RAMONA VNA AND HOSPICE

"Keeping the Heart in Hospice"

July 11, 2005

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

Re: File Code CMS-3844-P

Dear Sir or Madam:

Enclosed herewith, please find our comments for submission and consideration relative to the proposed rule changes to 42 CFR Part 418, Medicare and Medicaid Programs, Hospice Conditions of Participation; Proposed Rule.

Respectfully Submitted,

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2005 Proposed Medicare Conditions of Participation
for Hospice Programs Request for Comments
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2005 CMS Proposed CoP's	Request for Comments
418.3 Definitions Drug Restraint (*pg 3*)	This definition is inappropriate for hospice care, as many drugs that would fit this definition are widely used and considered the industry standard in treating restlessness, terminal restlessness, anxiety, etc. Often medications fitting this definition are in fact used to decrease suffering for the patient, up to and including providing terminal sedation if all other measures have failed to relieve suffering. Effective treatment of terminal agitation and poorly controlled pain requires medications at doses currently considered to be "drug restraints" by various regulatory bodies. For example, skilled nursing facilities prohibit or strongly discourage using Ativan (lorazepam), at doses greater than **2 mg per day**, regardless of the clinical situation. The American Academy of Hospice and Palliative Medicine (AAHPM) recommends using Ativan (lorazepam) at doses of **1-2 mg per hour** in the treatment of moderate to severe agitated delirium.[1] The terminology "standard treatment" is particularly problematic. Standards created by state regulatory agencies pertaining to nursing home and skilled facility residents in California currently make no exception for patients under hospice care. Because of this, many patients are currently being denied access to medications that would be considered "standard treatment" by the AAHPM. It is often necessary to use narcotics and psychotropic medications in hospice patients at doses which are likely to "control behavior… (and)...restrict the patient's freedom of movement". These outcomes are unintended consequences of using the necessary agents to relive pain and manage terminal agitation. [1] Pocket Guide to Hospice/Palliative Medicine, Table 57, page 106, ISBN1-889296-35-X
418.3 Definitions Licensed professional (*pg 4*)	In some states, Social Workers are not licensed, but they are included in this definition. Social Worker should be defined by itself.
418.3 Definitions Physical Restraint (*pg 5*)	This definition is inappropriate for hospice care, as many DME pieces that are commonly used to assist the patient would be inappropriate under this definition. It is common practice to use bedrails (full and half), over bed tables (which must be placed over or next to the patient for access), Geri-Chair's, Merry Walker's, w/c lap belts, Lap Buddy's to assist patients in being safe, and mobile as long as possible. Sometimes families request Posey vests to prevent the patient (who is confused, weak, and/or unrealistic about their ability to ambulate) from harming themselves.
418.3 Definitions Terminally Ill (*pg 6*)	Many patients reject hospice care because of the short prognosis language and what that represents to them. Many physicians hesitate to refer to hospice thinking they will suffer consequences if the patient does not die in the 6 months. Consider the following:

	✓ Prognostic error is widespread ✓ Only around 20% of estimates are accurate[2,3] ✓ Physicians are much more likely to overestimate than underestimate life expectancy[4] Irene J Higginson and Massimo Costantini[5] conducted a prospective cohort study regarding the accuracy of prognosis by skilled palliative care teams in terminally ill patients. One would expect that teams specializing in palliative care would be more likely to provide an accurate prognosis than physicians at large. One finding of the study was that offering a prognosis range (i.e. 6 to 12 months) was much more accurate than a specific prognosis. The study concluded that: ***"Offering a prognosis range has higher levels of accuracy (about double) than traditional estimates, but is still very often inaccurate, except very close to death. Where possible clinicians should discuss scenarios with patients, rather than giving a prognosis range."*** Because the Medicare Hospice benefit requires a patient be "terminally ill" to qualify, it seems imperative that a more accurate definition than that proposed be used. Both of these things combine to result in patients accepting and entering into hospice care much too late to truly receive the benefits of hospice in its finest form. Removing language that causes the most concern to patients, families and physicians would improve access to this entitled benefit. Given the above evidence based findings regarding prognosis, and the tendency of physicians to overestimate life expectancy, a more suitable definition of "*Terminally Ill*" is suggested below: ***Terminally Ill*** **means that a patient has a medical prognosis such that it is more likely than not that the patients life expectancy is 6 to 12 months (or less) if the illness runs its normal course.** [2] Mackillop WJ, Quirt CF: **Measuring the accuracy of prognostic judgments in Oncology.** *J Pain Symptom Manage* 1997, **50:**21-9. [1]3Christakis NA, Lamont EB: **Extent and determinants of error in doctors' prognoses in terminally ill patients: prospective cohort study.** *BMJ* 2000, **320:**469-73. [4] Lamont EB, Christakis NA: **Some elements of prognosis in terminal cancer.** *Oncology (Huntingt)* 1999, **13:**1165-70. [5] Higginson, Irene J and Costantini, Massimo: **Accuracy of prognosis estimates by four palliative care teams: a prospective cohort study.** *BMC Palliative Care* 2002, 1:1.
418.52 Condition of Participation: Patient's Rights Standard: Notice of Rights (*pg 6*) (a) (1)	This standard as written would be nearly impossible for agency's to comply (both verbal and written). In addition to the difficulty in finding an Interpreter for more obscure languages, most languages have words that mean many different things, and there are regional differences (dialects) that would not translate accurately, or appropriately. Even

