Submitter : **Ms. Deborah Randall** **Date: 07/21/2005**

Organization : **Arent Fox PLLC**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-3844-P-61-Attach-1.DOC

CMS-3844-P-61-Attach-2.DOC

Attachment #61

July 21, 2005

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

To the Members of the CMS Staff concerned with the Medicare Hospice Conditions of Participation [COPs]:

Arent Fox is a health regulatory law practice whose attorneys represent many hospice providers throughout the United States. As such, we appreciate the opportunity to comment upon the proposed revisions to the Medicare Hospice COPs. While we are aware that many of our firm's clients and the national associations in the hospice industry will be submitting comments upon many aspects of these proposed regulations. we direct ours to one provision only, which we believe is an improper restriction by CMS of the rights of hospices under the Medicare Act to utilize contracted services for core services in circumstances of unusual staffing needs. Although the overly narrow interpretation was likely inadvertent on CMS's part, nonetheless, it should be changed in the final rule.

Comment on proposed 42 CFR 418.112 (c), changing existing 42 CFR 418.80 and 42 CFR 418.90

The "core services" requirement of the Medicare statutory provisions of the hospice benefit has, for many years, been difficult for well-managed hospices to meet when certain staffing peaks, changes in census and other circumstances alter the hospices' ability to serve patients with the high levels of quality of care and the immediacy of response that patients deserve, and the Statute contemplates.

In recognition of the need for flexibility, Congress enacted amendments to certain sections of the Social Security Act's Medicare hospice program requirements, specifically, Section 1861 (dd)(5)(D). This section covers hospice entities entitled to statutory waivers of the core requirements and includes hospices established before 1983 and operating in rural areas, and hospices in non-urban areas that are unable with diligent efforts to staff physical therapists or dieticians.

Additionally, in regulatory sections of the existing hospice COPs, CMS has for years recognized that it would be appropriate to allow waivers of core services and the contracting of services in times of unexpected and pressing staffing needs. These regulations, included in current sections 42 CFR 418.80 allow for supplemental contracted staffing, and, in 42 CFR 418.83, provide for the statutory waiver for the hospices which are non-urban and in existence prior to 1983.

Attachment #61

In the proposed section 42 CFR 418.112(c), CMS appears to *limit* supplementary staffing for hospices serving nursing facility residents to only contracted staff provided by "*another Medicare certified hospice*" for either core services, or supplemental employees or "other non-routine circumstances" as provided in proposed section 418.64. This section includes:

> "Unanticipated periods of high patient loads, staffing shortages due to illness or other short-term temporary situations that interrupt patient care; and temporary travel of a patient outside of the hospice's service area."

This overly narrowed provision and its potential impact are not highlighted in CMS's preamble section. Arent Fox's inquiry to CMS staff resulted in an emailed CMS staff comment that this was what Congress "preferred". We see no indication that Congress "preferred" to restrict the flexibility of hospices with regard to **supplemental** staffing, nor the intent to eliminate the abilities of rural hospices extant since before 1983 to seek waivers no matter where their patients reside. [We note it is also imperative that CMS not use the recent wage index changes to narrow the rights Congress granted such hospices in the primary statutory entitlements.] We urge that CMS revisit the existing statutory provisions and recognize that non-urban hospices in existence before 1983 should not be so restricted, and that the supplemental staffing for any hospice need not be from other Medicare-certified hospices if it is for the supplemental kind of staffing, referred to in the Statute

Thank you for the opportunity to participate in this comment period.

Respectfully submitted,

Deborah A. Randall, Esq.

Health Law Group
Arent Fox PLLC

Submitter : **Ms. Judy Regotti** **Date: 07/21/2005**

Organization : **TrinityCare Hospice**

Category : **Hospice**

Issue Areas/Comments

GENERAL

GENERAL

Proposed 418.52(a)(1) "PATIENTS RIGHTS"Please do not require hospices to provide 'written' rights in the language of the patient in all instances. For those of us who serve patients from some 20 different cultures and languages in Los Angeles, this would be an extreme financial burden in printed materials, and we would have to decline patients because we do not have written patient rights in obscure languages. Please clarify the standard to include that hospice must ensure that the patient understands their rights via an interpreter, a family member or other who understands the rights.

Submitter : **Ms. Judy Regotti** **Date: 07/21/2005**

Organization : **TrinityCare Hospice**

Category : **Hospice**

Issue Areas/Comments

Issues 11 - 18

Outcome-Based Performance Measures

Welcome and valuable addition to the CoP standards, thank you!!!!

QAPI

1. Welcome and valuable addition to the CoPs standards. Thanks for allowing the hospices to identify the elements and customize the program to meet the needs of the particular hospice. Most of the state and national hospice organizations as well as our accrediting bodies already require hospices to meet a standard for Quality Assessment and Performance Improvement programs.
2. However, in proposed 418.102 Coordination of medical care, CMS is mandating that the medical director be responsible for directing the QAPI program. Please change this mandate, (and move it as well under the proposed 418.58 Quality Assessment and Performance Improvement, where it is more relevant.) We recommend that the standard language be changed to reflect the valuable and unique 'interdisciplinary' nature of hospice. It could read much the same as the language in the first statement in the proposed standard 418.102 'jointly responsible' for the direction of the QAPI programs. Many hospices have multiple medical directors as they have multiple interdisciplinary groups so in the very least the standard should have language that deals with that situation. Not all elements of QAPI programs are medical, so they do not pertain to the medical director, these elements may be financial or operational and need to have the oversight of an administrator that has authority in those areas. Our best recommendation for the oversight for the QAPI program is for the direction to come from the hospice leadership team,of which the medical director is a member, sometimes also called the 'designated interdisciplinary group' for policy making and oversight of day to day provisions such as required in proposed 418.56. This is the best way to ensure that not only are all disciplines represented but all facets of hospice operations are included/embraced in the QAPI program. One additional point is that for many hospices, the medical director is no longer an employee, but a contracted individual with responsibilities to participate in QAPI programs but not to direct them. This mandate may severely limit the 'medical' activities that the medical director will perform, spending more time directing a QAPI program. PS.......the QAPI Burden Assessment Study performed by CMS with the new proposed CoPs for the time it takes to perform data capturing and analysis for QAPI is off by many hours. This is a process that is ongoing and takes at least 12 hours a month not 12 hours a year (and even that time estimation is conservative)please take this recommendation from one who has performed these duties for 5 years, and amend accordingly. Please do not set us up for failure from the beginnig of this new and valuable section of the CoPs.

Patients Rights

Please see "General" section for our comments for this area.

Assessment Time Frames

1. Since 33% of our patients on service die within 7 days (this percentage is close to the national average) we are in agreement with CMS requirement of the 4 day completion of the comprehensive assessment.
2. Hospices have little control over the attending physician's involvement in the hospice comprehensive assessment within the limited time frame however, for this reason there should be a provision for the attending physician to opt out, defer to the Interdisciplinary group or to another physician. As the credential of Certification in Hospice and Palliative Medicine is more recognized, physicians are viewing hospice and palliative care as a speciality and therefore they prefer to transition patients at the end of life to the physician 'specialist' for the best practice in the field.

Submitter : **Ms. Judy Regotti**

Date: 07/22/2005

Organization : **TrinityCare Hospice**

Category : **Hospice**

Issue Areas/Comments

Issues 1 - 10

Inpatient Care

Proposed 418.108 (a)(1)(2) We recommend that this standard language be changed to maintain the present language that for the General Inpatient level of care 24 hour registered nurse staffing is required! This is the only solution to ensure that nurses are working within their practice acts. The CMS definition of General Inpatient care criteria warrants a registered nurse be on duty to perform the necessary assessments, and level of skilled nursing that may be required at any point of the general inpatient stay of a particular patient. LVN/LPN practice acts do not allow them to perform the level of skill that is often necessary and unable to be predicted i.e. transitioning a patient from oral administration of opioid medications to Intervenous administration of opioid medications with titration for pain control. 2. Respite care is entirely different in this regard and is usually a level of care offered to patients who's care doesn't require registered nursing skill. This level of care should be able to be provided in a facility that meets just the general nursing requiremcmts.

Short Term Inpatient Care

Proposed 418.108. We recommend that language be added back from initial CoPs that includes an allowance for the inpatient level of care for patiaents suffering from "caregiver breakdown", a crisis that is psychosocial in nature. Families/caregivers often perform duties that are defined as "skilled nursing care" and when there is a caregiver crisis and the caregiver can no longer perform those duties or continue to keep the patient at home, the hospice cannot hire unskilled professionals to perform those duties, as the license of the unskilled professional prohibits them from doing so. We must have the option of placing the patient at the General Inpatient level of care for a short period to make another plan, while providing continuity of care with skilled nursing interventions in the hospice Plan of Care. Respite care would be contraindicated, again for the reason of the skilled nursing need. (nurses do not have to be on duty 24hours/day for respite level)

Drugs, Supplies, and DME

Proposed 418.110 This section is the only place in the new CoPs that has language that pertains to pharmacy consultation. We recommend that this language be included in the appropriate section for hospices in general, not just those that provide inpatient care directly. All hospices provide drugs to patients, and should have the requirements for pharmacist oversight.
Proposed 418.106(b)For freestanding home hospices we recommend a language change for this section, hospices that provide home services do not have the authority nor do we want to put our staff at safety risk to be "collecting" controlled substances. The medications belong to the patient, once they are no longer needed we recommend and have a procedure to dispose of them if patients agree, however, we would never want to put our nurses safety in jeopardy by having them "collect" the medications, placing them in their nursing bags and traveling with them, not a good idea! We also recommend another language change. The hospice and palliative care movement has for 20 plus years now have been on the forefront of educating patients/caregivers at the end of life about the safe use of opioid medication. By requiring us to educate about the potential dangers of these medications we are giving conflicting messages. Please take the recommendation from those of us performing hospice care, the general public is already very very educated on the dangers of these medications, and quite the opposite is usually needed..... educating them to their safe and useful purpose at the end of life.

CMS-3844-P-65

Submitter : **Mrs. Rachel Chaddock** **Date: 07/22/2005**

Organization : **VNA Home Health and Hospice Services, Inc**

Category : **Hospice**

Issue Areas/Comments

GENERAL

GENERAL

My comments are attached

CMS-3844-P-65-Attach-1.DOC

VISITING NURSE ASSOCIATION
OF MANCHESTER & SOUTHERN NEW HAMPSHIRE, INC.
Serving the community since 1897

Attachment #65

July 18, 2005

Center for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8010
Baltimore, MD 21244-8010

Dear Sir/Madam:

I am writing regarding 42 CFR Part 418 Medicare and Medicaid Programs: Hospice Conditions of Participation; Proposed Rule. I appreciate the hard work and time spent on the preparation of these rules. My comments on the proposed rule are outlined below.

"OUTCOME BASED PERFORMANCE MEASURES"

I agree that it is important for hospice providers to collect data to identify quality improvement opportunities. As a hospice provider we appreciate the opportunity to utilize data sets which already exist. While I am not opposed to CMS identifying particular measures of outcomes or reporting data to CMS I believe that hospice's should be involved in the development, testing, and implementation of such measures. We need to work collaboratively to insure that the data has value, can be accurately measured and is not duplicative of other initiatives.

"PATIENTS RIGHTS"

418.52 (a) (3) Regarding the requirement that the hospice inform the patient and family of the hospice's drug policies and procedures.
I agree that hospice providers should educate patients and family regarding hospice procedures. However, I am concerned regarding the wording related to tracking and disposing of controlled substances. This implies narcotic counts are being done for each hospice patient in the home setting. This is not the usual and customary practice when a patient resides in their own residence. Additionally, I am concerned regarding the implication that this teaching be done on the first visit. The patient/family often times are overwhelmed with their situation and this may not be the most conducive time to educate.

"ASSESSMENT TIME FRAMES"

418.54 (a) The initial assessment visit sometimes is not made within 24 hours after the hospice receives a physician's admission order for care or on the date specified by the physician. There are many instances where a patient/caregiver will be phoned to arrange a time for a visit and they are not agreeable to the ordered date. Possible causes include:

1850 ELM STREET
MANCHESTER, NH 03104-2911
TOLL FREE 800.624.6084
PHONE 603. 622.3781
FAX 603.641.4074
www.manchestervna.org

VNA HOME HEALTH & HOSPICE SERVICES | VNA COMMUNITY SERVICES | VNA PERSONAL SERVICES
HOME MEDICAL EQUIPMENT AND INFUSION SERVICES OF MANCHESTER & SOUTHERN N.H.

AN AFFILIATE OF ELLIOT HEALTH SYSTEM

the patient wants another family member to be present at the assessment visit, the legal representative is not available, or the date is not convenient for them.

Recommendation: Reword to allow for patient choice regarding the date of the assessment visit when it falls outside of the 24 hour period.

418.54 (b) I find this section confusing. My understanding is that the comprehensive assessment is completed in the home by the registered nurse.

Recommendation: Reword this section to have the hospice interdisciplinary group in consultation with the hospice medical director or physician designee and/or the individual's attending physician be alerted to the status of the patient after the initial home visit. Require that within 4 calendar days after the patient elects the hospice benefit those individuals identified above would provide suggestions or feedback regarding the proposed plan of care for the patient.

418.54 (d) Again I am confused by the use of the word comprehensive assessment. This needs further clarification. I am concerned that the comprehensive assessment would need to be updated every 14 days. Is the comprehensive assessment intended to be a standard form utilized on admission and then every 14 days? We utilize a lengthy comprehensive assessment tool for our initial visit. From that point forward we assess problematic areas and identify new problems at each visit however, we do not update the original assessment nor utilize the same tool. Depending upon how this is meant to be implemented this could produce unnecessary paperwork.

Recommendation: Define comprehensive assessment in the definitions. Suggested wording for this section: "the hospice interdisciplinary group review the plan of care and update it as needed as frequently as the patient's condition requires, but no less frequently than every 14 days."

"STATUTORY NURSING WAIVER"

I am unsure of how urban is defined. I am also concerned that many hospices may have been in existence and good standing for several years but not as far back as 1983. With the current nursing shortage it is difficult to compete for nurses. Some nurses choose to work for staffing agencies and with adequate training and supervision by the hospice these nurses could be used to supplement nursing levels on a short term basis such as to cover leaves of absences or illness. A lack of nursing availability impacts patient access to hospice services. I also believe that the request for a waiver should be approved or denied within 30 days not 90 days so as not to further impact access.

In addition, due to nursing shortages and an inconsistent need for continuous care services it is difficult to recruit/retain nurses for continuous care. I believe the waiver should be accessible if a hospice has difficulty staffing this type of care.

Recommendation: Define urban area. Perhaps change the requirement to read that to obtain a waiver the hospice must have been in operation for a specified time period (? 2 years) and must have demonstrated a good faith effort to hire a sufficient number of nurse employees. Change wording to read the waiver will be deemed granted unless the request is denied in 30 days after the request is received by the Secretary.

Allow hospices to contract for nursing services for continuous care.

"MEDICAL DIRECTOR"

418.102(b) Confusion regarding the term assessment. Should this be referencing the plan of care?

418.102 (c) I believe the hospice medical director should participate in the hospice quality improvement program. I do not believe that it should be required of the medical director that they be responsible for the program. I believe responsibility for the program should rest with the person responsible for the operations of the hospice program. However, they should work collaboratively with the medical director.

"CLINICAL RECORDS"

418.104 (b) I am concerned that the hospice not be held responsible to maintain signature logs for attending physicians not employed by the hospice as they sign documents filed in the hospice medical record such as the certifications/plan of cares. I agree with the safe guards of authentication for electronic medical records. I am not certain that this should be required when paper documentation is utilized and physically signed.

418.104 (e)(1) I believe that a copy of the whole clinical record is not always necessary to be furnished to the receiving facility.

<u>Recommendation:</u> Medicare/Medicaid-approved hospice facilities forward a copy of the hospice discharge summary and other clinical record documents (requested from the receiving facility) to the facility to which the patient is being transferred.

418.104 (e)(2) I believe that the hospice discharge summary and medication profile at the time of discharge would be adequate to send the attending physician if the pt revoked the election of hospice care or was discharged as eligibility was no longer met.

<u>Recommendation:</u> Delete wording related to sending a copy of the entire clinical record.

"DRUGS, SUPPLIES, AND DME"

418.106(b) I believe it is important to educate patients and families regarding the appropriate disposal of controlled drugs. However, I am concerned that it is difficult to hold the hospice accountable to how drugs are tracked, collected, and disposed of during time periods where the hospice is not present in the patient's home.

SHORT TERM INPATIENT CARE

I agree that a Registered Nurse should not be required to provide direct patient care on each shift for inpatient respite. However, I believe that the requirement for a Registered Nurse to be present and available on each shift to provide inpatient care for a patient receiving inpatient hospice services due to symptom control should remain in place.
I would like to see the addition of assisted living facilities as an appropriate site for hospice respite services.

RESIDENTS RESIDING IN A FACILITY

418.112 I do not agree that the medical director must communicate with all facility physicians and the attending physician, and other professionals involved in developing and/or implementing the patient's plan of care routinely.

<u>Recommendation:</u> Change this requirement to read, "on an as needed basis"

418.112(e)4 iii What is meant by a "life threatening condition"? Could all hospice patients be considered to have a life threatening condition?

418.112(i) What frequency would be required for inservices to a facility's staff on the hospice philosophy and unique program features be considered adequate? Would we be expected to inservice every staff member whenever there is a change in staffing which at some facilities occurs frequently?

"SOCIAL WORK"

I believe that a social worker with a bachelor's degree could provide appropriate clinical care to hospice patients and their families.

"PERSONNEL QUALIFICATIONS"

418.114(d) Would criminal background checks be required of the hospice if the licensing entity of the personnel completes their own background checks for renewal of licenses? Would criminal background checks be required for employees already hired by the hospice at the time the new rule goes into effect?

