosophy and procedures.
- Corresponding language should mandate that hospice administrative and direct care staff must also be oriented to the governing practices and procedures of the SNF/NF or ICF/MR.

Again, AAHSA appreciates the opportunity to comment on the CMS Proposed Rule for the Hospice Conditions of Participation, and hope our comments will be helpful to you. Please do not hesitate to contact us if you have any questions or would like further discussion. We look forward to our continued work with you on this and related issues.

Sincerely,

Evvie F. Munley
Sr. Health Policy Analyst