	hospitals are not held to this standard of providing this information both verbally and written. Family members should also qualify as interpreters in addition to others providing interpretation.
418.52 Condition of Participation: Patient's Rights Standard: Notice of Rights (*pg 6*) (a) (3)	Patients and families are overwhelmed enough trying to comprehend the information related to philosophy of care, scope and frequency of services, 24 hour availability, levels of care, certification, etc. Many times hospice providers receive calls resulting from confusion in understanding information only moments after staff leaves the home. While very important, trying to clarify drug policies, procedures, tracking, etc. at this time would be ineffective at best. If in fact, providing the information in writing and leaving it with the patient/family would be deemed sufficient by surveyors, this would seem to be the most appropriate way of dispensing this information. Also, there should be some grace period in providing this information, and agree with the suggestion that this correspond to the time frame for the comprehensive assessment.
418.52 Condition of Participation: Patient's Rights Standard: Exercise of rights and respect for property and person (*pg 7*) (b) (iv)	Suggest the addition of "...including the right to refuse treatment." at the end of the sentence.
418.52 Condition of Participation: Patient's Rights Standard: Exercise of rights and respect for property and person (*pg 7*) (b) (4) (i) (ii) (iii) and (iv)	Concur with the proposed language from HHA CoP Requirement 484.10 and the deletion of the language under (4) (i), (ii), (iii), and (iv). Our current practice in this area includes providing the patient/family information on admission regarding contacting the Agency with any concerns about their care or our staff providing care. The patient/family is encouraged to call the Team Manager or the Director. The Medicare and State Hotline numbers are provided upon admission, and if there is not satisfactory resolution after discussion the situation with a manager/director, then the patient and family are reminded of their right to call one or both Hotlines. All complaints are investigated fully, documented and resolved, if possible, in a timely manner. If employee counseling is required it is accomplished in a timely manner. Follow up is accomplished in meetings, through plans of correction, and, if necessary, changes in Policy and Procedure.
418.52 Condition of Participation: Patient's Rights Standard: Patient liability (*pg 8*) (e)	Again, the requirement for verbal and written translation is overly burdensome and would be very difficult for hospice to operationalize this standard. Suggestion that this information is provided in writing, *or* verbally, and that a copy of the information is left with the patient/family for reference, if the translation is available in writing. It is impossible to accurately determine the patient's liability with respect to Room and Board under Medicaid (State) programs at the time of admission. Because State's have many different ways of operationalizing their programs, it requires time to get consent for services, and then investigate coverage and liability. We believe this language is too restrictive and would cause hospices to be out of compliance with this standard through circumstances beyond their control.
418.54 Condition of Participation: Comprehensive Assessment of the Patient. *(pg 9)*	The statement regarding the hospice's responsibility to perform a comprehensive assessment (later referred to as and "initial" assessment, does not indicate whether this is an "evaluation visit", or the "admission visit". Many

	hospices utilize Social Workers, LVN/LPN's, business development, and volunteers to perform these evaluation visits. If that is what this is referring to, it would place an undue burden on hospice providers, especially in light of the nursing shortage and the recommendation for setting time parameters. Hospices can respond much more timely and efficiently if allowed to use other than RN's for these visits. A recommendation was discussed to change "care" to "assessment" in the last sentence. Our disagreement is based upon the fact that a LVN cannot "assess." If in fact this is referring to an admission visit then our position is as follows. The requirement that the initial visit occur within 24 hours of the physician order seems to overlook the common issue of family preference and availability. Admission to the hospice program requires both a physician certification as well as a patient's consent. Perhaps the language should indicate that the initial assessment requires a physician's certification of eligibility and must be completed within 24 hours of the patient's consent to begin hospice services. The regulation should not impose a time restraint based on the physician's certification that does not allow for the family to elect when to begin their hospice benefit. The proposed language seems to suggest that the physician, not the patient controls the election of hospice services. What if the physician gives the certification while the patient is in a SNF for treatments covered under Medicare and the patient elects to utilize their skilled care days before initiating hospice? The proposed language seems to mandate the timing of the assessment based on the physician certification as opposed to the patient's election of hospice. Changes in the language are suggested below: ***"The hospice registered nurse must complete an initial assessment visit within 24 hours of admission to hospice, after the hospice receives both the physician's certification for hospice care and the election of hospice consent forms completed by the patient or his/her designee. The purpose of the initial assessment is to determine the patient's immediate care and support needs. The patient reserves the right to determine when to initiate hospice services. "***
418.54 Condition of Participation: Comprehensive Assessment of the Patient. (a) Standard: Initial Assessment *(pg 9)*	Again, the confusion related to the definition of "initial assessment" is very problematic here. Also, Home Health is allowed 48 hours in this area, and hospice should be afforded at least the same. Operationalizing this standard would prove very difficult, even impossible, for some providers. As to the physician's order, depending on the definition, this could be an order for a pre-admit visit/explanation or an order for admission to hospice. This needs to be clarified. We concur with the suggestion to add language which allows for the patient/family to impact the timeframe of the admission. This should not be in the control of the physician. Again, depending on the definition of initial assessment, this standard should not restrict the provision of a pre-admit visit to being performed by the RN. It is impractical. If in fact this standard is not referring to a pre-admit visit, but truly the intake assessment, then the RN is the appropriate person.