Recommendation: Do not require duplicative efforts as it pertains to criminal background checks. Grandfather in current employees.

I appreciate having the opportunity to respond to these proposed rules. Thank you again for the time that you have committed to enhancing the quality of care hospice patients and their families receive.

Sincerely,

Rachel Chaddock RN MS
Director of Home Health Services

Submitter : **Mrs. Carissa Dobrinski** **Date: 07/22/2005**

Organization : **Integris Health**

Category : **Social Worker**

Issue Areas/Comments

GENERAL

GENERAL

SOCIAL WORK: I am a Medical Social Worker at a rural hospital in Oklahoma. I have a MSW and am a Licensed Clinical Social Worker. I occasionally work for Hospice and I believe that the care furnished by a MSW should be considered the standard of care for hospice patients given the clinical work provided while receiving hospice services and during bereavement. I believe that an MSW would be able to provide a higher level of care than a BSW due to more advanced training. It is my opinion that a BSW is not equipped to handle the more complex issues of the dying process (both emotionally and physically) and the bereavement process of in depth counseling. I also believe that CMS should require that any social worker (BSW or MSW)have one year of experience in a health care setting due to the complexities of the health care setting in general. The experience would prepare him or her with valuable knowledge that cannot be learned from working elsewhere (child welfare, school setting). From working in a rural part of Oklahoma, I know the challenges of finding social workers with MSW degrees. I would allow BSW's to to function under the supervision of MSW's but not allow anyone with a related degree in psychology or sociology to work as social work assistants because they are not trained uniquely to work with hospice patients. I am advocating for only professional social workers to provide social work services to hospice patients. Whether that be a MSW or a BSW working under the close supervision of an MSW. This arrangement, in my opinion, would greatly impact the patient's ability to have more access to social work services. Thank you for your time.

CMS-3844-P-67

Submitter : **Mrs. Mary Beach**

Date: 07/22/2005

Organization : **Caring Community Hospice of Cortland**

Category : **Hospice**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : **Mrs. Sally Rittenhouse** **Date: 07/22/2005**

Organization : **Trans Health Mgt, Inc.**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

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Please direct your questions or comments to 1 800 743-3951.

Submitter : **Mrs. Judith Lentz** **Date: 07/22/2005**

Organization : **Hospice and Palliative Nurses Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Thank you for the opportunity for HPNA, a nursing specialty organization, representing nearly 8,000 nursing practitioners, to comment on these Conditions of Participation

CMS-3844-P-69-Attach-1.DOC

Attachment #69

HOSPICE AND PALLIATIVE NURSES ASSOCIATION

RECOMMENDATIONS IN RESPONSE TO THE RECENTLY PUBLISHED CONDITIONS OF PARTICIPATION

FEDERAL REGISTRY VOL. 7 NUMBER 10

NUMBER	PROPOSED CoP	CONCERN
418.3	**Definitions** For the purposes of this part—	**Clarifications needed with several definitions as noted below**
418.31	***Attending physician*** means a— (1) (i) Doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she performs that function or action; or (ii) Nurse practitioner who meets the training, education and experience requirements as the Secretary may prescribe; and (2) Is identified by the individual, at the time he or she elects to receive hospice care, as having the most significant role in the determination and delivery of the individual's medical care.	**Ask that Nurse Practitioner be replaced with "Advanced Practice Nurse"**
	Drug restraint means a medication used to control behavior or to restrict the patient's freedom of movement, which is not a standard treatment for a patient's medical or psychiatric condition.	**Clarification is needed. Some medications that may be viewed as a chemical restraint in some instances may be normal patient care protocol in hospice.**
*****	***Nursing services*** No definition noted. Should be defined as the nursing care, including dietary counseling, provided by a Registered Nurse, who meets the training, education and requirements and is licensed by the state. This care may be delegated as allowed by individual state laws.	**Should be defined to include the fact that nurses may delegate duties to LPN/VN or unlicensed personnel such as nursing assistants. This should be consistent with State Laws.**
418.52	**Patient's rights.** The patient has the right to be informed of his or her rights, and the hospice must protect and promote the exercise of these rights.	
	(a) Standard: Notice of rights. (1) The hospice must provide the patient or representative with verbal and written notice of the patient's rights and responsibilities in a language and manner that the patient understands during the initial evaluation visit in advance of furnishing care. (2) The hospice must comply with the requirements of subpart I of part 489 of this chapter regarding advance directives. The	

	hospice must inform and distribute written information to the patient concerning its policies on advance directives, including a description of applicable State law. (3) The hospice must inform the patient and family of the hospice's drug policies and procedures, including the policies and procedures regarding the tracking and disposing of controlled substances. (4) The hospice must maintain documentation showing that it has complied with the requirements of this section and that the patient or representative has demonstrated an understanding of these rights.	**We believe it is too overwhelming to require information of the hospice's drug policies be presented at the time of admission. Too much information is given at that time. It is also not always possible to waste medication at the time of death. It is NOT the property of the hospice. It is NOT legally appropriate and violates many state and federal laws regarding hazardous waste. We recommend this be removed completely. Staff will be in jeopardy.**
418.54	**Comprehensive assessment of the patient.** The hospice must conduct and document in writing a patient-specific comprehensive assessment that identifies the patient's need for hospice care and services, and the patient's need for medical, nursing, psychosocial, emotional, and spiritual care. This care includes, but is not limited to, the palliation and management of the terminal illness and related medical conditions.	
	(a) *Standard: Initial assessment.* The hospice registered nurse must make an initial assessment visit within 24 hours after the hospice receives a physician's admission order for care (unless ordered otherwise by the physician), to determine the patient's immediate care and support needs.	**Need to clarify. Request you not ask for an order for admission. If you need an order, not a certification, then an Advanced Practice Nurse should be included. If you ask for "certification for care", then it should be the physician. More time may be needed if the family has a preference. The comprehensive assessment is not necessarily done by a nurse. The initial physical assessment should be done within 24 hours of admission to a hospice program, NOT after receipt of an order or certification. Some portions of the admission may be done by other members of the interdisciplinary team.**
	(b) *Standard: Time frame for completion of the*	**Request this be changed to a**

	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.	**maximum of 3 days. The role of the attending physician should be at the discretion of the attending physician.**
418.64	**Core services.** A hospice must routinely provide substantially all core services directly by hospice employees. These services must be provided in a manner consistent with acceptable standards of practice. These services include nursing services, medical social services, and counseling. The hospice may contract for physician services as specified in § 418.64(a). A hospice may, under extraordinary or other non-routine circumstances, enter into a written arrangement with another Medicare certified hospice program for the provision of core services to supplement hospice employee/staff to meet the needs of patients. Circumstances under which a hospice may enter into a written arrangement for the provision of core services include: Unanticipated periods of high patient loads, staffing shortages due to illness or other short-term temporary situations that interrupt patient care; and temporary travel of a patient outside of the hospice's service area.	
	(a) *Standard: Physician services.* The hospice medical director, physician employees, and contracted physician(s) of the hospice, in conjunction with the patient's attending physician, are responsible for the palliation and management of the terminal illness, conditions related to the terminal illness, and the general medical needs of the patient. (1) All physician employees and those under contract, must function under the supervision of the hospice medical director. (2) All physician employees and those under contract shall meet this requirement by either providing the services directly or through coordinating patient care with the attending physician. (3) If the attending physician is unavailable, the medical director, contracted physician, and/or hospice physician employee is responsible for meeting the medical needs of the patient.	
	(b) *Standard: Nursing services.* (1) The hospice must provide nursing care and services by or under the supervision of a registered nurse. Nursing services must ensure that the nursing needs of the patient are met as identified in the patient's initial comprehensive assessment and updated assessments. (2) If State law permits nurse practitioners (NPs) to see, treat and write orders for patients, then NPs may provide services to beneficiaries receiving hospice care. The role and scope of the services provided by a NP that is not the	**Request this is changed to read Advanced Practice Nurse instead of NPs.**

	individual's attending physician must be specified in the individual's plan of care. (3) Highly specialized nursing services that are provided so infrequently that the provision of such services by direct hospice employees would be impracticable and prohibitively expensive, may be provided under contract.	
	(c) *Standard: Medical social services.* Medical social services must be provided by a qualified social worker, under the direction of a physician. Social work services must be based on the patient's psychosocial assessment and the patient's and family's needs and acceptance of these services.	
	(d) *Standard: Counseling services.* Counseling services for adjustment to death and dying must be available to both the patient and the family. Counseling services must include but are not limited to the following: (1) *Bereavement counseling.* The hospice must: (i) Have an organized program for the provision of bereavement services furnished under the supervision of a qualified professional with experience in grief/loss counseling. (ii) Make bereavement services available to the family and other individuals in the bereavement plan of care up to one year following the death of the patient. Bereavement counseling also extends to residents and employees of a SNF/NF, ICF/MR, or other facility when appropriate and identified in the bereavement plan of care. (iii) Ensure that bereavement services reflect the needs of the bereaved. (iv) Develop a bereavement plan of care that notes the kind of bereavement services to be provided and the frequency of service delivery. A special coverage provision for bereavement counseling is specified in § 418.204(c). (2) *Nutritional counseling.* Nutritional counseling, when identified in the plan of care, must be performed by a qualified individual, which include dietitians as well as nurses and other individuals who are able to address and assure that the dietary needs of the patient are met. (3) *Spiritual counseling.* The hospice must:	**Note the registered nurse is able to provide nutritional counseling.**

Attachment #69

	(i) Provide an assessment of the patient's and family's spiritual needs; (1) Provide spiritual counseling to meet these needs in accordance with the patient's and family's acceptance of this service, and in a manner consistent with patient and family beliefs and desires; (2) Facilitate visits by local clergy, pastoral counselors, or other individuals who can support the patient's spiritual needs to the best of its ability. The hospice is not required to go to extraordinary lengths to do so; and (3) Advise the patient and family of this service.	
418.76 A	**Home health aide and homemaker services.** All home health aide services must be provided by individuals who meet the personnel requirements specified in paragraph (a) of this section. Homemaker services must be provided by individuals who meet the personnel requirements specified in paragraph (j) of this section.	**Do not agree that the homemaker qualifications should match the home health aide**
	(a) *Standard: Home health aide qualifications.* (1) A qualified home health aide is a person who has successfully completed— (i) A training program and competency evaluation as specified in paragraphs (b) and (c) (ii) of this section respectively; or (iii) A competency evaluation program; or (iv) A State licensure program that meets the requirements of paragraphs (b) and (c) of this section. A home health aide is not considered to have completed a training program, or a competency evaluation program if, since the individual's most recent completion of the program(s), there has been a continuous period of 24 consecutive months during which none of the services furnished by the individual as described in § 409.40 of this chapter were for compensation. If there has been a 24-month lapse in furnishing services, the individual must complete another training and/or competency evaluation program before providing services, as specified in paragraph (a)(1) of this section.	**Clarification of terminology needed – should use terminology of nursing assistant since inpatient hospice beds would be served by nursing assistants not home health aides. These nursing assistants should be certified in hospice and palliative nursing assistant care.**
	(b) *Standard: Content and duration of home health aide classroom and supervised practical training.* (1) Home health aide training must include classroom and supervised practical classroom training in a practicum laboratory or other setting in which the trainee demonstrates	

	knowledge while performing tasks on an individual under the direct supervision of a registered nurse or licensed practical nurse, who is under the supervision of a registered nurse. Classroom and supervised practical training combined must total at least 75 hours. (2) A minimum of 16 hours of classroom training must precede a minimum of 16 hours of supervised practical training as part of the 75 hours. (3) A home health aide training program must address each of the following subject areas: (i) Communication skills, including the ability to read, write, and verbally report clinical information to patients, care givers, and other hospice staff; (ii) Observation, reporting, and documentation of patient status and the care or service furnished; (iii) Reading and recording temperature, pulse, and respiration; (iv) Basic infection control procedures; (v) Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor; (vi) Maintenance of a clean, safe, and healthy environment; (vii) Recognizing emergencies and the knowledge of emergency procedures and their application; (viii) The physical, emotional, and developmental needs of and ways to work with the populations served by the hospice, including the need for respect for the patient, his or her privacy, and his or her property; (ix) Appropriate and safe techniques in performing personal hygiene and grooming tasks, including items on the following basic checklist— (A) Bed bath; (B) Sponge, tub, and shower bath; (C) Hair shampoo (sink, tub, and bed); (D) Nail and skin care; (E) Oral hygiene; and (F) Toileting and elimination; (x) Safe transfer techniques and ambulation. (xi) Normal range of motion and positioning. (xii) Adequate nutrition and fluid intake. (xiii) Any other task that the hospice may choose to have an aide perform. The	**Should state that the nursing assistant**

	hospice is responsible for training home health aides, as needed, for skills not covered in the basic checklist, as described in paragraph (b)(3)(ix) of this section. (2) The hospice must maintain documentation that demonstrates that the requirements of this standard are met.	**can help patient self-administer medications.**
	(c) *Standard: Competency evaluation.* An individual may furnish home health services on behalf of a hospice only after that individual has successfully completed a competency evaluation program as described in this section. (1) The competency evaluation must address each of the subjects listed in paragraphs (b)(1) through (b)(3) of this section. Subject areas specified under paragraphs (b)(3)(i), (b)(3)(iii), (b)(3)(ix), (b)(3)(x) and (b)(3)(xi) of this section must be evaluated by observing an aide's performance of the task with a patient. The remaining subject areas may be evaluated through written examination, oral examination, or after observation of a home health aide with a patient. (2) A home health aide competency evaluation program may be offered by any organization, except as specified in paragraph (f) of this section. (3) The competency evaluation must be performed by a registered nurse in consultation with other skilled professionals, as appropriate. (4) A home health aide is not considered competent in any task for which he or she is evaluated as unsatisfactory. An aide must not perform that task without direct supervision by a registered nurse until after he or she has received training in the task for which he or she was evaluated as ''unsatisfactory,'' and successfully completes a subsequent evaluation. (5) The hospice must maintain documentation that demonstrates the requirements of this standard are being met.	**Clear guidelines are given for competency of the home health aide. Suggest this be changed to nursing assistant to be appropriate for inpatient hospice care.**
	(e) *Standard: Qualifications for instructors conducting classroom supervised practical training, competency evaluations and in-service training.* Classroom supervised practical training must be performed by or under the supervision of a registered nurse who possesses a minimum of two years nursing experience, at least one year of which must be in home health care. Other individuals may provide instruction under the general supervision of a registered nurse.	

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	(f) *Standard: Eligible training organizations.* A home health aide training program may be offered by any organization except by a home health agency that, within the previous 2 years— (1) Was out of compliance with the requirements of paragraphs (b) or (c) of this section; (2) Permitted an individual that does not meet the definition of a "qualified home health aide" as specified in paragraph (a) of this section to furnish home health aide services (with the exception of licensed health professionals and volunteers); (3) Was subjected to an extended (or partial extended) survey as a result of having been found to have furnished substandard care (or for other reasons at the discretion of CMS or the State); (4) Was assessed a civil monetary penalty of $5,000 or more as an intermediate sanction; (5) Was found by CMS to have compliance deficiencies that endangered the health and safety of the home health agency's patients and had temporary management appointed to oversee the management of the home health agency; (6) Had all or part of its Medicare payments suspended; or (7) Was found by CMS or the State under any Federal or State law to have: (i) Had its participation in the Medicare program terminated; (ii) Been assessed a penalty of $5,000 or more for deficiencies in Federal or State standards for home health agencies; (iii) Been subjected to a suspension of Medicare payments to which it otherwise would have been entitled; (iv) Operated under temporary management that was appointed by a governmental authority to oversee the operation of the home health agency and to ensure the health and safety of the home health agency's patients; or (v) Been closed by CMS or the State, or had its patients transferred by the State.	
	(g) *Standard: Home health aide assignments and duties.* A registered nurse or the appropriate qualified therapist that is a member of the interdisciplinary team makes home health aide assignments. (4) Home health aides are assigned to a specific patient by a registered nurse or the appropriate qualified therapist. Written patient care	

	instructions for a home health aide must be prepared by a registered nurse or other appropriate skilled professional (*i.e.*, a physical therapist, speech-language pathologist, or occupational therapist) who is responsible for the supervision of a home health aide as specified under paragraph (h) of this section. (5) 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. (6) The duties of a home health aide include: (i) The provision of hands-on personal care; (ii) The performance of simple procedures as an extension of therapy or nursing services; (iii) Assistance in ambulation or exercises; and (iv) Assistance in administering medications that are ordinarily self-administered. (7) Home health aides must report changes in the patient's medical, nursing, rehabilitative, and social needs to a registered nurse or other appropriate licensed professional, as the changes relate to the plan of care and quality assessment and improvement activities. Home health aides must also complete appropriate records in compliance with the hospice's policies and procedures.	**Interdisciplinary care is provided and includes the care of the nursing assistant who is directed by the registered nurse. An order for the number of visits and scope of care is not needed. This can be determined by the registered nurse and these services can be delegated to the nursing assistant as allowed by state law.**
	(h) *Standard: Supervision of home health aides.* i. A registered nurse or qualified therapist must make an onsite visit to the patient's home no less frequently than every 14 days to assess the home health aide's services. The home health aide does not have to be present during this visit. A registered nurse or qualified therapist must make an onsite visit to the location where the patient is receiving care in order to observe and assess each aide while he or she is performing care no less frequently than every 28 days. ii. The supervising nurse or therapist must assess an aide's ability to demonstrate initial and continued satisfactory performance in meeting outcome criteria that include, but is not limited to— (i) Following the patient's plan of care for	**Request this be changed to mirror home health requirements. Home health agencies have 60 days to observe and assess each aide. Hospices should have the same amount of time. The length of stay of the patient under hospice care should not be a factor in determining the time frame for assessment of the aide. This is a human resource issue and the assessment would go in the personnel file rather than the clinical record. Competency assessments should take care of this issue. Supervision in an inpatient setting is continual and should not be required beyond signature of oversight by the registered nurse.**