	Suggested changes: (i) A doctor of medicine or osteopathy ~~(who is not the patient's attending physician).~~ Patients may select the Hospice Medical Director as their "attending physician" for a number of reasons: ✓ The patient has relocated from out of state and has no attending physician. ✓ The patient's attending can not provide house calls, which may be required ✓ The patient's attending elects not to follow patient's receiving hospice care The hospice regulations require the hospice to provide a physician to be available to patients in the event that they do not have an attending physician available. The regulations also support the patient's right to select the hospice physician as their attending physician.
418.54 Condition of Participation: Comprehensive Assessment of the Patient. (b) Standard: Time frame for completion of the comprehensive assessment. *(pg 10)*	We strongly support NHPCO's recommendation of 7-calendar days for completion. Also, we would not mind to see the imposition of time frames for Social Services and Chaplaincy, as long as the language allows for patient/family preference to supersede the regulatory time frame. As to the involvement of the attending physician, this language is too restrictive. Most Attendings do not desire this much input, but rather rely on the hospice to manage the plan of care with only minimal input from them. This should be 7 days due to logistics of convening an IDT outside of the normal schedule. A time frame of 4 days would not allow adequate time for the social worker and /or chaplain to accomplish an initial assessment. The language that specifically identifies the attending physician seems redundant as the attending physician is already considered a member of the patient's interdisciplinary team. The proposed language should be changed as the requirement to "consult" with the attending is onerous. In many instances, attending physicians refer their patients to hospice to obtain expertise in palliative pain and symptom control (i.e. the Hospice Medical Director is serving as the "Consultant" to the attending physician). In our experience, the attending physician does not want to be "consulted" regarding palliative care, and requests that the palliative interventions be managed by the Hospice Medical Director. The proposed wording is also problematic in that the Hospice has no control over the availability of the attending physician. In many instances the attending physician is simply not available for "consultation". ***"The hospice interdisciplinary group must complete the comprehensive assessment no later than 7 days after the patient elects to begin the hospice benefit. This assessment should be coordinated with the attending physician or his/her designee. "***
418.54 Condition of Participation: Comprehensive Assessment of the Patient. (c) Standard: Content of the comprehensive assessment. *(pg 11)*	We concur with the addition of language to indicate that this needs assessment is driven by the patient/family. Agree with the suggestion that the language limits coverage and hospice should be responsible for assessing comprehensively, but be charged ONLY with providing

	palliation and management of the terminal illness. Also, there should be clarification in the language about what is appropriate/not appropriate to cover. Many hospices have elected to cover ALL patient meds, related or not. We feel strongly that taking this approach drives patient choice and is in effect solicitation/enticement. Hospices need to be limited to the provision of medications/DME, etc. related solely to the terminal diagnosis and the symptoms related to by the terminal diagnosis. There is also the question of palliative driven medications, versus disease driven medications. The regulation would lead you to the disease driven approach which would eliminate hospices paying for patient's pre-existing pain or other medications.
418.54 Condition of Participation: Comprehensive Assessment of the Patient. (d) Standard: Update of the comprehensive assessment. *(pg 11-12)*	We strongly agree with recommendation for *updating every 2 calendar weeks rather than every 14 days*. The 14 days causes many operational issues, especially around weeks with holidays. It would be difficult to argue that a review which took place on day 15 would be any less effective or appropriate than a review on day 14. We would suggest that the reassessment prior to recertification would occur within the two calendar weeks prior to the end of the current certification period.
418.56 Condition of Participation: Interdisciplinary group care planning and coordination of services. (a) Standard: Approach to service delivery *(pg 13)*	We would be in agreement with leadership of the IDT/care plan being unrestricted to qualified health care professionals. Nursing dominance of the plan of care has long been an issue. As we are regulated to be interdisciplinary, it would seem to be appropriate for oversight to not be restricted.
418.56 Condition of Participation: Interdisciplinary group care planning and coordination of services. (a) (1) (i) Standard: Approach to service delivery *(pg 13)*	We would agree with removing the language in parenthesis after (a) (1) (i) "(who is not the patient's attending physician)" – many hospices contract with physicians and often they may in fact be the attending physician and hospice medical director.
418.56 Condition of Participation: Interdisciplinary group care planning and coordination of services. (a) (2) Standard: Approach to service delivery *(pg 13-14)*	It should NOT be the responsibility of the IDT to establish policies governing the day-to-day provision of hospice care and services. This responsibility belongs to the administrative team with oversight by the Board or other governing body.
418.56 Condition of Participation: Interdisciplinary group care planning and coordination of services. (c) Standard: Content of the plan of care. *(pg 14)*	Agree strongly with the insertion of the language "services for the palliation and/or management of the terminal condition including…" so that it is clear the hospice is not to treat all the patient's problems.
418.56 Condition of Participation: Interdisciplinary group care planning and coordination of services. (c) (2) *(pg 14)*	Would suggest that scope and frequency for patients in any setting are fluid and ever changing. It is possible to pick a starting point, based upon the patient/family/caregiver input and adjust appropriately as needs change.
418.56 Condition of Participation: Interdisciplinary group care planning and coordination of services. (c) (6) *(pg 15)*	Based upon the patient's right to self determination of their end of life care, many times there is NOT "agreement" between the parties with regard to the plan of care. We agree with removing the word agreement to allow for these instances.
418.56 Condition of Participation: Interdisciplinary group care planning and coordination of services. (d) Standard: Review of the plan of care *(pg 15)*	We find this language too restrictive in terms of the involvement of the attending physician. As stated earlier, most Attendings do not want to be involved in the care planning process, only to be kept updated as to what is occurring with the patient. We do have concerns that the

	Medical Director is being elevated above the IDT rather than a very integral part of the IDT. We would be supportive of the suggested re-write.
418.56 Condition of Participation: Interdisciplinary group care planning and coordination of services. (e) Standard: Coordination of services (4) *(pg 15)*	This sharing of information has proven very frustrating within providers interpretations of the HIPAA guidelines. Many times the patient is a shared patient, but providers interpret very differently what they may or may not share which makes coordination of services difficult at best. We would support the proposed additions.
418.58 Condition of Participation: Quality assessment and performance improvement. (a) (2) Standard: Program Scope. *(pg 16)*	Suggest consistency of verbiage related to QAPI throughout regulations.
418.58 Condition of Participation: Quality assessment and performance improvement. (b) Standard: Program Data. *(pg 16-17)*	We simply request that the data collected by reasonable to collect, relevant, and meaningful to hospice care. Many current data set models are irrelevant to hospice and it is a burden to collect meaningless information.
418.58 Condition of Participation: Quality assessment and performance improvement. (c) Standard: Program Activities *(pg 17)*	Need to define "adverse event" in a way appropriate to hospice care. We define "adverse event" as "An unplanned event which causes significant injury or hastens death as compared to the normal, expected progression of the terminal diagnosis." The definition in the CMS comment would mean that any death would be adverse.
418.58 Condition of Participation: Quality assessment and performance improvement. (e) Standard: Executive responsibilities. *(pg 17)*	We propose that the Governing Body maintains *oversight* of the QAPI program in order to identify trends in care and process improvement areas. This is typically accomplished through a QI Sub-committee which reports back to the full governing body. This would seem most appropriate.
418.62 Condition of Participation: Licensed professional services (b) *(pg 18)*	Agree with the addition of the word "hospice".
418.64 Condition of Participation: Core services *(pg 19)*	We support contracting services for Continuous Care in order to meet the needs and provide this level of care; however we do recognize that there could be issues of continuity and quality of care when using non-employee providers. It would be the responsibility of the hospice to ensure the continuity and quality and address issues related to this immediately. Our hospice RN's visit daily patients on Continuous Care, and provide oversight through this visit.
418.64 Condition of Participation: Core services (d) Standard counseling services *(pg 20)*	We, like many hospice providers, extend bereavement care to patients, families, and staff in the nursing home setting. Under this proposed regulation there are many definition areas of concern. (1) Burden of widely providing bereavement services to all caregivers. (2) HIPAA concerns related to extending bereavement to residents of a facility. (3) Need for a definition of "available", "counseling" and "identified" in the Bereavement plan of care. (4) Should there be a timeframe for developing the bereavement plan of care? (5) What does CMS propose as they look to improve bereavement services? (6)
418.76 Condition of Participation: Home health aide and homemaker services. (f) Standard: Eligible training organizations *(pg 27)*	We support the substitution language proposed.