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	completion of tasks assigned to the home health aide by the registered nurse or qualified therapist; (ii) Creating successful interpersonal relationships with the patient and family; (iii) Demonstrating competency with assigned tasks; (iv) Complying with infection control policies and procedures; and (v) Reporting changes in the patient's condition. (3) If the hospice chooses to provide home health aide services under contract with another organization, the hospice's responsibilities include, but are not limited to— (i.) Ensuring the overall quality of care provided by an aide; (ii.) Supervising an aide's services as described in paragraphs (h)(1) and (h)(2) of this section; and (iii.) Ensuring that home health aides who provide services under arrangement have met the training and/ or competency evaluation requirements of this condition.	**What about homemaker services?**
	(i) *Standard: Individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit.* An individual may furnish personal care services, as defined in § 440.167 of the Code of Federal Regulations, on behalf of a hospice or home health agency. Before the individual may furnish personal care services, the individual must be found competent by the State to furnish those services. The individual only needs to demonstrate competency in the services the individual is required to furnish.	
	(j) *Standard: Homemaker qualifications.* A qualified homemaker is a home health aide as described in § 418.76 or an individual who meets the standards in § 418.202(g) and has successfully completed hospice orientation addressing the needs and concerns of patients and families coping with a terminal illness.	**A homemaker does not need the same qualifications as a nursing aide. This level of care is primarily used for light household chores, not patient care as described in 418.76**
	(k) *Standard: Homemaker supervision and duties.* Homemaker services must be coordinated by a member of the interdisciplinary group. Instructions for homemaker duties must be prepared by a member of the interdisciplinary group. Homemakers must report all concerns about the patient or family to the member of the interdisciplinary group who is coordinating homemaker services.	**This speaks to the fact that homemaker care is not care that requires nursing supervision, so who is responsible for their supervision?**

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418.102	**Condition of participation: Medical director.** The hospice must designate a physician to serve as medical director. The medical director must be a doctor of medicine or osteopathy who is 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.	**This last sentence seems to elevate the role of the physician above the other members of the interdisciplinary team. The responsibility is the entire teams responsibility.**
418.106	**Drugs, controlled drugs and biologicals, medical supplies, and durable medical equipment.** Medical supplies and appliances, as described in § 410.36 of this chapter; durable medical equipment, as described in § 410.38 of this chapter; and drugs and biologicals related to the palliation and management of the terminal illness and related conditions, as identified in the hospice plan of care, must be provided by the hospice while the patient is under hospice care.	
	(a) *Standard: Administration of drugs and biologicals.* (1) All drugs and biologicals must be administered in accordance with accepted hospice and palliative care standards of practice and according to the patient's plan of care. (2) The interdisciplinary group, as part of the review of the plan of care, must determine the ability of the patient and/or family to safely self-administer drugs and biologicals.	
	(b) *Standard: Controlled drugs in the patient's home.* The hospice must have a written policy for tracking, collecting, and disposing of controlled drugs maintained in the patient's home. During the initial hospice assessment, the use and disposal of controlled substances must be discussed with the patient and family to ensure the patient and family are educated regarding the uses and potential dangers of controlled substances. The hospice nurse must document that the policy was discussed with the patient and family.	**Nurses are not, and should not be collecting controlled drugs in a patient's home. This is inappropriate. Nurses would be at risk. The medication is the property of the patient and the nurse can not remove them at the time of death. It is the responsibility of the family. The nurse can educate them on the risk, but they can not take them, or waste them. It is not their property. There are rules regulating what can be placed in the public sewer system by healthcare providers. This education can not be done effectively at the time of admission. Also, if the nurse is to discuss safety with narcotics, we suggest you remove the wording**

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		"dangers" and replace with "safe controlled substance usage."
418.108	**Short-term inpatient care.** Inpatient care must be available for pain control, symptom management, and respite purposes, and must be provided in a participating Medicare or Medicaid facility.	
	(a) *Standard: Inpatient care for symptom management and pain control.* Inpatient care for pain control and symptom management must be provided in one of the following: (1) A Medicare-approved hospice that meets the conditions of participation for providing inpatient care directly as specified in § 418.110. (2) A Medicare-participating hospital or a skilled nursing facility that also meets the standards specified in § 418.110(b) and (f) regarding 24-hour nursing services and patient areas.	**Nursing care should be provided by a registered nurse for Inpatient care. Therefore GIP should not be provided where 24 hour professional registered nursing is not available.** **RN and LP/VNs should be able to administer controlled substances in locations where GIP is offered.** **Nursing care for respite care should be provided at the level needed by the patient. This can be LPN/LVN if appropriate and part of the patient's plan of care.**

Submitter : **Mr. Harland Robinson** **Date: 07/22/2005**

Organization : **Arizona Hospice and Palliative Care Organization**

Category : **Hospice**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3844-P-70-Attach-1.DOC

DRAFT

Attachment #70

ARIZONA
AHPCO
HOSPICE PALLIATIVE
CARE ORGANIZATION

July 15, 2005

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

Re: Comments on CMS-3844-P (Medicare and Medicaid Programs: Hospice Conditions of Participation)

Dear Sir or Madam:

The Arizona Hospice and Palliative Care Organization welcomes the opportunity to provide comments on CMS-3844-P. As the membership organization representing almost ninety percent of the licensed hospice providers in the state of Arizona, we are committed to advancing quality end of life care for all Arizonans. Our comments on the proposed Conditions of Participation, gathered at a meeting of our membership on June 20, 2005, are provided below in the order in which they appear in the proposed regulations.

§418.3 - Definitions

Attending Physician: We ask that you include a statement that a hospice medical director, contract physician or nurse practitioner may also act as the attending physician should the patient so designate. As the real number of Medicare recipients accessing hospice care increases, so too has the number of patients who do not have an attending physician. This is especially true of patients being referred to hospice from hospitals whose attending physician during their hospital stay was a Hospitalist.

Clinical Note: We believe that the definition as currently written does not sufficiently reflect the holistic model of patient care intended by the hospice philosophy or Medicare Hospice Benefit. We ask that CMS include spiritual care as part of the clinical note by revising the last sentence of the definition to read "...and any changes in physical, emotional or spiritual condition."

Counseling Services: We would suggest adding a definition of Counseling Services as a means of clarifying CMS' expectation of what services are to be provided and the purpose/goals to be pursued by such counseling services. As an example, we propose the following definition:

PO Box 5189 ~ Sun City West, Arizona 85376-5189 ~ Voice: 623-544-3505 ~ Fax: 623-544-3533 www.arizonahospice.org

"**Counseling Services** means services that assist the patient/family to minimize the emotional and spiritual stress and problems that arise from the terminal illness, the dying process and post-death bereavement."

Comprehensive Assessment: We ask that CMS include a definition of the Comprehensive Assessment and the process involved. There was quite a bit of confusion with regard to what is meant by the term "Comprehensive Assessment" and how it interrelates with the Plan of Care. If our understanding of the process is correct, an initial assessment is to be completed by an RN within 24 hours of the physician order for services to be followed by a comprehensive assessment within 4 calendar days after the patient elects the hospice benefit, which is then used to develop a plan of care.

Dietitian: As §418.64(d)(2) discusses "nutritional counseling" and provides that such counseling may be performed by "dietitians and others who are able to address and assure that the dietary needs of the patient are met" and §481.74 discusses "dietary counseling" we recommend that a definition for "Dietitian" be added. We propose the following for your consideration:

"**Dietitian** means a person who is registered by the Commission of Dietetics Registration or the American Dietetic Association."

Facility: As the term "facility" is used throughout the regulations, we request that a definition be provided to clarify its use. With the proliferation of "hospice homes", "residences", "inpatient units" and other facilities this would be helpful. We would propose the following:

"**Facility** means a place where the patient resides where care is provided for the patient."

Licensed professional: In conjunction with the definition of Dietitian requested above, we would ask that the term "dietary therapy" be added to the definition of licensed professional. As will be seen under §418.72, we recommend that the term "dietary therapy provided by a Dietitian" be added as a non-core service, as opposed to nutritional counseling under §418.64(d)(2).

Nursing Services: We believe that a definition of "Nursing services" should be included to clarify what services are considered to be "nursing services". For example, does nursing services mean services provided by a RN only, or does it include the services of an LPN/LVN? Also we would ask that this definition provide that, at times, certain nursing services may be delegated to a home health aide.

Patient residence: As Arizona does have a transient population, especially during the winter, many hospice patients reside in mobile home and RV parks or have no residence at all. We feel that a definition of "patient residence" reflecting that a patient's residence is wherever the patient resides would be helpful.

Progress Note: We ask that further clarification be provided for the term "Progress Note" as it seems to approximate what is already being documented in the Clinical Note. Both notes describe the "services provided" (which seems to include treatments/medications) and patient response.

§418.52 - Condition of participation: Patient's rights

As patient involvement in their plan of care is paramount in the provision of quality care that addresses a patient's needs and goals, we believe that their right to participate in the care planning process should be enunciated in the Condition. As a suggestion, we would recommend an additional subparagraph "***(f) Standard: Patient Involvement in Care Planning***. The patient or representative has the right to be involved in the development and accomplishment of the plan of care."

§418.52 (a) Standard: Notice of Rights.

(3) We are concerned that adding a requirement to inform the patient/caregiver of drug policies and procedures, including the policies and procedures regarding the tracking and disposal of controlled substances, at the time of admission is adding another layer of information at a time when the patient and family are already dealing with not only a terminal diagnosis, and the stresses related to it, but also with a tremendous amount of information regarding hospice services. As such, this important information may not receive the focused attention necessary to ensure a demonstrated understanding of drug policies and procedures. We recommend that specific information regarding drug policies and procedures should be provided to the patient and family at the time medications are first dispensed. Information regarding the tracking and disposal of controlled substances should be provided at the time a narcotic, if any, is prescribed and dispensed. We would also note that it has been the experience of many of our hospices that attempts to inform patients and families about narcotics in advance tends to "scare off" patients and undermines their willingness to access narcotics as a treatment option.

(4) We would like further clarification of the term "demonstrated an understanding of these rights." Demonstrating an understanding of rights is much more restrictive than documenting that a patient or representative has received a notice of rights. Demonstrating an understanding would tend to mean that the patient or representative would have to take a quiz or test. Rather than demonstrating an understanding, we would suggest that the patient or representative sign a rights acknowledgment form, much as is done under HIPAA, indicating that they have received and understand the Notice of Rights.

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

(1) We would like to recommend that a patient right to refuse treatment be included in this subparagraph. We would offer the following language as appropriate to hospice patients:

"The patient has the right to refuse treatment at any time for any reason or no reason at all."

(4) We would ask that CMS include more descriptive language with regard to the term "injury". Our concern is that skin tears or hematomas could be broadly defined as an "injury" when they are the result of natural disease progression in a hospice patient.

§418.54 - Condition of participation: Comprehensive assessment of the patient.

We would ask that the final sentence of the Condition be clarified with regard to the term "but is not limited to" the palliation and management of the terminal illness and related medical conditions. We believe the term "but is not limited to" to be so broad as allow for subjective and arbitrary interpretation of the patient's need for hospice care. We also feel that the final sentence refers to the comprehensive assessment itself rather than hospice care and should be changed to reflect this. We would propose that the final sentence be changed as follows to address both of these issues:

> "This assessment will, at a minimum, address all facets of hospice care, to include the palliation and management of the terminal illness and related medical, nursing, psychosocial, emotional and spiritual care."

There is some confusion regarding the terms "initial assessment", "comprehensive assessment" and "plan of care". If we look at assessments as a process, we believe what CMS is proposing is as follows:

Step 1 – Physician's order for care received.
Step 2 – Hospice RN make visits within 24 hours to complete initial assessment.
Step 3 – Hospice IDG makes visits and completes comprehensive assessment within 4 days.
Step 4 – Completion of Plan of Care under timelines established by FI's.
Step 5 – Update of the comprehensive assessment at a minimum of every 14 days.
Step 6 – Update of the Plan of Care under timelines established by FI's.

Our comments on the standards in this section will be based upon the above process.

§418.54*(a) Standard: Initial assessment.*

We feel that the current wording of the standard removes the patient/family from the decision making process and places it in the hands of the physician. We would recommend that instead of a "physician's order for care" the physician provide a "certification for care" and recommend that the words "unless ordered otherwise by the physician" be changed to read, "unless ordered otherwise by the physician or otherwise requested by the family".

We also feel that the standard is too prescriptive in mandating the initial assessment visit being made within 24 hours of the physician's admission order for care. Given the rural nature of over 30% of our hospice programs, as well as patient/family dynamics, we believe this requirement is unrealistic. We would propose that the standard be changed to require an initial assessment be completed within 24 hours of the patient's admission to hospice care.

There appears to be some confusion with this standard as now worded. A physician's admission order for care should generate a visit to the patient/family by a qualified hospice employee to evaluate appropriateness for hospice care and to review/explain hospice services (Admission's Process). This is especially true if a patient is still hospitalized and we are unable to admit to hospice care until discharge from the hospital. Once the patient elects hospice care, then an initial assessment visit would be made by the RN within 24 hours of admission to determine immediate care and support needs.

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

We believe that the CMS proposed 4-day time frame is too restrictive and places additional stress on the patient and family during a period when they are already overwhelmed. We must keep in mind that for the majority, if not all, of our patients, the first week after receiving a terminal diagnosis is fraught with emotional and psychological stresses, in addition to dealing with RN's, HHAs, SW's, DME providers, medications, volunteers, etc. Given this situation, we feel that, as a standard, seven days is necessary in order for the various disciplines of the IDG to complete their comprehensive assessment of the patient and family, especially if the standard requires a completed bereavement assessment of the needs of the patient's family and other individuals (such as SNF/NF employees). A timeframe of seven days would also allow the hospice to take into account the needs of the patient and family when scheduling assessment visits.

We also believe that the term "dependant upon the patient's condition and severity of condition" should be added to the standard after the words "hospice benefit" as the severity of the patient's condition may preclude completion of a comprehensive assessment prior to patient death.

§418.54*(c) Standard: Content of the comprehensive assessment.* As the comprehensive assessment provides the basis for development and execution of the plan of care, it should be a patient-driven process that focuses on the patient's physical, psychosocial, emotional and spiritual needs, wants and goals. We would propose to add the words "consistent with patient self-determination" in this standard in order to convey that the comprehensive assessment is patient-driven.

§418.54*(d) Standard: Update of the comprehensive assessment.*

(1) We would comment that the 14-day update is too restrictive and does not take into account unforeseen circumstances which may preclude an update of the patient due to patient absence, family visits, absence of staff due to illness, holidays, vacations, etc. We feel that a more appropriate standard would be to require an update of the comprehensive assessment "As frequently as the condition of the patient requires, but no less frequently than twice per month."

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

§418.56(a) Standard: Approach to service delivery.

(1) We recommend that the word "social" in the first sentence be changed to "psychosocial" to maintain consistency with other conditions and standards. We also feel that the standard must address the issue of hospice medical directors who are also a patient's attending physician as this issue is becoming more prevalent in hospice.

§418.56(d) Standard: Review of the plan of care. We are concerned that the medical director or physician designee should not be separately identified from the rest of the interdisciplinary team. Hospice has always taken a team approach to patient to encourage a collegial atmosphere that cultivates open communication and consensus amongst all members of the IDG, to include the patient and family. By separately identifying the medical director or physician designee, we feel that the role of the physician is elevated above that of the rest of the IDG members with a risk of undermining the team approach to patient care. We would suggest that a more appropriate wording would be "The hospice interdisciplinary team, including the medical director or physician designee, (in collaboration with the individual's attending physician to the extent possible) must review, revise and document the plan as necessary…"

We also believe that the requirement to review, revise and document the plan of care "no less than every 14 days" is too restrictive and does not allow for unforeseen circumstances that may preclude completion in that time frame. We feel that a more appropriate standard would be to require an update of the comprehensive assessment "As frequently as the condition of the patient requires, but no less frequently than twice per month."

§418.60 Condition of Participation: Infection Control.

§418.60*(b) Standard: Control.*

(2) The tracking of infections in hospice patients, especially in a home setting, is difficult when the patient/family choose to forego tests and treatments. Further, in many cases infection is a natural progression of the disease and is not unexpected nor does treating the infection positively impact desired outcomes of patient care.

§418.64 Condition of Participation: Core services.

We would ask that CMS authorize hospices to contract for core services on a routine basis with non-hospice agencies. Due to the geographic separation of hospices in rural Arizona, and the fact that many of our rural counties are served by only one hospice, it is impossible to contract with another Medicare certified hospice program for the provision of core services to supplement hospice employees/staff to meet the needs of patients. Also, the current waiver process for nursing services in nonurbanized areas identified in 418.66 is complex, cumbersome and time consuming to the extent that the patient has normally died before approval is obtained. In this era of severe nursing shortages nationwide, relief must be provided to our rural hospices to preclude degradation in the level and quality of care being provided to our patients. As a recommendation, we would ask that CMS consider allowing hospices to contract for core services with non-hospice, Medicare certified agencies, for a percentage of their employees/staff necessary to meet patient demand during periods of high patient loads, staffing shortages due to illness or other temporary situations that interrupt patient care. This is especially important for the provision of continuous care to patients as the demands placed upon the hospice staff can seriously degrade service to other patients while the needs of the continuous care patient are being met. It should be stipulated that the hospice retains responsibility for the training and supervision of such contracted staff.

§418.64(c) Standard: Medical social services. We recommend that the words "under the direction of a physician" be deleted from this standard as being unnecessary and inappropriate. A social worker provides medical social services as part of the IDG just like any other member of the team.