418.76 Condition of Participation: Home health aide and homemaker services. (g) Standard: Home health aide assignments and duties. (1) *(pg 28)*	Would this definition allow for LVN/LPN's to make assignments for HHA's? We STRONGLY disagree with HHA's administering medication at any time.
418.76 Condition of Participation: Home health aide and homemaker services. (g) (2) (i) *(pg 28)*	We do not support needing a physician's order to adjust the HHA plan of care, scope or frequency of visits. The team (including the patient/family/caregiver) should be allowed total authority in adjusting the plan of care in order to meet the very fluctuating needs.
418.76 Condition of Participation: Home health aide and homemaker services. (g) (3) (iv) *(pg 28)*	We do not support HHA's administering medications at any time.
418.76 Condition of Participation: Home health aide and homemaker services. (h) Standard: Supervision of Home Health Aides *(pg 29)*	"Qualified therapist" needs to be defined. Why is an onsite visit required every 14 days? We believe that a phone assessment also provides the same information and is entirely appropriate. We again would support this being "every two calendar weeks" rather than every 14 days. The requirement for direct observation every 28 days is restrictive and does not relate to short length of stay. Direct supervision is not currently required. If it is to be required, then we would support the language "every month" so as not to be out of compliance if the visit is done on the 29th day. We support the issue of competency testing, which at our agency is done upon hire and then again annually or any time a need is identified and believe that this process eliminates the need for direct supervisory visits.
418.78 Condition of Participation: Volunteers (e) Standard: level of activity *(pg 30-31)*	Would appreciate guidance/recommendations for volunteer documentation issues. Also, for guidance as to what "counts" toward the 5%. If, for example, a group of volunteers gets together and makes quilts 4 times a year, which are then distributed to patients throughout the year, these hours should count as volunteer hours. The intent is that while the name of the individual(s) may not yet be known, the quilt is made for the express use of a patient/family and therefore all the time was specifically dedicated to patients. This area is very vague and not consistently calculated from hospice to hospice.
418.100 Condition of Participation: Organization and administration of services (e) Standard: Professional management. *(pg 32)*	We concur with the requirement about "supervision of staff" (as opposed to requiring supervision of services) as per the comments. We disagree STRONGLY with the language "Furnished in a safe and effective manner by personnel having at least the same qualifications as hospice employees…" This language would make contracting or arranging for service by anyone impossible. The people we contract with, nurses in the hospital or SNF are not trained in hospice care. We feel this language is too restrictive.
418.102 Condition of Participation: Medical Director *(pg 34)*	The COP's already state that the Hospice is responsible to coordinate and manage all aspects of professional care. To reiterate this requirement here is redundant and unnecessary. The proposed language is also problematic because it seems to exclude other members of the IDG from the communication/coordination process. Below are suggested revisions to the wording: *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*

	(or the hospice) *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.*~~ *(Or)* *The* ***(IDG, including 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.* With regard to the language concerning when the medical director is unavailable and choosing a physician designee, if that physician is not under contract with the hospice doesn't this present a HIPAA violation (neither an employee nor contract)?
418.102 Condition of Participation: Medical Director (c) Standard: Coordination of medical care. (*pg 35*)	We believe that it would be impossible for the majority of hospices to find contract medical directors who are willing or able to head the QAPI program. Further, this takes away from the patient care time the medical director has and removes him/her from patients that much farther. The Medical Director certainly should participate in the QAPI program, but need not be set aside as having this primary responsibility. If the duties can be assigned to another staff member, nearly 100% of hospices would choose to do this. We fully support the suggestion to expand this to "or other qualified professional" so that an employee could do this work and oversee the program.
418.104 Condition of Participation: Clinical Records (*pg 35-36*)	Agree with clarification requested as to "accurate" records.
418.104 Condition of Participation: Clinical Records (b) Standard: Authentication (*pg 37*)	We question what is required to authenticate the signatures? This standard is too broad and burdensome given the "mobile" nature of hospice work. Home Health Agencies and Nursing Facilities are not held to this standard. We strongly support removing this issue from the standard.
418.104 Condition of Participation: Clinical Records (e) Standard: Discharge or transfer of care (*pg 38*)	The burden placed by this standard far exceeds the attempt to require communication between providers. The need to copy the entire medical record and provide it to either another facility or primary physician is a waste of resources (staff and paper); impractical and the real question is "who will honestly read that chart?" No one. We strongly support using the discharge summary, whose content could be defined, and any other appropriate documentation needed.
418.106 Condition of Participation: Drugs, controlled drugs and biologicals, medical supplies, and DME. (b) Standard: Controlled drugs in the patient's home (*pg 39*)	Please see our earlier concern (418.52 (a) (3)) about this information being a required part of the initial assessment. We disagree with the use of the phrase "potential dangers of controlled substances." We would support language detailing side effects, benefits and risks of therapy, and safety issues related to use of controlled substances when place in the home environment.
418.104 Condition of Participation: Clinical Records (c) Standard: Use and maintenance of equipment and supplies. (*pg 39*)	We strongly support the recommendation regarding DME provider being responsible for information and training related to equipment placed in their home by hospice. Another suggestion would be reframing the information, i.e., "If a Hospice provides, cleans, and maintains its own