§418.64(d) Standard: Counseling service

(1)(iv) Bereavement Counseling. We would ask that CMS consider changing the word "provided" in the first sentence of this subparagraph to "offered" as bereavement services are offered but many times are not elected by the caregivers.

§418.72 Condition of Participation: Physical therapy, occupational therapy, and speech-language therapy.

We recommend that CMS add, "dietary therapy performed by a registered dietitian" to this condition. While nutritional counseling must be available, there are times when dietary therapy is necessary and appropriately provided by the hospice as a non-core service.

§418.76 Condition of Participation: Home health aide and homemaker services.

§418.76(g) Standard: Home health aide assignments and duties.

(2)(i) We would comment that the requirement that home health aide services be ordered by the physician or nurse practitioner tend to place these individuals apart from the IDG as a team and that HHA assignments should be established by the IDG based upon the initial and comprehensive assessments and are provided under the plan of care, subject to the wishes of the patient/caregiver. It should not be necessary for this service to be specifically ordered by the physician or nurse practitioner.

§418.7(h) Standard: Supervision of home health aides.

(1) We feel that clarification of this section is necessary. If the purpose of the supervisory visit is to assess the level of service being provided to a patient, then as a patient care issue, an onsite visit to assess the home health aide's services with the update of the comprehensive assessment is sufficient and the requirement to observe and assess a home health aide while he or she is actually performing care every 28 days is unnecessary. Since the purpose of the 28-day observation is to assess the HHA and not the services being provided, it seems that it is a performance issue more properly addressed as a Human Resource issue dealt with through regular performance evaluation.

§418.7(i) Standard: Individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit. We would ask that CMS add definitive language specifying that Personal Care Aide-Only services provided under a Medicaid personal care benefit is an additional, separate benefit of the Medicaid program and is neither a duplication of hospice HHA/Homemaker services under Medicare nor "double-dipping" of Medicare monies. The Arizona Medicaid provider, Arizona Health Care Cost Containment System (AHCCCS), has routinely declared Personal Care Aide-Only services provided to Medicaid hospice recipients to be duplicative of the hospice HHA/Homemaker services and a "double-dipping" by beneficiaries. AHCCCS terminates Personal Care Aide-Only services to Medicaid hospice patients upon admission to hospice and expects hospices to provide HHA services to the same level and extent as those services performed by the personal care aide. Thus, if a patient was receiving personal care aide services for 40 hours per week, AHCCCS expects the hospice to provide a HHA for that same number of hours. This is unrealistic and untenable as well as contrary to the Medicare Hospice Benefit standard that hospice is not a 24-hour presence in the home.

§418.78 Condition of Participation: Volunteers.

§418.78(e) Standard: Level of activity. We ask that CMS specify what portions of volunteer time can be counted in the level of activity (i.e., does travel time to/from a patient's residence count as part of direct patient care hours? As volunteers may be reimbursed for mileage to and from a patient's residence, or can claim such mileage for tax purposes under the Internal Revenue Code, it would seem that travel time spent could be included. Are phone calls made by the volunteer to a patient/caregiver part of qualifying hours? For example: Bereavement Volunteer phone calls to survivors.

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

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

(1) We ask that the word "ensure" in the standard be changed to "promote". As the patient has the final say in what services he or she will agree to, despite the best efforts of the hospice to educate, it is unrealistic to expect hospices to "ensure" subparagraph (1). Rather we should promote optimization of comfort and dignity consistent with patient needs and goals.

(2) We recommend that the word "desires" be changed to "goals", as hospice care is defined by a Plan of Care based on clearly defined patient/family goals. Further, "goals" can be objective and, therefore, measurable, whereas "desires" tend to be subjective.

We do have an additional concern with subparagraph 2 in that, at times, the patient and family may not be in agreement as to the election of hospice care and the plan of treatment. While State law provides that the patient, or the patient's legal representative, has the final say in his or her election and plan of treatment, CMS may wish to consider adding a subparagraph (3) stating that patient needs and desires, as voiced by the patient, or legal representative, will have primacy in the plan of care.

§418.100(e) Standard: Professional management responsibility. We are concerned that, as currently worded, hospice staff may be required to supervise the staff of hospitals, skilled nursing facilities, nursing homes, etc., providing care to hospice patients, resulting in friction or complications in the delivery of care. We would comment that the role of hospice should exercise professional oversight of the patient's care, as the actual supervision of staff in these circumstances would rightfully be the responsibility of the facility's management.

We also are concerned that this standard requires the delivery of service to hospice patients be made by "personnel having at least the same qualifications as hospice employees." We believe the wording of the preamble with respect to services being provided by "qualified personnel" is a more appropriate language as the qualifications of staff of these facilities, as established by state regulations, may be different from hospice.

§418.102. Condition of participation: Medical director.

Again, we would comment that the last sentence of the condition casts the IDG in a secondary role under the supervision of a physician rather than basing patient care on a team approach. We would also point out the difficulty of ensuring that each patient experience medical care that reflects hospice policy. We feel that a more appropriate wording would be: "The IDG will coordinate with other physicians and health care professionals to provide each patient with medical care that reflects the hospice plan of care."

§418.102(b) Standard: Recertification of the terminal illness. We recommend omission of subparagraphs (1) and (2) from the standard as being unnecessary as the medical director or physician designee are required to participate in the comprehensive assessment update and plan of care review as a matter of routine under §418.56. Also, as the patient always has the ability to terminate hospice care, we believe a positive statement of desires to continue is unnecessary. The patient/family's desire to continue should be automatic unless otherwise stated.

We also believe that the current wording of standard removes the IDG from the process to the detriment of patient care. We recommend that CMS consider changing the language of the standard to indicate, "…the medical director or physician designee, with the IDG, must review each patient's eligibility for continued hospice services."

§418.102(c) Standard: Coordination of medical care. We feel that the medical director should not be responsible for directing the hospice's quality assessment and performance improvement program. While the medical director is responsible for the medical care of a patient, the Quality Assurance/Performance Improvement (QAPI) Program should address all facets of a patient's hospice care, to include volunteers, bereavement, etc. This is a responsibility of the IDG as a whole with the medical director participating as a member of QAPI Program. Further, many hospice medical directors are either volunteers or very part-time in the nature of their service to a hospice and to expect them to assume direction of the QAPI Program would place an unnecessary administrative burden on them to the extent that they may consider terminating their association with the hospice. While we support the participation of the medical director in the QAPI process, the responsibility for the program should rest with a qualified professional designated by the governing authority.

§418.104 Condition of participation: Clinical records.

<u>General Comment</u>: The migration to electronic health records represents a substantial investment on the part of the hospice. Depending upon agency size, software and hardware costs to implement electronic health records can range from tens of thousands of dollars for a small hospice (ADC of 20) in startup fees, training, and maintenance fees to millions of dollars for the

largest hospices. This is significant for our stand-alone hospices, especially in rural areas, and may be prohibitive as well as not cost-effective for our smaller hospices. It can also be difficult for surveyors to conduct a survey of an agency using electronic health records due to the many different software programs on the market requiring familiarity with each. Our experience is that surveyors will request a paper copy of the entire chart in order to perform their tasks. This requires agencies to print out literally hundreds of pages of documents, which must then be destroyed after the survey. While we support migration to electronic health records as beneficial to our patient's care through increased accuracy, thoroughness, and timeliness, we would caution mandating such a migration over a relatively short period of time and would postulate that special financial assistance may be necessary to achieve a standard mandating electronic health records.

§418.104(b) Standard: Authentication. We believe that this standard, as written, holds hospices to the hospital standards when more appropriately we should be held to the standards of a home health agency or nursing facility. We would point out that almost 73% of hospice patients in 2003 received care in their home or a nursing facility as opposed to a hospital (NHPCO National Data Set – 2003).

We would also ask for clarification of the term "authenticate". Does the fact that an individual is assigned a unique username and password that allows access to, creation, and electronic signing of an electronic health record constitute "authentication"? If a paper health record is used by the hospice, are they required to maintain a sample signature on file as authentication?

§418.104(e) Standard: Discharge or transfer of care. The requirement to forward a copy of the patient's clinical record is contrary to the "Minimum Necessary" standard of HIPAA and places a burden upon the hospice. Our experience has been that the hospice discharge summary is sufficiently detailed to provide the patient's attending physician with the necessary information to ensure continuity of care. We would point out that hospices do not request hospital clinical records upon discharge and referral of a patient to hospice as the hospital discharge summary is sufficiently detailed to effect care.

§418.106 Condition of Participation: Drugs, controlled drugs and biologicals, medical supplies, and durable equipment.

§418.106*(b) Standard: Controlled drugs in the patient's home.* We believe that the word "collecting" should be removed from the standard. As the drugs are the patient's property the role of hospice should be limited to tracking medications and education on the use, risks/benefits, and disposal of medications. We also are concerned that requiring hospice staff to collect controlled drugs may expose them to risk in high crime areas. We also recommend that the word "danger" be changed to "risks/benefits" of controlled substances as use of the word "danger" has a negative connotation that may preclude patient acceptance of controlled substances as viable palliative treatment.

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

We would ask that "nursing services" include LPN services for short-term inpatient care. CMS currently allows LPN's to care for continuous care patients who have the same criteria and problems as an inpatient.

§418.108(b) Standard: Inpatient care for respite purposes. As inpatient care for respite purposes is not due to patient acuity, but rather for caregiver respite, we strongly believe that the use of appropriately licensed group homes providing 24 hour on-site care (not necessarily nursing care) that meets the needs of the patient should be authorized for inpatient respite purposes.

§418.108(c) Standard: Inpatient care provided under arrangement.

(3) We believe the requirement to provide a copy of the inpatient clinical record and discharge summary at the time of discharge is not medically necessary, administratively burdensome and contrary to the HIPPA Minimum Necessary standard. A discharge summary provided within a reasonable time frame should be sufficient.

(5) Since many inpatient facilities provide services to more than one hospice, it would seem to be more effective to have the inpatient facility arrange for the training of personnel by a hospice and that the inpatient facility provide documentation of the training and names of participants to each hospice they serve. It would be the responsibility of the individual hospice to be able to show such documentation on demand.

§418.110 Condition of Participation: Hospices that provide inpatient care directly.

§418.110(b) Standard: Twenty-four hour nursing services. We are in agreement with the use of the term "nursing services" rather than "RN services", however, we would suggest that the term "nursing services" be further defined as "nursing services 'within the scope of practice' that meets the needs of all patients..."

§418.110(c) Standard: Physical environment.

(1)(i) Safety management. We would ask for clarification of the term "breach of safety" as we are unclear as to what constitutes a breach of safety. We would also like clarification of the term "appropriate State and local bodies".

§418.110(f) Standard: Patient rooms. We agree with the room size and occupancy standards as written, however, we believe that an exception to the standard be authorized during periods of community disasters, emergencies or evacuations.

§418.110(m) Standard: Pharmaceutical services. While this standard requires that "drugs and biologicals must be obtained from community or institutional pharmacies or stocked by the hospice" it does not address the issue of existing medications being brought into the facility from the patient's home and should contain wording to allow this.

§418.110(o) Standard: Seclusion and restraint.

(1) We would comment that, as currently worded, medications and physical restraints, routinely used as a part of the hospice patient's plan of care would be objected to by nursing facilities due to their own liability as the use of drug or physical restraints necessary to protect the safety of a hospice patient could be readily misconstrued or prohibited by nursing facility staff and management. Also, a hospice patient provided a private room either as a standard of care or due to low census could be considered secluded.

We would point out that bedrails or medications such as Haldol used to prevent injury to frail hospice patients experiencing restlessness or convulsiveness are standard hospice protocols for symptom management. In light of these concerns, we would ask that CMS consider more definitive language for this standard. We would propose that the following statement with regard to bed rails be included: "Bed rails are not included in this definition of physical restraint if used solely for the safety of the hospice patient or to assist the hospice patient in independent functioning."

We also ask that CMS consider using the term "hospice patient" as opposed to "patient" throughout this standard to preclude any confusion that may arise when coordinating care with nursing facility or hospital staff and lessen the chance of misinterpretation of the standard.

We also feel that it is necessary to further define seclusion as the "restricted confinement" of a person as opposed to the "confinement" of a person. This will also lessen any confusion or misinterpretation of the standard.

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

§418.112(d) Standard: Medical Director. We recommend that the coordination of the medical care of the hospice resident be vested in the IDG, as we believe the current wording can be construed as placing the primary responsibility on hospice medical directors rather than the facility medical director. This could also have the affect of making it more difficult for hospice medical directors to obtain malpractice insurance. We also recommend that the second sentence of the standard should be changed to require the IDG to communicate with the medical director of SNF/NF.

§418.112(e) Standard: Written Agreement.

(4)(iii) We would ask for clarification of the term "life threatening condition" as used in this standard. As these are hospice patients with a terminal diagnosis, the language as currently written is confusing. How would this apply to a hospice patient with terminal lung cancer who develops pneumonia? We would suggest that this subparagraph should read "A life threatening condition not related to the terminal diagnosis appears."

§418.112(f) Standard: Hospice plan of care.

(3) As commented earlier, we recommend that CMS consider requiring the plan of care to be reviewed twice each month as opposed to every 14 days.

(4) The requirement that all caregivers must have discussed any changes in the plan of care would be cumbersome, especially for hospice patients residing in a facility as we would need to attempt to coordinate with a large staff with many shift workers whose availability to attend a care planning meeting would be problematic. We would suggest that this language be more concise and require that "any changes in the plan of care be discussed by the IDG, facility representatives and the patient/family and must be approved by the hospice before implementation."

§418.112(h) Standard: Transfer, revocation, or discharge from hospice care. We would comment that this standard does not address the fact that some patients who reside in a facility (i.e., hospice inpatient unit, contracted beds in SNF/NF, hospice residence, etc) do so only because they are hospice patients and their transfer, revocation or discharge from hospice care will, in fact, result in their loss of eligibility to continue to reside in the facility and that continued residence in such facility is dependent upon their eligibility for hospice care under Medicare or private insurance.

§418.112(i) Standard: Orientation and training of staff. We are concerned that facilities in urban areas that contract with multiple hospice providers may be overwhelmed by each hospice attempting to orient their staff. We recommend that each facility with an agreement to furnish care to hospice patients coordinate such training and maintain a record of the training. Each hospice would then only need to assure that the facility staff had received the training.

§418.114(d) Standard: Criminal background checks. While we agree that criminal background checks are of benefit to our patients as a means of ensuring safety and protection we believe that its inclusion in the regulations is not necessary. It has been our experience that most professional liability insurance carriers, such as Glatfelter Underwriting, already require that hospices conduct civil and criminal, licensure, education, motor vehicle and residency checks on staff as a condition of their liability coverage. In addition, States have taken a lead in requiring criminal background checks based upon fingerprints for health care professionals, teachers and others who serve our at-risk populations. We believe that this requirement more properly should be addressed by each State.

We also would ask for clarification on the extent of the criminal background checks necessary to compliance and its applicability to volunteers and employees of contractors. We can envision where the expectation may be that all employees of a DME provider, pharmacy, or nursing facility are required to undergo a criminal background check paid for by the hospice. As a civil and criminal background check can cost up to $100 or more and fingerprint checks can cost up to $52 per individual, the cost can be prohibitive to many hospices.

We would propose that, if retained, this standard be limited to hospice staff and volunteers who have direct patient care responsibilities in order to limit the financial burden on a hospice. There should be no need for a thrift shop volunteer or office volunteer that has no contact with a patient to undergo a criminal background check. Contracted providers of DME, medications, and therapies should be required to certify that their employees have undergone satisfactory criminal background checks.

Conclusion

We appreciate the opportunity to provide the above comments to CMS and acknowledge the effort and dedication of the staff of the Clinical Standards Group, Office of Clinical Standards and Quality in advancing these important revisions to the Hospice Conditions of Participation. Should you have any questions or wish to discuss any of these issues with us, we would be more than happy to work with you.

Sincerely,

Harland C. Robinson
Executive Director

Cc: AHPCO Board of Directors

Submitter : **Mr. RAY MC DONALD** **Date: 07/22/2005**

Organization : **Cross Timbers Hospice**

Category : **Social Worker**

Issue Areas/Comments

GENERAL

GENERAL

July 22, 2005

I supervise three bachelor level social workers (BSW). This should be the only qualification for hospice or any other social service discipline. I feel a BSW social worker should have the opportunity to gain hands on experience and training beyond the classroom internships and field instructions.

It appears to me, we are losing sight of our goal and mission to our profession as social workers. We are the only profession with so many requirements and stipulations that we are terminating ourselves as professional social workers. An example is registered nurses (RN) are now being called ?case managers? and supervising social workers of all levels and licenses. The nurses are not required to obtain any licensure or certification from the CSWE or any other social work competency. I wonder what would the pioneers of the social work movement such as Jane Addams and Sidney Hook say about this new design for lack of a better word.

There is a huge shortage of social workers especially in the rural communities. We don not get paid what other professionals receive nor do we get even what some Para professional receive. If we allow these recommendations to become policy, I assure you social workers will be allowing the systemic genocide of the social work profession. The case manager is no longer exclusively a social worker. Notice the attempt to use other disciplines and the suggestion be called ?social work assistant?. This is another attempt in diluting the strength of the social work profession.

Why not allow the policy to remain as is with the qualifications be BSW with a MSW as supervisor. The policy as it is now applied allows only the MSW supervisor to administer:
? Staff Training
? Preparation of a Plan of Care
? Discharge Planning
? Patient Counseling
? Patient Transfer
? Family Counseling
? Interdisciplinary team work with staff and other agencies
? Coordination of Services

No BSW will be able to qualify for a job in hospice if this change takes affect. This will eventually decrease and possibly eliminate many BSW programs at many universities. Eventually decreasing the MSW programs because of the requirements for admission. This will have a domino affect on the entire social work profession. Case in point: the child welfare program is now desiring (in some states requiring) only MSW with LCSW licensure. They cannot keep social workers plus the benefits do not compensate for the stress.

We must now advocate for ourselves. I believe we all should strive for continuous knowledge but let us not be forced into situations where the social worker (BSW) who wish to support, empower, and advocate for others suffer.

Let us oppose this new policy and push for no change in the criteria of social workers including the demand for licensure. I am for change if it makes something better. This change does not. Please remember, ?be careful what you ask for, you may just get it?.

Ray Mc Donald, MSW
Social Worker Coordinator
Crosstimbers Hospice
Ardmore, OK. 73401
(580) 223-0655

Submitter : **Mrs. Rebecca Anthony**

Date: 07/22/2005

Organization : **Iowa Hospice Organization**

Category : **Hospice**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3844-P-72-Attach-1.DOC

Attachment #12

IOWA HOSPICE
ORGANIZATION

July 22, 2005

The Honorable Dr. Mark McClellan
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244-8010

RE: CMS-3844-P Medicare and Medicaid Programs: Hospice Conditions of Participation

Dear Dr. McClellan:

On behalf of 83 Iowa hospices, the Iowa Hospice Organization (IHO) is pleased to take this opportunity to comment on the proposed Hospice Conditions of Participation published in the May 27, 2005 *Federal Register*. In most instances, IHO agrees with the comments the National Hospice and Palliative Care Organization (NHPCO) will provide to CMS. However, IHO feels as though we need to submit our own comment letter to ensure that the rural hospice perspective is heard and considered. IHO's comments are outlined below.

§ 418.54(e) Comprehensive Assessment of the Patient: Patient Outcome Measures.

Data collection by Iowa hospices is in the infancy stage. **IHO as an organization recognizes the importance of data collection; however, many of our smaller hospices have difficulty finding the value and return on investment of finite resources (time, people, and money).**

When a hospice has an average daily census of 3-4 patients, as many Iowa hospices do, the data collected is not statistically significant. Therefore, the hospice arguably does not realize value in data collection because it does not have a large enough patient base to enable meaningful data analysis. Each case can quickly be examined and judged on its own merits and distinguished from others.

In addition, 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.

§ 418.56(a) Interdisciplinary Group Care Planning and Coordination of Services: Approach to Service Delivery.

Iowa hospices have serious concerns regarding § 418.56(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 Iowa, the medical director for hospice almost always has their own practice in the community, with their own patients. In fact, many Iowa hospice medical directors, although under contract, are volunteering for the position. **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 Iowa to comply with this prohibition, nor can many Iowa hospices afford to hire a full-time staff position of medical director with an average daily census of 3-4 patients.

§ 418.56(c)(2) Interdisciplinary Group Care Planning and Coordination of Services: Content of Plan of Care. Detailed statement of the scope and frequency of services necessary. . .
IHO recommends the removal of 'detailed' before statement. Surveyors in Iowa have been extremely prescriptive regarding the enforcement of the stated plan of care. This is especially troubling in the environment of family and patient centered plan of care. For example, an Iowa hospice was recently cited because its chaplain provided *more* visits to the patient than was cited in the plan of care.

If this standard is strictly enforced as it has been in Iowa, access to good care could be prevented because of worries about the documentation. **Hospices should be able to state 'at least two (2) times' in the plan of care to allow for flexibility of going beyond minimum requirements for care; rather than having to prescribe to such a regimented, detailed plan of care.**

§ 418.56(d) Interdisciplinary Group Care Planning and Coordination of Services: Review of the plan of care.
This theme of this comment will be echoed throughout different sections of the proposed Conditions of Participation (COPs) that address the responsibilities of the Interdisciplinary Group (IDG) and the physician. **IHO has very significant concerns regarding the separation of the medical director from the IDG in the proposed COPs. The IDG is a cornerstone of what makes hospice care distinctive—its patient-centered, collaborative treatment for patients at the end of life. IHO strongly disagrees with the proposed COPs taking a medical focus, rather than a hospice care focus. IHO urges CMS to retain the IDG framework for hospice, including no separation between the IDG and the medical director/physician.** Rather, the medical director/physician should remain part of the IDG.

§ 418.64(a) Core Services: Physician Service.
This is another area where CMS changes the responsibilities of the physicians, making them distinct from the Interdisciplinary Group (IDG). This distinction crumbles one of the foundations of hospice care—patient-centered, collaborative treatment for patients at the end of life.

§ 418.64(c) Core Services: Medical Social Services
Once again, CMS proposes to separate the physician from the Interdisciplinary Group (IDG). IHO strongly believes that the social worker should remain under the direction of the IDG, rather than the physician as proposed in this section of the COPs. Hospice care is founded on patient-centered, collaborate care for patients at the end of life. The separation of the physician from the IDG, in a more authoritative position, destroys this cornerstone of hospice care. **IHO urges CMS to reconsider the change to the roles of the physician and the IDG, realizing that there is a difference between hospice care and medical care.**

§ 418.76(g)(2) Home Health Aide and Homemaker Services: Home Health Aide Assignments and Duties
Again, the proposed COPs separate the physician from the Interdisciplinary Group (IDG) by stating that the home health aide's services must be ordered by the physician or nurse practitioner. **Home health aide services should be provided at the direction of the IDG as part of the plan of care.**

§ 418.76(h) Home Health Aide and Homemaker Services: Supervision of Home Health Aides
IHO feels that the supervision requirements for home health aides are too restrictive. It is unclear why CMS is placing such additional scrutiny on home health aides, especially since home health aides are already required to have competency training.

IHO recommends that the supervision requirements remain in their current form or reflect the current home care regulations. Most rural hospice providers also provide home care services, and it would reduce the administrative burden of having to track and comply with potentially conflicting regulations.

The regulation also needs to clarify whether the supervision visit needs to be done per each patient or per each aide. Especially in the hospice environment, where there are often short stays, IHO believes that counting the visits per aide is more appropriate. The visits are designed to evaluate the aide, so they should be counted per aide.

§ 418.102 Medical Director

The description of the medical director clearly separates the physician from the Interdisciplinary Group (IDG), creating a hierarchy similar to that in medical care. Although hospices provide medical care, there is a distinction between the hospice care model and the medical care model. At center of the hospice care model is the patient-centered, collaborative care for patients at the end of life which includes plans of care directed by the IDG. **By singling out the physician, the proposed COPs are trying to move hospice towards a medical model, which IHO believes in not appropriate or desirable.**

§ 418.102(c) Medical Director: Coordination of Medical Care

IHO thinks that placing the hospice's quality assessment and performance improvement program under the responsibility of the medical director, rather than the IDG is a big misstep. First, this responsibility is too burdensome for a volunteer medical director (which many are in Iowa). Further, in rural Iowa, medical directors also maintain their own practice. The additional responsibility for the QA/PI program may cause many physicians to choose not to serve as medical director, creating huge problems for rural hospices and potential access issues for patients. **IHO recommends placing the QA/PI program under the responsibility of the IDG, with the medical director reviewing.**

§ 418.104(b) Electronic Records: Authentication

IHO agrees that electronic records are great for the continuity of care. Yet, electronic records face many barriers which include cost, training, and software focused on home care rather than hospice. One disadvantage that hospices find with electronic records is that surveyors are not conversant with all the different software. Iowa hospices have been cited because surveyors cannot locate particular information (although information is in the record).

A specific recommendation that IHO has with electronic records concerns authentication. IHO recommends that the hospice COPs track more closely with home care in regards to electronic records and authentication. **Specifically, IHO recommends that CMS remove the signature requirement for hospice electronic records, which would mirror home care in not having a signature requirement.** Electronic medical records already have multiple protections in place like frequently changed passwords making the signature requirement duplicative and unnecessary.

In rural areas, programs providing hospice care often provide home care services as well. By aligning the requirements of the two conditions, programs will be able to utilize the same software. Unless the requirements are the same, the software cannot be utilized by both problems because the set up options cannot continually be changed between hospice and home care patients. By eliminating the signature requirement for hospice electronic medical records and thus aligning the hospice COPs with home care, more programs will be able to institute electronic medical records because software, hardware, and employee training costs would be divided among the programs.

§ 418.110 Hospices That Provide Inpatient Care Directly

IHO has a general concern with inpatient care that is unique to rural areas. Rural hospices are often faced with providing inpatient care to patients because the referral comes from outside of the community and there is no other hospice available to provide the service. In these cases, the entire patient stay is inpatient, which causes many rural hospices to be very close to the 20% limitation for inpatient care and may later compel the rural hospices to deny access. **IHO hopes that CMS will examine this issue so that the 20% limitation does not create a barrier to access in rural Iowa or other rural areas.**

§ 418.114 Personnel Qualifications for Licensed Professionals

IHO supports the proposed COPs reliance upon state licensure requirements for Licensed Professionals providing hospice care. IHO would oppose any movement towards requiring a Masters of Social Work for hospice social workers. Rural areas currently have a very difficult time finding social workers with a degree from a school accredited by the Council on Social Work Education. Requiring a MSW would compound the problem and create an access problem. Hospices can always go beyond minimum requirements; policy measures should not be so restrictive as to create barriers to access.

Thank you for your review and consideration of these comments. If you have any questions, please contact Shannon Strickler or me at 515-243-1046.

Sincerely,

Becky Anthony

Rebecca Anthony
Executive Director

Cc Iowa Congressional Delegation
Iowa Hospice Organization Board

Submitter : **Ms. carla braveman** **Date: 07/22/2005**

Organization : **VNA & Hospice of Cooley Dickinson,INC**

Category : **Hospice**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-3844-P-73-Attach-1.DOC

VNA & HOSPICE OF COOLEY DICKINSON
DARTMOUTH-HITCHCOCK ALLIANCE

Attachment #73

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

CMS-3844-P-74

Submitter : **Ms. Marjorie Mulanax** **Date: 07/22/2005**

Organization : **Hospice Austin**

Category : **Hospice**

Issue Areas/Comments

Issues 1 - 10

Medical Director

See Attachment

CMS-3844-P-74-Attach-1.DOC

Attachment #74

HOSPICE AUSTIN™

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July 22, 2005

Via Electronic Transmittal
http://www.cms.hhs.gov/regulations/ecomments

Centers for Medicare and Medicaid
Services
Department of Health and Human
Services
Attn: CMS-3884-P

RE: File Code CMS-3884-P
Issue: " Medical Director"

Dear Sir/Madam:

Hospice Austin, a not-for-profit hospice located in Austin, Texas, hereby submits these comments regarding the Medical Director requirements set forth in the proposed rule at 70 *Federal Register* 30840, governing Hospice conditions of participation.

Specifically, we are commenting on the proposed regulation § 418.102 and proposed revisions to § 418.54, which would require that:

> ...the medical director or physician designee appointed by the medical director, must either be a hospice employee or under contract with the hospice. A contractual arrangement with another agency or organization is not permitted.

70 *Federal Register* at 30854. Under the proposed revisions as we understand them, hospices would only be allowed to employ medical directors, or directly contract with hem, for medical services, and would not be permitted to contract with other entities that employ or contract with physicians, particularly the physicians' own professional association, professional corporation or professional medical group. We are concerned about the limitations that this requirement could place on hospices and their ability to obtain medical director services.

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Many physicians are themselves employed by their own professional associations ("P.A.s"), professional corporations ("P.C.s") or groups, rather than self-employed. Under the proposed rule, the hospice would not be allowed to contract with a physician's own P.A. or P.C. for medical director services. Rather, the physician would have to be self-employed solely for the purpose of serving as a hospice medical director. Requiring physicians to be self-employed where they already have a professional entity through which they furnish professional services places a host of additional burdens on the physicians, including having to be organized as self-employed physicians and contracting separately for medical director services only, maintaining strict corporate separateness between their hospice medical director services and other services, having to pay self-employment taxes and report income separately on their tax returns, possibly having to obtain separate or additional professional liability insurance to cover hospice medical director services, among other things. We are concerned that these additional burdens will create disincentives to physicians to serve as hospice medical directors, and in turn, make it harder for hospices to meet the CoPs.

Instead, we would propose that hospices be permitted to contract for medical director services with any professional entity or organization that itself contracts with or employs the physicians.

We would be pleased to provide any additional information at your request. Thank you for your consideration of these comments.

Sincerely Yours,

Marjorie Mulanax

Marjorie Mulanax
Executive Director

C National Hospice and Palliative Care Organization
Texas NonProfit Hospice Alliance
Texas-New Mexico Hospice Organization

Submitter : **Karen Paris**

Date: 07/23/2005

Organization : **Hospice of Central Pennsylvania**

Category : **Hospice**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

CMS-3844-P-76

Submitter : **Mr. Gary Gardia**

Date: **07/24/2005**

Organization : **Self**

Category : **Hospice**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3844-P-76-Attach-1.DOC

Attachment #76

NCHPP SW Section
CMS/CoP Recommendations

IDT Leader/Case Management

Case management is central to the model of hospice care. It serves to promote patient and family care that is coordinated, comprehensive, and smooth. The complex needs of hospice patients and their families call for the case manager to lead the interdisciplinary team in order to achieve the most ideal care possible. Professional expertise such as understanding of communication and group dynamics, leadership, advocacy and a strong grounding in the biopsychosocial-spiritual approach make social workers especially well suited for leadership of the interdisciplinary team. Due to the skills needed to effectively lead a hospice team, we recommend that case managers be social workers or nurses rather than "any member" of the interdisciplinary team.

4Day/7Day

We strongly support the standard that completion of the comprehensive assessment by the hospice social worker should be no later than 4 calendar days after the patient elects the hospice benefit. With the increasingly short lengths of stay in hospice, such immediate involvement of social work with patients and families is important for provision of thorough interdisciplinary care. The 4 calendar-day requirement timeframe would help ensure the vast majority of patients and families receive the benefit of social work expertise, such as skilled psychosocial assessment, psychotherapeutic and cognitive-behavioral interventions, knowledgeable family assessment and interventions, and practical assistance with social and community systems and resources. We applaud the recommendation to move to a 4 calendar-day requirement. We welcome a future opportunity to encourage and support a change to a 2 calendar-day requirement.

Definition of Counseling

Counseling is the professional and psychotherapeutic process of helping individuals, couples, families and groups to enhance or restore their capacity for optimal social, emotional, spiritual and psychological health. The goal is to empower them to identify and utilize strengths, effectively solve problems and make difficult decisions about health, social, financial and other interpersonal and intrapersonal concerns that arise when dealing with the dying process, terminal illness and grief.

Attachment #76

MSW/BSW

I support the use of MSWs, (from a CSWE accredited program) with one year of mental health/health care experience, who are qualified to perform the functions of a hospice social worker. When a qualified MSW is not available, such as in a rural area, a BSW (again from a CSWE accredited program and not someone with a bachelor's degree in psychology, sociology or another related field and with one year of health care experience) would qualify, and the BSW would be under the supervision of an MSW, hired in some capacity by the hospice to provide supervision.

CMS-3844-P-77

Submitter : **Nancy Wertz, RN, CHPN** **Date: 07/24/2005**

Organization : **New Mexico Association of Home and Hospice Care**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-3844-P-77-Attach-1.DOC

Attachment #77

COMMENTS ON
42 CFR Part 418
Medicare and Medicaid Programs:
Hospice Conditions of Participation;
Proposed Rule, dated May 27, 2005
Proposed by the New Mexico Association of Home and Hospice Care

§ 418.3 Definitions

Attending Physician— We request that the definition be rewritten to clearly acknowledge that the hospice medical director and/or nurse practitioner may also act as the patient's attending physician as this is a common practice in many instances.

Clinical Note— Since hospice also provides or assists in the provision of spiritual care, we recommend that it be added to this definition.

Comprehensive Assessment—A definition is needed that provides a clear understanding that this is an assessment conducted by a Registered Nurse that identifies for the IDG those immediate needs of the patient and family.

Counseling Services—A definition is needed for counseling services that will also include bereavement services.

Dietician-- It is recommended that the following definition be added to clarify the difference between nutritional counseling and those services that must be performed by a Dietician in the provision of dietary therapy.

Drug Restraint—Clarification is needed that recognizes that hospice utilizes medications in its normal patient care protocol that may be viewed in other settings as chemical restraints.

Licensed professional—Dietary Services are also provided and should be included in this definition.

Physical restraints—Some restraints, such as bedrails, are not attached to a patient's body. The definition should include " attached or adjacent to the patient's body".

Attachment #77

PATIENT'S RIGHTS

§ 418.52 Condition of Participation: Patient's Rights

§ 418.52 (a) (1)

The language as proposed should acknowledge the impossibility of providing written materials in all languages and dialects and clearly make it permissible to convey the information to the patient through an interpreter who could be a family member or other person. In New Mexico we have a diverse Native American population, each with their own distinct language. Not all of these languages have a written form, only are spoken.

§ 418.52(a) (3)

Informing the patient of drug policies and procedures (especially disposal policies) at the time of admission will be confusing to the patient & primary caregivers. Patients and their caregivers are given a tremendous amount of information at the time of admission and it is impossible to retain all of the details of hospice. It is recommended that it be made clear that these policies can be provided as a part of an admission packet.

§ 418.52(a) (4)

We would like the "demonstrated an understanding of these rights" be deleted from this section. There is a lot of information discussed with the patient and the family at the time of the admission to hospice. It is truly difficult to ascertain how much information they are retaining. We that the wording be changed to reflect that the patient/representative was presented the information for retention.

§ 418.52(b)(1)

We would like to see under this provision that the specifically states that the patient has the right to refuse treatment.

§ 418.52(b)(5)

We concur with the comment from NHPCO that the language from the Home Heath CoP requirement at 484.10 would be more appropriate to the hospice/home environment.