	equipment, the ..." (insert the rest of number (1)). If the Hospice contracts for DME and supplies, the vendor maintains this responsibility.
418.108 Condition of Participation: Short-term inpatient care (*pg 40*)	We strongly agree with the need to put psychosocial crisis back into this area. We are interdisciplinary because of the multifaceted issues of our care. If we value those things equally, then needing General Inpatient level of care related to a psychosocial, or psycho spiritual crisis would be appropriate. Caregiver breakdown is a huge issue and truly leaves a patient in crisis if the caregiver has been providing for their needs.
418.108 Condition of Participation: Short-term inpatient care (a) Standard: Inpatient care for symptom management and pain control. (*pg 40*)	Would broaden this description to include psychosocial/psycho spiritual issues as a reason for GIP. Strongly agree that the requirement for an RN to be present providing 24 hour nursing care be dropped. The expertise of the staff needed should be dependant on the needs of the patient. Our hospice visits all GIP's daily so the hospice RN could provide oversight without the facility having to have an RN on board. Further, facilities will misrepresent their actual staffing leading the hospice to be out of compliance, through no real fault of their own.
418.108 Condition of Participation: Short-term inpatient care (b) Standard: Inpatient care for respite purposes. (*pg 40*)	We strongly support removing the requirement for an RN around the clock for respite patients, as they are placed not for medical needs, but for caregiver relief. Would appreciate more specific guidance as to the frequency of respite per cert period.
418.108 Condition of Participation: Short-term inpatient care (c) Inpatient care provided under arrangements. (*pg 40*)	We strongly agree with the suggestion that the provider be the custodian of the record with access by hospice or surveyor. It is very difficult to get facilities to follow up post discharge with copies of the record to the hospice provider. It almost requires additional staffing just to monitor this area.
418.110 Condition of Participation: Hospices that provide inpatient care directly (b) Standard: 24 hour nursing services (*pg 42*)	Please see earlier support for removing this requirement (418.108 (a).
418.110 Condition of Participation: Hospices that provide inpatient care directly (f) Standard: Patient rooms (*pg 45*)	We are in agreement with the space requirements outlined to provide sufficient space to families who wish to stay with their loved ones.
418.110 Condition of Participation: Hospices that provide inpatient care directly (m) Standard: Pharmaceutical services. (*pg 47*)	We strongly agree with allowing pharmaceuticals to be brought from home as long as they are in their original package.
418.110 Condition of Participation: Hospices that provide inpatient care directly (o) Standard: Seclusion and restraint (*pg 48*)	Please see response for Definitions: Drug restraint at the beginning of this document. Many patients are admitted to GIP level of care related to terminal restlessness or anxiety. In order to keep the patient from harm, restraint may be necessary until the patient can be calmed and medications titrated to symptom management.
418.110 Condition of Participation: Hospices that provide inpatient care directly (o) (3) (ii) (d) (*pg 49*)	We endorse the suggested changes related to the timeframes when restraints are in use.
418.112 Condition of Participation: Hospices that provide hospice care to residents of a SNF/NF, ICF/MR, or other facilities. (b) Standard: Professional Management (*pg 51*)	This is a very conflicted area. It often seems that we are in "no win" conflicts with facilities. While hospice is regulated to retain professional management of the patient, facilities show a general lack of disregard for our regulatory requirements. We have the responsibility without the authority to enforce issues with facilities. Facilities are often argumentative when a hospice consult is written on a

	patient on Skilled A days (takes revenue from the facility pocket). The patient may desire hospice instead, and the facilities often REFUSE to allow the patient to elect. Additionally, the hospice and facility regs are often in direct opposition with one another, and facilities fear being cited related to decubitus ulcers, medications, restraints, and poor nutrition, even though hospice is involved. There is very poor interpretation of how the care plan is supposed to be integrated with facilities. Additionally, it is nearly impossible to use a facility, other than a hospital or free-standing inpatient unit, for patients who are confused or agitated and need general inpatient care to control symptoms. Our medication protocols for these symptoms out of control send facilities through the roof with worry and dread about a survey. We make attempt after attempt to be informed of care plan meetings so we can attend, and time after time we are not informed. We have tried calendars to track, but the facilities often change the meetings without notice.
418.112 Condition of Participation: Hospices that provide hospice care to residents of a SNF/NF, ICF/MR, or other facilities. (d) (*pg 53*)	Communication and coordination of care is already very difficult. This proposed regulation again leaves out the IDT and other facility staff who are more directly related to the care of the patient than the physicians specified. We strongly feel that the Medical Director is a valued member of the IDT, and should not be set apart from the team. We STRONGLY disagree with facility Medical Director(s) serving as the Hospice Medical Director. This opens up the potential for "double dipping" as the facility Medical Director is already being paid for seeing these patients, and then receiving additional reimbursement for hospice patients. Additionally, it sets up potential kickback issues related to referrals only coming to a hospice because the facility medical director is the hospice medical director. In our area, we have seen hospices intentionally hiring facility medical directors with an expected side effect of securing all their referrals. As we look to raise the bar in hospice care, this is one door that should be closed.
418.114 Condition of Participation: Personnel Qualifications for Licensed Professionals. (a) (*pg 56*)	We support following State guidelines in this area.
418.114 Condition of Participation: Personnel Qualifications for Licensed Professionals. (7) (*pg 60*)	We think that many small or rural hospices may have difficulty hiring at the MSW level. However, we support following State guidelines for Social Work practice.
418.114 Condition of Participation: Personnel Qualifications for Licensed Professionals. (d) Standard: Criminal Background Checks. (*pg 60*)	The language is too broad. Suggest adding "independent contractors", otherwise this would imply that anyone who works with Hospice through a contracted arrangement (DME, Pharmacy, etc) would require the hospice performing a background check. We would suggest limiting background checks to those with patient contact, which would include Volunteers (who should be treated as an employee). The time and cost burden of this proposed regulation, could prove very difficult to small or rural hospices.