Attachment #77

ASSESSMENT TIME FRAMES

§ 418.54

We feel that the times frames that CMS has defined are unrealistic for our member hospices. The word "**care**" in the first paragraph should be replaced with "**assessment** includes, but not limited to the palliation and management of the terminal illness and related medical conditions."

§ 418.54(a) We feel that it is very appropriate to add "at the patient and/or family's request.

418.54(b) We concur with NHPCO's comment that the time frame for the completion of the comprehensive assessment be 7 days.

§ 418.54(d)

The continuing update of the assessment is an important portion of hospice care. However, as written, the 14 day requirement does not take into account holidays or unforeseen problems. We also feel that there should be a 5 day "grace" period at the time of recertification to capture that assessement update at the regular meeting of the hospice IDT.As such we are recommending some minor changes.

PLAN OF CARE/COORDINATION OF SERVICES

§ 418.56

This section does not recognize that in some instances the hospice physician can also be the attending physician when the patient either does not have an attending physician or their attending physician does not want to continue in that capacity. It also adds the word "spiritual counselor" in the makeup of the IDG, when the law only uses "counselor ". We suggest the deletion of "spiritual" from this.

§ 418.56(c)

This section needs clarification to show that the hospices' responsibility is for palliation and management of the terminal illness rather than the comprehensive care of all of the patient's problems. In addition, patient and family agreement with the plan of care is not always guaranteed. We also question as to whether the "family" has the right to override the autonomous decision of the patient.

§ 418.56(d)

The medical director has a well defined role as a part of the hospice team and as such, should not be singled out in this portion. We feel that that phrase should be removed. We feel that the inclusion of collaboration with the attending physician is a positive move.

§ 418.64

Continuous care is particularly burdensome on small and rural hospices that are not staffed to be able to provide this infrequent and unpredictable level of care on the when it is needed. Without the ability to contract for continuous care staff on a routine basis, a barrier is created that may preclude a patient being able to easily access this level of care. We urge CMS to rethink their stand on this issue.

§ 418.64(b)(3)

We recommend that the word "infrequently" be deleted from this because it is so unspecific. It will lead to confusion in its interpretation.

§ 418.649(c)

We did not understand why this says "by a qualified social worker, under the direction of a physician". We feel that this should say "under the direction of the hospice medical director."

§ 418.64(d)(1)(ii)

We would like to delete from this section "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." We feel that this will place an additional financial burden on our many small, rural hospices that is unacceptable and many will find difficult to provide due to staff shortage issues.

§ 418.64(d)(2)

The recognition that nursing standards of practice allow them to make general dietary assessments and provide dietary counseling is a very positive change.

§ 418.66

We urge CMS to streamline and simplify this process and also make it available for hospice in urban areas who cannot find sufficient nursing staff.

§ 418.72

We recommend that dieticians be added to non-core service providers in order to allow hospices to contract for their services.

§ 418.76(g)(2)(i)

We are recommending that the phrase "ordered by the physician or nurse practitioner" be changed to the "interdisciplinary team" to allow the IDT to order these services.

§ 418.76(h)

We join other hospice providers in opposing the every 28 day onsite supervisory visit of the home health aide services is very burdensome to hospice providers. We feel that a supervisory visit by phone or in person is sufficient. We are also recommending an annual on site observation and skills assessment to be sufficient. The proposed recommendation are impractical and a waste of valuable nursing or therapy hours.

ORGANIZATION & ADMINISTRATION

§ 418.100(a)(2)

The requirement that a hospice "ensure" care that is "…consistent with patient and family needs and desires" may create expectations beyond that which is under the control of the hospice. Every hospice strives to ensure care that provides optimal comfort and dignity that is consistent with needs and desires, but that is not always possible, especially when the patient and family are not in agreement with the plan of care. We recommend adding "with patient and family needs and desires that are consistent with hospice practices."

MEDICAL DIRECTOR

§ 418.102

It needs to be noted that many hospices utilize the services of volunteer medical directors. In addition, it should be the hospice rather than the medical director who is responsible for designating the physician that takes the medical director's place when the medical director is not available. Finally, it is the responsibility of the whole hospice team to ensure that each patient experiences good hospice care. We ask that the last sentence be changed to "ensure that each patient experiences medical care that reflects hospice philosophy" instead of "policy".

§ 418.102(b)

The requirement that the medical director must review the patient's and family's expectations and wishes for the continuation of hospice seem to add another unnecessary step in the recertification process. The patient and family are notified during the initial certification that they have the option to opt out of hospice at any time. They willingly entered into hospice and remain there as a matter of choice. We ask that 418.102(b)(2) be deleted.

Attachment #77

§ 418.102(c)

The requirement that the medical director or physician designee be responsible for directing the hospice's quality assessment program is unworkable at best. The physician and the remainder of the team should have continual input into the program, but the hospice should be able to manage it own QAPI program.

CLINICAL RECORDS

§ 418.104(b)

This standard is too broad for hospices that work with a large undefined number of physicians and health care professionals and as written would require each hospice to set up a credentialing office. Unlike hospitals that have a defined physician base, hospices can potentially work with hundreds of physicians across various settings in-state and out of state locations. This burden should be on the author of the entry to verify his or her own signature, written initials or computer entry.

§ 418.104(d)

We recommend that this standard follow the HIPAA requirement for records retention.

§ 418.104(e)

We recommend that the release of information follow the Minimum Necessary Standards and limited to the discharge summary and any other information the accepting facility might request. The cost of duplicating entire charts is an added burden to hospice providers. To our knowledge, this is not a requirement of other agencies, i.e home health agencies or facilities such as hospitals or SNF or ICF.

§ 418.106(b)

The language in this section referring to "potential dangers" merely reinforces the myths that hospices have been trying to over come for years. In addition, the hospice cannot collect and dispose of drugs unless that desired by the family. We suggest deleting the proposed language and replacing it with "to ensure the patient and family are educated regarding the appropriate use of controlled substances."

§ 418.106(c)

The maintenance and training in the use of durable medical equipment can be handled in most case through contractual agreements.

Attachment #77

SHORT TERM INPATIENT CARE

§ 418.108

This standard should be expanded to include short term stays for crises of a family psychosocial nature. The requirement for 24 hour nursing care should not be applied for either respite or for care during a_short-term family psychosocial crises.

§ 418.108(c)(3)

The hospital discharge summary would be sufficient for the hospice to ensure continuity of care.

SECLUSION & RESTRAINT

§ 418.110(o)

This section needs to be amended to recognize that certain chemicals that may be considered in other disciplines as chemical restraints are commonly used in hospice for treatment of terminal restlessness. A few examples are: Haldol, Ativan, Xanax, ABH, any benzodiazepines, Phenergan, phenobarbitol, and Thorazine. It should also acknowledge that bed rails are not considered a restraint when used for safety purposes. It is also recommended that it be clarified that orders for restraint cannot exceed 24 hours and that the patient should be reassessed every 4 hours rather than orders issued every 4 hours.

RESIDENTS RESIDING IN A FACILITY

§ 418.112(b)

> The standard as written may negatively impact the hospice's relationship with the SNF since the nursing home COP's currently hold the nursing home responsible for the professional management of the patient. As such we suggest that "must assume full responsibility for" be deleted from this paragraph. We would also like a last sentence added that the nursing facility continues to provide services at the same level as they would have provided before the election of the hospice benefit.

§ 418.112(c)

We are recommending that this section be rewritten for clarity and simplification. The hospice would be required to provide all necessary core services to its patients in the same manner that it would provide core services to a patient residing in a home in the community.

§ 418.112(d)

We are concerned that this standard will unnecessarily strain the relationship between the hospice and the NF as well impeding coordination/communication by limiting coordination to physicians. We also see problems in that the hospice medical director might not be credentialed in all nursing facilities in a provider's service area.

§ 418.112(e)

We feel that this section needs some modifications for clarity and simplicity. For example, a contract with a NF does not need the written consent of the patient or the family. We would recommend that 418.112(e)(1) be deleted. We also recommend that 418.112(e)(1) would then read "The services to be provided by the hospice." 418.112(e)(2) would then read "The services to be provided by the facility". We would delete 418.112(e)(6). In 418.112(e)(8), we feel that the hospice should be able to use the facility's nursing personnel where permitted by law to assist in the administration of prescribed therapies included in the plan of care.

§ 418.112(f)

The wording of this section may objectionable to nursing facility staff as it requires them to update their plan of care with the family every 14 days rather than their normal time frame of 3 months. It is assumed that nursing facility COP's will eventually address this area. We would like to recommend changes to 418.112(f)(4) that "Any changes impacting the hospice plan of care must be discussed with and approved by the hospice before implementation."

PERSONNEL QUALIFICATIONS

§ 418.114(c)(7)

Some hospices or other states may require social workers with MSW's, but New Mexico allow BSW's to fill this capacity. If the standard was changed to require MSW's, it would create major problems for most of the hospices operating in our both as to the retention of those individuals currently employed and the recruitment of qualified MSW's (especially in the predominately rural areas) in our states. We would also like to suggest that CMS consider the addition of licensed counseling professionals as an alternative to BSW's. Many of our hospices, either urban or rural are having a difficult time even finding BSWs to fill their social work positions.

Submitter : **Dr. Barbara Olevitch** **Date: 07/24/2005**

Organization : **Dr. Barbara Olevitch**

Category : **Individual**

Issue Areas/Comments

Issues 1 - 10

Residents Residing in a Facility

I am concerned about hospice staff training the staff of other facilities in the hospice philosophy. In a government report "Synthesis and Analysis of Medicare Hospice Benefit Executive Summary and Recommendations" it states that there is an expected "spillover" effect upon the other nonhospice patients in the facility. To hospice proponents this effect might seem desirable. However, to patients and families who have deliberately selected to be treated according to a curative philosophy, this "spillover" effect would be undesirable.

Issues 11 - 18

Statutory Nursing Waiver

Waiver of requirement - Physical therapy, Occupational therapy, Speech-language pathology, and dietary counseling

These services are so critical that it seems inappropriate to waive the requirement.

Patients Rights

I don't believe that "Being informed in advance regarding the care to be provided" is sufficient for informed consent for entering hospice.
I believe that it should be specified to the patient what treatments will not be provided (that would have been provided in a nonhospice medical setting) and what the possible consequences might be to the patient of not undergoing these treatments.

CMS-3844-P-79

Submitter : **Susan Balfour** **Date: 07/25/2005**

Organization : **The Carolinas Center for Hospice and End of Life C**

Category : **Hospice**

Issue Areas/Comments

GENERAL

GENERAL

See attached assessment.

A general comment: We applaud the shift in emphasis to outcomes rather than process. However, given the infrequent surveys for hospices, we have concerns that, when this propsed rule becomes final, a hospice provider could find itself in the position of changing practice to meet the new rules but then have to wait 5-7 years for a survey. The hospice would have no way of knowing in a timely fashion if their practice was meeting the intent of the new regulations.

418.76 Home health aide and homemaker services
(h) Supervision of home health aides: Although we support continuation of evaluation of home health aides services every 14 days (with or without the aide present), we most emphatically cannot support the requirement for the 28 day observed visit for each home health aide. Home health aides have a very finite set of tasks that they may complete; they receive specific training in these tasks as well as competency testing at intervals defined either by state regulation or agency policy. If there is situation in which an aide has a knowledge deficit, it becomes apparent in the 14-day evaluation cycle. Requiring the 28-day evaluation is just not defensible. Please consider changing this to requiring an observed visit for each home health aide once every calendar quarter.

Issues 1 - 10

Personnel Qualifications

We have great concerns that the proposed standard, by deferring to state law, would actually serve to lower the standard for qualifications for social workers in some states. We feel strongly that the current social worker requirement should remain as the minimum.

Medical Director

418.102(c) We do not agree with the portion of this standard that states that the medical director or physician designee is responsible for directing the hospice?s QAPI program. While the physician is certainly a critical participant and, in some agencies, might be the person chosen to direct the program, there is no evidence that QAPI is a knowledge or skill set possessed by each physician (actually, far from it).

The hospice?s governing body has responsibly for assuring that this function is completed; it makes much more sense to allow the agency administrator to determine who will direct the program. That decision will be based more correctly on the skills and knowledge level of all staff members.

We have had conversations with both the medical directors and the administrators of a large number of our affiliate hospice members; no one understands or agrees with this component of the standard.

Inpatient Care

We appreciate removing the requirement for 24 hour nursing care and agree that it is unnecessary for respite level of care. However, we feel strongly that the 24 hour requirement for an RN should remain for general inpatient level of care.

Seclusion and Restraint

Please make clear that this definition applies to the standard treatment for hospice patients. A number of the medications that are critical to manage symptoms at end of life are considered, in other settings, to be chemical restraints. It is imperative that a clear differentiation be drawn.

Residents Residing in a Facility

418.112 General Comment: We are uncertain of what is meant by ?other facilities? and are concerned about the broad range of settings that could be included in this category. Please define or consider limiting the requirements in this section to only the SNF/NFs and ICF/MRs.

418.112 (d) Medical Director: This standard shifts the role of the hospice and the nursing facility medical directors from a broader role responsible for facility or agency wide medical policies to a role that requires coordination of care for each individual resident/patient. The medical directors do need to communicate on larger issues; requiring communication on each resident?s medical care is a poor use of resources that we do not think will lead to improved patient outcomes.

Social Work

418.114 We wish that every hospice social worker could be MSW prepared. We are well aware, however, that this would leave many of our providers, particularly those in the rural areas, unable to meet this requirement because there just aren?t enough MSWs available. The end result would be that access to hospice care in these areas would be limited.

Drugs, Supplies, and DME

418.106 (b) Controlled Drugs in the Patient's Home
While we understand from CMS staff members that there was a situation that involved a teenager and diversion of controlled substances from a hospice patient?s home, sound regulation is not written based on a few experiences, no matter how tragic. This language, with its emphasis on danger, will serve to cause far more human suffering if patients and family members decide not to access needed medications because they are too frightened of the medications. The sad thing is that

this will not serve to stop diversion, only to frighten people about an entire class of medications.

Clinical Records

418.104 (b): We are puzzled as to exactly what is required to authenticate (other than in the case of electronic signatures). Was this standard drawn from current hospital CoPs? If so, please realize that the two setting are not compatible.
418.104 (c)Requiring that a copy of the entire record be provided when a patient is discharged or transferred to another care setting will most likely be counterproductive?no one will take the time to wade through the entire thing. Requiring a summary of information would go further towards insuring that pertinent information is transmitted to the new provider. Additionally, hospice medical records also include information about family members; this information does not need to be shared with the new provider.

Issues 11 - 18

QAPI

We also support this area and appreciate that, according to language in the preamble, CMS recognizes that hospice providers will require time and support to move towards implementation.

Assessment Time Frames

418.54 (a) Initial Assessment: Please add language that would (1) allow for the initial assessment to be outside of the 24-hour time frame if requested by the patient and/or family and (2) allow the hospice RN or hospice physician to visit within the specified time frame.
418.54 (b) Time Frame for completion of comprehensive assessment: While completion of the comprehensive assessment within 4 days sounds reasonable and desirable, it does not take into account the frequency in which patients present with pronounced symptoms that require immediate attention and can often take a few days to bring under control. Until these immediate needs are addressed, necessary time and attention cannot be given to completion of the entire comprehensive assessment. Additional flexibility is necessary here; we request extending this time frame to read ?no latter than 7 days.?
418(d) Update of the comprehensive assessment: Please remove the requirement for update of the comprehensive assessment at the time of recertification. The hospice is already doing an update each 14 days; requiring an additional update at the time of recertification is not a wise use of resources. How does CMS feel that it would contribute to desired outcomes?

Patients Rights

The emphasis on controlled substances in this section is quite puzzling. Although hospices do identify (and implement strategies to address) occasional situations in which drug diversion is suspected, the larger problem is dispelling the myths around this class of medications so that adequate pain management can be achieved. All medications can be dangerous; drawing attention to opioids in that manner is ill-advised and likely to create a new level of unnecessary anxiety leading to incidents of undertreatment of pain.

CMS-3844-P-79-Attach-1.DOC

CMS-3844-P-79-Attach-2.DOC

CMS-3844-P-79-Attach-3.DOC

CMS-3844-P
Comments: 2005 PROPOSED HOSPICE MEDICARE CONDITIONS OF PARTICIPATION
The Carolinas Center for Hospice and End of Life Care

PO Box 4449
Cary, NC 27519
919-677-4129

Attachment #79

2005 CMS PROPOSED COPS	*REQUEST FOR COMMENTS*
§ 418.2 Scope of the part.	
§ 418.3 Definitions	
Attending physician means a— (1) (i) Doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she performs that function or action; or (ii) Nurse practitioner who meets the training, education and experience requirements as the Secretary may prescribe; and (2) Is identified by the individual, at the time he or she elects to receive hospice care, as having the most significant role in the determination and delivery of the individual's medical care.	
Bereavement counseling means emotional, psychosocial, and spiritual support and services provided after the death of the patient to assist with issues related to grief, loss, and adjusting.	
Cap period means the 12-month period ending October 31 used in the application of the cap on overall hospice reimbursement specified in §418.309.	
Clinical note means a notation of a contact with the patient that is written and dated by any person providing services and that describes signs and symptoms, treatments and medications administered, including the patient's reaction and/or response, and any changes in physical or emotional condition.	
Drug restraint means a medication used to control behavior or to restrict the patient's freedom of movement, which is not a standard treatment for a patient's medical or psychiatric condition.	Please make clear that this definition applies to the standard treatment for **<u>hospice</u>** patients. A number of the medications that are critical to manage symptoms at end of life are considered, in other settings, to be chemical

2005 CMS PROPOSED COPS	***REQUEST FOR COMMENTS***
	restraints. It is imperative that a clear differentiation be drawn.
Employee means a person who works for the hospice and for whom the hospice is required to issue a W–2 form on his or her behalf, or if the hospice is a subdivision of an agency or organization, an employee of the agency or organization who is appropriately trained and assigned to the hospice or is a volunteer under the jurisdiction of the hospice.	
Hospice means a public agency or private organization or subdivision of either of these that is primarily engaged in providing hospice care as defined in this section.	
Hospice care means a comprehensive set of services described in 1861(dd)(1) of the Act, identified and coordinated by an interdisciplinary team to provide for the physical, psychosocial, spiritual, and emotional needs of a terminally ill patient and/or family members, as delineated in a specific patient plan of care.	
Licensed professional means a licensed person sanctioned by the State in which services are delivered, furnishing services such as skilled nursing care, physical therapy, speech-language pathology, occupational therapy, and medical social services.	
Palliative care means patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice.	
Physical restraint means any manual method or physical or mechanical device, material, or equipment attached to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body.	
Progress note means a written notation, dated and signed by any person providing services, that summarizes facts about the care furnished and the patient's response during a given period of time.	
Representative means an individual who has the authority under State law (whether by statute or pursuant to an appointment by the courts of the State) to authorize or	Please assure that this definition would cover healthcare powers of attorney.

2005 CMS PROPOSED COPS	***REQUEST FOR COMMENTS***
terminate medical care or to elect or revoke the election of hospice care on behalf of a terminally ill patient who is mentally or physically incapacitated. This may include a legal guardian.	
Restraint means either a physical restraint or a drug used as a restraint.	
Satellite location means a Medicare-approved location from which the hospice provides hospice care and services within a portion of the total geographic area served by the hospice location issued the provider agreement number. The satellite location is part of the hospice and shares administration, supervision, and services in a manner that renders it unnecessary for the satellite location to independently meet the conditions of participation as a hospice.	
Seclusion means the confinement of a person in a room or an area where a person is isolated and physically prevented from leaving.	
Terminally ill means that the patient has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course.	

2005 CMS PROPOSED COPS ***Subpart C***	***REQUEST FOR COMMENTS***
§ 418.52 Condition of participation: Patient's rights.	
(a) *Standard: Notice of rights.*	The emphasis on controlled substances in this section is quite puzzling. Although hospices do identify (and implement strategies to address) occasional situations in which drug diversion is suspected, the larger problem is dispelling the myths around this class of medications so that adequate pain management can be achieved. All medications can be dangerous; drawing attention to opioids in that manner is ill-advised and likely to create a new level of unnecessary anxiety leading to incidents of undertreatment of pain.
(b) Standard: Exercise of rights and respect for property and person.	
(c) *Standard: Pain management and symptom control.*	
(d) *Standard: Confidentiality of clinical records*	
(e) *Standard: Patient liability.*	
§ 418.54 Condition of participation: Comprehensive assessment of the patient.	
(a) *Standard: Initial assessment.*	Please add language that would (1) allow for the initial assessment to be outside of the 24-hour time frame if requested by the patient and/or family and (2) allow the hospice RN **<u>or hospice physician</u>** to visit within the

2005 CMS PROPOSED COPS *Subpart C*	*REQUEST FOR COMMENTS*
	specified time frame.
(b) *Standard: Time frame for completion of the comprehensive assessment.*	While completion of the comprehensive assessment within 4 days sounds reasonable and desirable, it does not take into account the frequency in which patients present with pronounced symptoms that require immediate attention and can often take a few days to bring under control. Until these immediate needs are addressed, necessary time and attention cannot be given to completion of the entire comprehensive assessment. Additional flexibility is necessary here; we request extending this time frame to read "no latter than 7 days."
(c) *Standard: Content of the comprehensive assessment.*	While both bereavement needs and drug therapy are important components of a comprehensive assessment, it is perplexing that they have been broken out in this fashion in this standard.
(d) *Standard: Update of the comprehensive assessment.*	Please remove the requirement for update of the comprehensive assessment at the time of recertification. The hospice is already doing an update each 14 days; requiring an additional update at the time of recertification is not a wise use of resources. How does CMS feel that it would contribute to desired outcomes?
(e) *Standard: Patient outcome measures.*	We support this area and appreciate that, according to language in the preamble, CMS recognizes that hospice providers will require time and support to move towards implementation.
§ 418.56 Condition of participation: Interdisciplinary group care planning and coordination of services.	
(a) *Standard: Approach to service delivery.*	
(b) *Standard: Plan of care.*	

2005 CMS PROPOSED COPS *Subpart C*	*REQUEST FOR COMMENTS*
(c) *Standard: Content of the plan of care*	
(d) *Standard: Review of the plan of care.*	
(e) *Standard: Coordination of services..*	
§ 418.58 Condition of participation: Quality assessment and performance improvement.	We also support this area and appreciate that, according to language in the preamble, CMS recognizes that hospice providers will require time and support to move towards implementation.
(a) *Standard: Program scope.*	
(b) *Standard: Program data.*	
(c) *Standard: Program activities.*	
(d) *Standard: Performance improvement projects.*	
(e) Standard: Executive responsibilities	.
§418.60 Condition of participation: Infection control.	
(a) *Standard: Prevention*	
(c) *Standard: Education.*	
§ 418.62 Condition of participation: Licensed professional services.	
§ 418.64 Condition of participation: Core services.	

2005 CMS PROPOSED COPS ***Subpart C***	***REQUEST FOR COMMENTS***
(a) *Standard: Physician services.*	
(b) *Standard: Nursing services.*	
(c) *Standard: Medical social services.*	
(d) *Standard: Counseling services* (i) *Bereavement counseling.* (2) *Nutritional counseling.* *(3) Spiritual counseling.*	While hospices routinely provide bereavement support services to staff members and residents of nursing facilities, we do not believe that requiring this in regulation is supported by statute and request that it be removed.
§ 418.66 Condition of participation: Nursing services—Waiver of requirement that substantially all nursing services be routinely provided directly by a hospice.	
Non-Core Services **§ 418.70 Condition of participation: Furnishing of non-core services.**	
§ 418.72 Condition of participation: Physical therapy, occupational therapy, and speech-language pathology.	
§ 418.76 Condition of participation: Home health aide and homemaker services.	
(a) *Standard: Home health aide qualifications.*	
(b) *Standard: Content and duration of home health aide classroom and supervised practical training.*	
(c) *Standard: Competency evaluation.*	
(d) *Standard: In-service training.*	
(e) *Standard: Qualifications for instructors conducting classroom supervised practical training, competency evaluations and in-service training.*	
(f) *Standard: Eligible training organizations.*	
(g) *Standard: Home health aide assignments and duties.*	As a matter of practicability, obtaining physician orders for home health aide services is an expenditure of time that makes little sense (an observation that physicians are not shy about sharing with hospices!). Please consider allowing the frequency of the home health aide services to be determined by the interdisciplinary team.
(h) *Standard: Supervision of home health aides.*	Although we support continuation of evaluation of home health aides services every 14 days (with or without the aide present), we most emphatically cannot support the requirement for the 28 day observed visit for each home health aide. Home health aides have a very finite set of tasks that they may complete; they receive specific training in these tasks as well as competency testing at intervals defined either by state regulation or agency policy. If there is situation in which an aide has a knowledge deficit, it becomes apparent in the 14-day evaluation cycle. Requiring the 28-day evaluation is just not defensible. Please consider changing this to requiring an observed visit for each home

2005 CMS PROPOSED COPS Subpart C	*REQUEST FOR COMMENTS*
	health aide once every calendar quarter.
(i) *Standard: Individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit.*	
(j) *Standard: Homemaker qualifications.*	
(k) *Standard: Homemaker supervision and duties.*	
§ 418.78 Conditions of participation: Volunteers.	
(a) *Standard: Training.*	
(b) *Standard: Role.*	
(c) *Standard: Recruiting and retaining.*	
(d) (d) *Standard: Cost saving.*	
(e) *Standard: Level of activity.*	
§ 418.100 Condition of participation: Organization and administration of services.	
(a) *Standard: Serving the hospice patient and family.*	
(b) *Standard: Governing body and administrator*	
(c) *Standard: Services.*	
(d) *Standard: Continuation of care.*	
(e) *Standard: Professional management responsibility.*	
(f) *Standard: Hospice satellite locations.*	
(g) *Standard: In-service training.*	
§ 418.102 Condition of participation: Medical director.	
(a) *Standard: Initial certification of terminal illness.*	
(b) *Standard: Recertification of the terminal illness.*	
(c) *Standard: Coordination of medical care.*	We do not agree with the portion of this standard that states that the medical director or physician designee is responsible for directing the hospice's QAPI program. While the physician is certainly a critical participant and, in some agencies, might be the person chosen to direct the program, there is no evidence that QAPI is a knowledge or skill set possessed by each physician (actually, far from it). The hospice's governing body has responsibly for assuring that this function is completed; it makes much more sense to allow the agency administrator to determine who will direct the program. That decision will be based more correctly on the skills and knowledge level of all staff members. We have had conversations with both the medical directors and the administrators of a large number of our affiliate hospice members; no one understands or agrees with this component of the standard.
§ 418.104 Condition of participation: Clinical records.	
(a) *Standard: Content.* Each patient's record must include the following:	
(b) *Standard: Authentication.*	We are puzzled as to exactly what is required to authenticate

2005 CMS PROPOSED COPS ***Subpart C***	***REQUEST FOR COMMENTS***
	(other than in the case of electronic signatures). Was this standard drawn from current hospital CoPs? If so, please realize that the two setting are not compatible.
(c) *Standard: Protection of information.*	
(d) *Standard: Retention of records.*	
(e) *Standard: Discharge or transfer of care.*	Requiring that a copy of the entire record be provided when a patient is discharged or transferred to another care setting will most likely be counterproductive—no one will take the time to wade through the entire thing. Requiring a summary of information would go further towards insuring that pertinent information is transmitted to the new provider. Additionally, hospice medical records also include information about family members; this information does not need to be shared with the new provider.
(f) *Standard: Retrieval of clinical records.*	
§ 418.106 Condition of participation: Drugs, controlled drugs and biologicals, medical supplies, and durable medical equipment.	
(a) *Standard: Administration of drugs and biologicals..*	
(b) *Standard: Controlled drugs in the patient's home.*	Please refer back to the comments in §418.52 (a). While we understand from CMS staff members that there was a situation that involved a teenager and diversion of controlled substances from a hospice patient's home, sound regulation is not written based on a few experiences, no matter how tragic. This language, with its emphasis on "danger," will serve to cause far more human suffering if patients and family members decide not to access needed medications because they are too frightened of the "dangerous" medications. The sad thing is that this will not serve to stop diversion, only to frighten people about an entire class of medications.
(c) *Standard: Use and maintenance of equipment and supplies*	
§ 418.108 Condition of participation: Short-term inpatient care.	
(a) *Standard: Inpatient care for symptom management and pain control.*	
(b) *Standard: Inpatient care for respite purposes.*	
(c) *Standard: Inpatient care provided under arrangements.*	
(d) *Standard: Inpatient care limitation.*	
(e) *Standard: Exemption from limitation.*	
§ 418.110 Condition of participation: Hospices that provide inpatient care directly.	
(a) *Standard: Staffing..*	
(b) *Standard: Twenty-four hour nursing services.*	We appreciate removing the requirement for 24 hour nursing care and agree that it is unnecessary for respite level of care. However, we feel strongly that the 24 hour requirement for an RN should remain for general inpatient level of care.

2005 CMS PROPOSED COPS ***Subpart C***	***REQUEST FOR COMMENTS***
(c) *Standard: Physical environment.*	
(d) *Standard: Fire protection.*	
(e) *Standard: Patient areas*	
(f) *Standard: Patient rooms.*	
(g) *Standard: Toilet/bathing facilities.*	
(h) *Standard: Plumbing facilities.*	
(i) *Standard: Infection control.*	
(j) *Standard: Sanitary environment..*	
(k) *Standard: Linen.*	
(l) *Standard: Meal service and menu planning.*	Thank you for the changes in the meal service area.
(m) *Standard: Pharmaceutical services.*	
(n) Pharmacist.	
(o) *Standard: Seclusion and restraint.*	Please refer back to our comments in the definition section.
§ 418.112 Condition of participation: Hospices that provide hospice care to residents of a SNF/NF, ICF/MR, or other facilities.	We are uncertain of what is meant by "other facilities" and are concerned about the broad range of settings that could be included in this category. Please define or consider limiting the requirements in this section to only the SNF/NFs and ICF/MRs.
(a) *Standard: Resident eligibility, election, and duration of benefits.*	
(b) *Standard: Professional management.*	
(c) *Standard: Core services.*	
(d) *Standard: Medical director.*	This standard shifts the role of the hospice and the nursing facility medical directors from a broader role responsible for facility or agency wide medical policies to a role that requires coordination of care for each individual resident/patient. The medical directors do need to communicate on larger issues; requiring communication on each resident's medical care is a poor use of resources that we do not think will lead to improved patient outcomes.
(e) *Standard: Written agreement.*	
(f) *Standard: Hospice plan of care.*	
(g) *Standard: Coordination of services.*	
(h) *Standard: Transfer, revocation, or discharge from hospice care.*	
(i) *Standard: Orientation and training of staff.*	
§ 418.114 Condition of participation: Personnel qualifications for licensed professionals. (a) *General qualification requirements.*	We wish that every hospice social worker could be MSW prepared. We are well aware, however, that this would leave many of our providers, particularly those in the rural areas, unable to meet this requirement because there just aren't enough MSWs available. The end result would be that access to hospice care in these areas would be limited. We have great concerns that the proposed standard, by deferring to state law, would actually serve to lower the standard for qualifications for social workers in some states. We feel strongly that the current social worker requirement should remain as the minimum.
(b) Personnel qualification for physicians, speech-language pathologist, and home health aides.	

2005 CMS PROPOSED COPS ***Subpart C***	***REQUEST FOR COMMENTS***
(c) *Personnel qualifications when no State licensing, certification or registration requirements exist.*	
(d) *Standard: Criminal background checks.*	
§ 418.116 Condition of participation: Compliance with Federal, State, and local laws and regulations related to health and safety of patients.	
(a) *Standard: Licensure of staff.*	
(b) *Standard: Multiple locations*	
(c) *Standard: Laboratory services.*	
§ 418.200 [Amended]	
§ 418.202 [Amended]	

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

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

CMS-3844-P-80

Submitter : **Marianne Missfeldt** **Date: 07/25/2005**

Organization : **State of Wisconsin Dept. of Health & Family Servic**

Category : **State Government**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-3844-P-80-Attach-1.TXT

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : **Mr. JOHN MCCAUGHN**

Date: 07/25/2005

Organization : **DR. KATE HOSPICE--MINISTRY HOME CARE**

Category : **Hospice**

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENTS

CORE SERVICES (PROPOSTE 418.64 PGS 39850-51)
IF CHAPLAINS ARE ALLOWED TO DO THEIR WORK AND NOT HAVE OTHER GOV. AGENCIES OR PROFESSIONALS, WHO DO NOT KNOW, CARE OR UNDERSTAND THE DIFFERENCE BETWEEN A CHAPLAIN, NURSE, DR. OR SOCIAL WORKER THERE IS NO QUESTION MORE PEOPLE WILL BE SEEN AND CARED FOR. TO ANY CHAPLAIN THE STAT THAT THE NUMBERS OF PEOPLE TO BE FOLLOWED WENT FROM 35 TO 90 PERCENT IS NOT NEW. WHAT TOOK YOU SO LONG TO FIGURE THIS OUT.

#2 CORE SERVICES (PGS 30844-51) YOUR ASKING FOR AN ASSESSMENT TO BE DONE IN FOUR WORKING DAYS. AS A CHAPLAIN IN HOSPICE WORKING 32 HOURS A WEEK AND CARING FOR 45 TO 55 PATIENTS PER WEEK THERE IS NO WAY THIS CAN BE DONE. TRY IT YOURSELF BEFORE YOU ASK OTHERS TO DO THIS. FOLLOW ME FOR A MONTH....THE 14 DAYS IS JUST ABOUT RIGHT.

#3 PERSONAL QUALIFICATIONS FOR LICENSED PROFESSIONALS (418.114 PG 30859) ANY PERSON WHO IS A HOSPICE CHAPLAIN.. THE QUALIFICATIONS SHOULD BE AT LEAST 40 YEARS OLD, SEVERAL YEARS EXPERIENCE IN THE MEDICAL FIELD, I.E. EMT., PARAMEDIC, NURSING ASS'T., RN AND CERTIFIED BY THE NACC OR SOME NATIONALLY KNOWN, RECOGNIZED ORGANIZATION. WHAT'S SO HARD?? YOU WOULD NOT LET A DR. PRACTICE WITH A LICENCE SO WHY A CHAPLAIN?? THINK ABOUT IT>>>>>>

Submitter : **Mrs. September Stone** **Date: 07/25/2005**

Organization : **Nebraska Health Care Association**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

To whom it may concern;

The following are four comments that our office has regarding the proposed hospice COP. Nebraska Health Care Association has a strong interest in the hospice regulations and believes that quality care at any point of life including the end of life is important to the long term care community.

1. Prior to the Hospice utilizing the services of Home Health Aides, the Home Health Aide must be trained and qualified pursuant to the requirements outlined in 418.76. The training requirements are the same as the requirements for a nurse aide as set forth in the requirements for states and for nursing homes at Title 42 section 483, Part D. The nursing facility regulations contain an outline and process for course approval, a process for competency testing, and a process for placement and removal from a registry. Since the hospice regulations appear to be raising the level of home health aide, it would simplify matters if Home Health Aide in the hospice regulations was defined to mean the same as a nurse aide in Title 42, section 483. There is then a registry available for use along with training material. If the educational requirements would change for one group, regulators would not be required to remember to change the other regulation.