One additional point of discussion focused around the "burden" these proposed regulations would cause to hospices. We would like for CMS to explain where they pulled the figures from because to our estimation they are not even close to our projected burden. Burden estimates should be derived from polling providers and guaging projections based on provider input.

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Julia M. Eckstein
Director

Matt Blunt
Governor

July 5, 2005

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

To Whom It May Concern:

The Missouri Department of Health and Senior Services, Unit of Home Care and Rehabilitative Standards, hospice survey staff, met several days to review and discuss the proposed rule for the hospice regulations. This group consisted of ten surveyors, six of who have been surveying hospices for eight plus years.

Enclosed you will find the compiled comments from the Unit of Home Care and Rehabilitative Standards.

If you should have any questions, I can be reached at 573-751-6336.

Thank you for your consideration of the enclosed comments.

Sincerely,

Lisa Coots

Lisa Coots, R.N., Administrator
Unit of Home Care and
Rehabilitative Standards

Enclosure

cc Maryalice Futrell, CMS, Kansas City Regional Office

www.dhss.mo.gov
The Missouri Department of Health and Senior Services protects and promotes quality of life and health for all Missourians by developing and implementing programs and systems that provide: information and education, effective regulation and oversight, quality services, and surveillance of diseases and conditions.

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER: Services provided on a nondiscriminatory basis.

FILE CODE: CMS-3844-P
Medicare and Medicaid Programs Hospice Conditions of Participation; Proposed Rule
Comments

418.3 DEFINITIONS:

CLINICAL NOTE: Request addition of psychosocial and spiritual services to this definition. These services are a very important part of hospice care and need to be included in this definition.

Please define: INITIAL ASSESSMENT, COMPREHENSIVE ASSESSMENT
PLAN OF CARE

DRUG RESTRAINT: Recommend the elimination of this definition. We feel this is not applicable to hospice as some medications that may be defined as chemical restraints, in some instances, may be normal patient care protocol in hospice.

EMPLOYEE: The definition states "an employee...who is appropriately trained." We recommend including in the definition "one who has been appropriately trained in death and dying."

LICENSED PROFESSIONAL: Recommend ending the sentence after the word "delivered." Each state may have different requirements and adding "such as" creates limitations.

RESTRAINT: We feel the definition does not define the word *restraint.* A recommendation is being made to delete this definition.

SECLUSION: Recommend deleting this definition for two reasons:

a. Some patient's want to be secluded at time of death or with severe pain.
b. The disease process itself could physically prevent the patient from leaving.

418.52 "*PATIENT RIGHTS*":

(a) Standard: Notice of Rights

(1) Recommend deletion of the word "language" from the sentence that states, "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 the patient understands." We feel it would be too cost prohibitive to have in all languages.

(3) Recommend deletion based on the following reasons:

a. The patient/family receives extensive information during admission and this may become very burdensome.

(3) b. The patient may not be receiving any controlled medications at the time of admission and could be informed at such a time as needed.

(4) Recommend the last part of the sentence be deleted and only state "The hospice must maintain documentation showing that it has complied with the requirements of this section." We feel the agency should state, in their own policy, how this documentation will be accomplished.

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

(1) Under (1) we recommend adding a (v) to this standard stating, "has right to Participate in their plan of care."

(4) We recommend deleting (i), (ii), (iii). These are not appropriate for hospice.

(e) Standard: Patient Liability:

The sentence states, " Before care is initiated, the patient must be informed, verbally and in writing, and in a language..." We recommend deletion of the word "language" and replace with the word "manner.

418.54 Comprehensive Assessment of the Patient

(c) Standard: Content of the comprehensive assessment

(1) Please clarify what it is you are asking. If it is the admission diagnosis, we recommend just asking for the diagnosis.