2. Section 418.144(d) provides for criminal background checks on each hospice employee and contracted employee. However, this section is within the section on "personnel qualifications for licensed professionals." An argument could be made that if someone is not a licensed professional, the requirement does not apply. This section should be clarified to match the intent in the preamble on pages 30860, 30871 and 30877 which indicate checks for all employees. Also, home health aides would not be licensed professionals in most states and may fall out of this section.

3. 415.54 Assessment of the Patient ? The narrative on page 30845, second column says a review of the patient?s drugs would be included in the initial assessment and in the development of the plan of care. This review could occur at any time, but specifically when a patient is prescribed or begins to take any new drug and/or when use of a drug is discontinued. The underlined directive is not included in the regulation itself. Furthermore, if this is to be performed, no time frame was included of when to complete this review.

4. 418.76 ? Home Health Aide services: reg on page 30886 says a HHA provides services that are ?(iv) Assistance in administering medications that are ordinarily self-administered.? 1): I think this is very vague; and 2) the HHA training failed to include anything related to medications.

CMS-3844-P-83

Submitter : **Mr. Bruce Pritschet** **Date: 07/25/2005**

Organization : **ND Department of Health -Div of Health Facilities**

Category : **State Government**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-3844-P-83-Attach-1.DOC

Attachment #83

Social Work

The preamble to the proposed rules discusses issues that may have a negative impact on our state. Consider limiting any change in the social work qualification requirement.

North Dakota is one of the most frontier (beyond rural) states in the nation. It continues to be difficult if not impossible to contract Masters prepared social workers in the rural parts of our frontier state. In addition, requiring a full time Masters prepared social worker negatively impacts the small hospice providers with low patient counts that are unable to provide enough hours to keep a social worker on at full time.

If CMS were to require a Master's of Social Work, I know our rural hospices would not be able to meet this personnel qualification, and even if CMS required the supervision of an MSW it will be difficult for the hospice to meet the requirement, in the end I fear the MSW would function in a name only position if the requirements were changed.

CMS-3844-P-84

Submitter : **Mr. Douglas Miller**
Organization : **Dynamic Homecare Inc.**
Category : **Hospice**

Date: 07/25/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachement

CMS-3844-P-84-Attach-1.DOC

Attachment #84

To: Centers for Medicare and Medicaid Services (CMS) & the National Association of Home Care and Hospice (NAHC)

From: Dynamic Homecare Inc. Medicare Hospice Benefit Conditions of Participation Advisory Committee

Date: 7/22/05

RE: 2005 Proposed Medicare Hospice Benefit Conditions of Participation

The following recommendations have been prepared by the Dynamic Homecare Inc. Medicare Hospice Benefit Conditions of Participation Advisory Committee. We would like to collectively thank the National Association for Homecare and Hospice for providing the teleconference detailing the potential changes to the Hospice CoPs as well as the Centers for Medicare and Medicaid Services for requesting input from hospice providers.

Below you will find a listing of the specific conditions and applicable standards that we as an agency felt were critical to address. Statements of agreement, disagreement, and points of clarification have been addressed. If there is a need for clarification regarding these points of interest please use the contact information found immediately below:

Douglas S. Miller
Quality Improvement Coordinator/Manager
Dynamic Homecare Inc.
546 W. Lincoln Ave.
Charleston Ill 61920
217-345-4614

418.52 Condition-Patient's Rights

Standard (a) (1) Notice of rights....in regards to providing patients rights in the language of the patient we suggest, as does NAHC, that it be permissible to ensure the patient understands via an interpreter (such as a family member or other)

Standard (a) (3) Regarding providing patients with information pertaining to drug policies.....we are in agreement with NAHQ and CMS that this information could be included in the admission packet, reviewed and left or patients and families to review.

Standard (b)-Exercise of rights and respect for the property and person.....language was omitted pertaining to the patient's rights to refuse treatment. We suggest with NAHQ that this language be included to allow the right for patients to refuse medical treatment.

Standard (c) Regarding the proposed requirement to inform the patient both verbally and in writing in a language that they can understand the extent to with payment may be expected from the patient or other payer sources....we ask that this language be removed....it is felt that there are numerous billing options from facility to facility. This complexity ultimately does not effect patient care and does not need to be detailed.

418.54 Condition- Initial Assessment

Standard (a). We feel that the wording to this standard should be changed to the following italicized language: "*The hospice representative must make and initial contact* *within 24 hours after the hospice receives a referral for services or by patient request".* We feel that the word "initial assessment, should be changed to "initial contact" to provide for more flexibility utilizing other members of the hospice team for initial contact. "We do not agree with NAHC's recommendation that the word "order" be changed to "certification". We feel that this time frame will not be difficult for hospices to meet. We also feel that other disciplines should be allowed to do the initial contact depending upon the patient's needs (this would act as an educational visit to identify hospice appropriateness as well as an opportunity to have the patient sign the hospice benefit if they so desire. This would allow flexibility with the utilization of team members. A hospice nurse will then provide the comprehensive physical assessment. Patient and family members request for a specific date of admission can be accommodated by contact w/in 24 hours to make arrangement for the specific admission date.

Standard (b) Time frame for completion of the comprehensive assessment. We feel that a more realistic timeframe for the initial assessment be changed to 7 calendar days. Language should be included regarding the inclusion of the attending physician pertaining to consultation with the IDG Team *"if he or she desires"*. This language provides the IDG team flexibility in regards to the level of inclusion that the attending physician desires with the IDG. In regards to the elimination that at least two members of the IDG team establish the Plan of care prior to the beginning of care, we agree with this elimination and feel that this will provide more flexibility with developing the plan of care regarding staffing flexibility as well as time constraints.

Standard (c) Content of the comprehensive assessment. We are pleased that CMS does not require a standardized form allowing for flexibility pertaining to agency needs regarding documentation.

Standard (d) Update of the comprehensive assessment. We feel that the time frame of 14 days needs to be changed to the date range of 14-16 days. This rage will provide flexibility pertaining to holidays and long months (more than 28 days).

Standard (e) Patient outcome measures. NOTE: *See references pertaining to Condition 418.58, regarding Quality assessment and performance improvement.*

418.56 Condition-Interdisciplinary group care planning and coordination of services

Standard (a) Approach to service delivery. We agree with the new flexibility that designating a "qualified health care professional" to coordinated care would add instead of limiting this role to that of a RN. This previous requirement had a times placed a burden on hospices regarding staffing needs and work loads for RNs.

Standard (b) Plan of Care. We feel that this standard should be reworded to read as follows. The words/phrases that have been changed are italicized with the previous word in parenthesis. Standard (b). Plan of Care- Hospices must *attempt to(this phrase was added*) include the patient and *primary caregiver* (the word family was changed to primary caregiver) when establishing the plan of care established by the IDG (the phrase in collaboration with the attending physician was omitted).

Standard (c) Content of the plan of care. The following is a copy of the last sentence of this standard. Following is a clarification of changes that we suggest. ".....The hospice IDG must document patient and family understanding, involvement and agreement with the plan of care." We feel that the word family should be changed to

Primary Caregiver and that the phrase involvement and agreement should be omitted. The acknowledgement of primary caregiver provides greater flexibility with caregiving arrangements that fall outside of the traditional "family caregiving framework" It is also felt that the words involvement and agreement could be problematical. Involvement can be seen within normal documentation but forced involvement and agreement could prove to be difficult to obtain in situations where there is little involvement by the family or the designated primary caregiver.

Standard (d) Review of the plan of care. We feel that the time frame of 14 calendar days should be changed to a 14-16 calendar day range that would allow for flexibility pertaining to holidays and months having greater than 28 days.

Standard (e) Coordination of services. We agree with the wording and content found in the new coordination of care standard. This activity is something that we as an agency currently do. We feel that many agencies are in compliance with this and this new standard would not provide a burden but instead codify what activities are currently in place.

418.58 Condition-Quality Assessment and Performance Improvement

While our agency understands the importance of quality improvement work and data analysis, there is some concern regarding the potential foreseeable requirements pertaining to outcome measures collection and reporting. Many of the requirements found in Standards (a-e) are in some manner or another being conducted within hospices already. Formalizing this process has both its positive and negative aspects. There was considerable debate within our agency pertaining to what measures could accurately be used as representative outcome measures. It was noted in standard (b) that the "focus of the data would be individualized to the hospice. Frequency and detail of data collection must be specified by the governing body". This flexibility would be beneficial to agencies. Formalization of these processes and specific data, and data collection tools could cause a significant burden upon hospices. Again it is understood that quality improvement activities are both beneficial to patients and agencies as a whole. We would stress the importance in providing great flexibility within the organization and areas of focus that an agencies QI program possesses. Agencies should be allowed to use agency specific data pertaining to patient data, high risk, high volume, problem prone activities, and adverse events. General data pertaining to symptom control (ie. pain management, quality of life, etc.) could be integrated with ease through the use of the comprehensive assessments and daily nursing notes. This flexibility would allow agencies to develop and design a QI program that provides proactive attention to agency and patient specific needs and concerns. Primary focus should be on outcomes that center on symptom management and control, quality of life indicators, level of coping, and spiritual assessments.

Standard (e)-Executive responsibilities

We feel that the Professional Advisory Committee should be directly responsible for the hospice's QAPI program, rather than the governing body. The governing body has ultimate oversight, but PAC has the ability to use the skills and expertise of its members to identify areas of concern and develop clinically sound, quality focused plans of action anchored in best practices and current literature.

418.64 Condition-Core services

Standard (d) (1) Counseling Services-We **disagree** that bereavement counseling should be extended to residents and employees of a SNF/NF, ICF/MR or other appropriate facility. Current arrangements between hospices and care facilities state specific and well defined roles for each participant in the contract for services. Many of these facilities have social service staff that are capable to provide bereavement services. These social service staff members work on a daily bases with residents and are in a position to understand the relationships between residents and hospice patients (within the facility) and the specific needs of these individuals. Hospice bereavement services could be utilized as supplemental services when needed. Mandating hospice bereavement services to be extended to facilities would produce a tremendous hardship pertaining to staffing needs and financial hardship. Current bereavement caseloads are difficult enough to finance given the lack of governmental funding. Further additions to this service would make it impossible to maintain a financially viable program ultimately being a determinate to the care that is provided to patients and their families.

Standard (d) (2)- We agree with the flexibility that is provided by extending nutritional counseling services to oversight by nurses and other individuals able to address the dietary needs of patients. This change is welcome flexibility.

418.72 Condition PT, OT and speech-language pathology- we agree that dietitians should be added to this section as a non-core service.

418.76 Condition-Home health aide and homemaker services.

Standard (g) (2) (i)-Home health aid assignments and duties. We are in agreement with the NAHC recommendation acknowledging that there is no need for a separate physician order for home health aide services because these services are a part of the IDG plan of care.

Standard (h) Supervision of home health aides. We **disagree** with the requirement to directly supervise the home health aide at least every 28days. Annual competency testing and monthly education should suffice to maintain skill and knowledge base. Normal supervisory visits would provide input directly from patients and families (many of these are direct supervision of the aide, but placing a strict requirement on direct supervision at least every 28 days could provide staffing problems with scheduling difficulties.

Standard (j) Homemaker qualifications. We agree with NAHC's recommendation to allow qualification to be based on CNA certification or successful completion of a hospice orientation addressing the specific needs of patients and families coping with terminal illness.

418.100 Condition-Organization and administration of services.

Standard (a) Serving the hospice patient and family. Using the term "desires" in the language provides for interpretive difficulty. This term needs specific clarification. It might be best to omit this word completely or substitute with a less subjective word. The use of the word expectations might add some clarity.

Standard (e) Professional management responsibility. We agree with NAHC recommendations to replace the word "supervision" with the word "oversight". The language "at least the same qualifications as hospice employees" should be replaced with the phrase "qualified personnel" Employees of arranged services need not have the same qualifications as direct hospice staff, but should have appropriate qualifications for their specific job duty.

418.102 Condition-Medical Director. We disagree for the need of the medical director to designate an alternate medical director. At times of the medical directors absence it is sufficient for the medical director to designate a physician for assistance or questions. For small agencies and/or rural agencies the requirement for a second medical director designee is unrealistic and could pose a burden upon the hospice.

Standard (b) Recertification. This standard should read as follows: "Clinical information and **patient/primary caregiver understanding** of hospice care must be reviewed". The phrase "patient/family expectations…." is unclear. The changed language would provide clarity.

Standard (c) Coordination of medical care-We feel that the Professional Advisory Committee should be responsible for directing the hospice's QAPI program. This advisory group would provide expertise in multiple disciplines as well as include the medical director.

418.104 Condition-Clinical Records

Standard (d) Retention of records. We agree that the time frame for retaining records should be extended to 6 years to mirror HIPAA.

Standard (e) Discharge or transfer of care. We agree that providers will not want a complete medical record as standard protocol. We agree with NAHC that a copy of the discharge summary would suffice with the ability to request further records as needed.

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

Standard (b) Controlled drugs in the patient's home. We feel that the word "collecting" should be removed and substituted with the word "education". Hospices do not regularly collect drugs from the patients home, but it is our responsibility to educate the family/primary caregiver to properly dispose of controlled drugs. It is also felt that the phrase "potential dangers" of controlled substances should be changed to "side effects". In general there are a lot of misconceptions and lack of understanding pertaining to the use and effectiveness of many of the controlled substances used in hospice care. We feel that this language would perpetuate unrealistic concerns regarding these medications, potentially providing areas of resistance to needed symptom control measures.

Standard (c) Use and maintenance of equipment and supplies. We agree with the recommendation from NAHC that this standard be rewritten to state that it is the DME's responsibility to write its own repair and routine maintenance policies when under contract with the hospice. DME companies have in place policies such as these, so the burden would not be great for contacted DME providers.

418.108 Condition-Short term inpatient care. We agree that short term respite care should also include availability for psychosocial/family crises.

Standard (a) Inpatient care for symptom management and pain control. We feel that the following language should be changed in this standard. The phrase in the opening statement of he standard should read "Medicare **certified** hospice that meets the CoP for providing……." The word "certified" should be substituted for "approved". The reference to "……24 hour nursing services and patient areas" at the end of the standard should be clarified by inserting the phrase "….provided by a LPN or RN…..". The language will read as follows: "….regarding 24-hour nursing services **provided by a LPN or RN** and patient areas."

418.110 Condition-Hospices that provide inpatient care directly.

Standard (o)-Seclusion and restraint. NAHC had acknowledged concern regarding the use of medications that are seen as restraints in other healthcare arenas, but are commonly used for pain control/symptom management within normal hospice protocol. To be able to come to an understanding regarding this concern, we feel it important that CMS is careful to look at the context as well as the purpose of the use of these medications within hospice care. It is very important to note that these medications are not typically used for restraint, but instead intended to provided much needed symptom management and control of pain. It has been well documented in hospice literature that patients experiencing high levels of pain tolerate doses of pain medications that in normal patients experiencing lesser symptomology would be unable to tolerate. The use of such meds should be seen through the lens of palliative care. Their propose is to provide quality of life and control of pain and related symptoms. The palliative care/hospice paradigm must be viewed within its own light, given its different context, purpose, and desired outcomes.

Standard (d) Medical Director. We agree with recommendations from NAHC that the IDT team should continue coordination of care with the medical director, attending physician, and the medical director of the facility. Current practice has assigned a RN to be involved in that process….we suggest that this be broadened to include a "hospice designee" which could include a member of the IDG. This would provide needed flexibility in coordination of care. It is not standard practice in our region to have the facility medical director providing care to the hospice patient. Direct hospice care is often through a physician of choice other than the facility medical director.

418.114 Condition-Personal Qualifications for licensed professionals.

Standard (c) (7) Social Worker-We feel that it is necessary for a social worker to have either a MSW or a baccalaureate degree from an accredited school of social work. The social work focused curriculum is a necessity for providing effective assistance and support to hospice patients and families.

Standard (d). Criminal background checks. Though we acknowledge the importance of criminal background checks for the safety of our patients and families, the timeframe for completion of background checks before hire can be problematic and difficult to manage. This does provide a burden on administrators attempting to fill vacant positions. Placing a window of completion of background checks around the time of hire extending to one month after start date would provide flexibility for staffing and fall within standard practices of probation periods for continuation of employment.

CMS-3844-P-85

Submitter : **Vicki Hoak**

Date: 07/25/2005

Organization : **Pennsylvania Homecare Association**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-3844-P-85-Attach-1.PDF

Attachment# 85

PHA
Pennsylvania Homecare Association

July 25, 2005

Via email

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

Dear Sir/Madame:

Thank you for the opportunity to offer comments on the 2005 Proposed Medicare Hospice Benefit Conditions of Participation published in the May 27, 2005, *Federal Register.*

The Pennsylvania Homecare Association (PHA) is a state trade association representing the interests of home health agencies, hospices and the patients they serve across the Commonwealth. The members of our association will be directly affected by this final rule.

Of particular concern for our membership is the language around drug restraints. Sine hospice programs commonly use drugs for terminal illnesses, many of the drugs used for treatment are viewed as chemical restraints in other health care settings. The language around chemical restraints should be modified to allow for continued treatment of patients receiving hospice care. This modification serves in the best interest of the patients needing such treatment.

Of additional concern are some of the proposed timeframes such as the need for an initial assessment by a registered nurse within 24 hours after a hospice receives a physician's admission order for care as well as an in person assessment by the nurse or social worker within the first 4 days of care. While providing timely, quality care to their patients, hospices are not immune to the nationwide workforce shortage. We ask that CMS carefully review these timeframes so they offer hospices the flexibility to meet the needs of their patients.

PHA appreciates CMS' interest in providing continued high quality hospice care while incorporating outcome-oriented quality assessment and patient improvement programs. We support the additional language calling for an integrated health care process involving the patient and family, including the new patient's rights condition, yet we implore CMS to ensure that conditions are not added at the cost of additional administrative burden.

Thank you for your consideration.

Sincerely,

Vicki Hoak
Executive Director

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