(2) Please clarify what it is you are asking. Are you asking for morbidity & co-morbidity factors? Are you asking for social or economical barriers? These first two questions do not seem to be clearly worded.

(3) (i) We are wondering why other important issues for the hospice patient are not addressed in as much detail as "bereavement" is here.

"ASSESSMENT TIME FRAMES"

(d) Standard: Update of the comprehensive assessment

Please clarify. Are you proposing the comprehensive assessment, encompassing all disciplines, be done every 14 days? Or is it the ongoing plan of care derived from the comprehensive assessment on admission with an update at recertification time?

(1) If the language is meant to describe a comprehensive assessment, it is our recommendation that it be updated every recert period & not every 14 days. We do feel the ongoing plan of care needs to be updated every 14 days.

418.56 Interdisciplinary group care planning and coordination of services

(a) Standard: Approach to service delivery

(1) We recommend changing "qualified health care professional" to "registered nurse". We feel it should be the RN that coordinates the patient's care.

(i) We recommend changing to...."A doctor of medicine or osteopathy (who may or may not be the patient's attending physician).

"PLAN OF CARE"

(b) Standard: Plan of care

We recommend there should be a time frame as to when the plan of care needs to be completed.

(c) Standard: Content of the plan of care

Please clarify. Are you expecting a complete comprehensive assessment by all disciplines every two weeks as well as updating the plan of care every two weeks? Our recommendation is to update the plan of care every two weeks or anytime a change in the patient's condition occurs. It's unrealistic that a full comprehensive assessment is to be done every two weeks by all disciplines. Not all hospice patients may want or need all disciplines every two weeks.

(2) We would recommend deleting the part of the sentence saying "a detailed statement of". It should be adequate just to say "The scope and frequency of services....."

(6) Would recommend changing "patient and family" to "patient/family".

(d) Standard: Review of the plan of care

We recommend the following:

- "The medical director or physician designee" be deleted and the sentence start with "The hospice interdisciplinary team..." (The reason for this is that the medical director is part of the interdisciplinary team.)
- "...at intervals specified in the plan" be deleted. The plan of care cannot forecast or project the patient's needs or change in condition.
- Delete "updated comprehensive assessment". Change to "a revised plan of care must include information from the patient's ongoing assessment...."

"COORDINATION OF SERVICES"

(e) Standard: Coordination of services

(1) We recommend deleting "through its designated professionals". The interdisciplinary group has already been defined, thus, we feel this is not necessary.

(4) For clarity purposes, we recommended changing this to "Provide for and ensure the ongoing sharing of information between all disciplines providing care and services in all settings, whether provided directly or under arrangement.

"QAPI"

418.58 Quality assessment and performance improvement

We have a general comment for this entire condition. We feel the standards under this condition are very "wordy" and unclear making it difficult to even comment. It seems Standard (c) with the addition of "data collection" could encompass and a QA program. From a surveyor perspective we feel these would be very difficult to enforce when we don't even understand them.

(d) Standard: Performance improvement projects

(1) Please define what is meant by "scope of distinct improvement projects". Define what "complexity" is.

418.64 Core Services

(b) Standard: Nursing services

(2) Please clarify NP. Is the NP an employee of the hospice or the attending Physician?

(d) Standard: Counseling services

(3) Spiritual counseling

(iii) It is our recommendation that if the hospice is not required to go to extraordinary lengths to do this than the sentence should be deleted.

"STATUTORY NURSING WAIVER"

418.66 Nursing Services – Waiver of requirement that substantially all nursing services be routinely provided directly by a hospice.

(a) (1) We recommend changing the sentence to include both rural and urban areas.

418.72 Physical therapy, occupational therapy, and speech-language pathology

We recommend adding dietitians to the non-core services.

418.76 Home health aide and homemaker services

(c) Standard: Competency evaluation.

Recommend adding the word "aide" after home health. The sentence should read "An individual may furnish home health aide services ...."

(e) Standard: Qualifications for instructors conducting classroom supervised practical training, competency evaluations and in-service training.

We recommend that qualifications should be " two years of nursing experience, at least one year of which must be in hospice care".

GENERAL COMMENT: All places in the document that states home health aide or home health agency should read hospice aide or hospice agency.

(f) Standard: Eligible training organization

Recommend changing "home health agency" to "hospice agency".

(2) Change from home health to "hospice".

(3) We recommend deleting this. It does not relate to hospice but instead relates to home health. There are no partial or extended surveys for hospice.

(4) Please explain. Is there a monetary penalty of $5000 for hospice?

(5) Change home health agency to "hospice agency".

(7)(ii) Again, can hospice be assessed this type of penalty?

(iv) Change home health to hospice

(g) Standard: Home health aide assignments and duties

We recommend removing "qualified therapist". In hospice care, the therapist does not visit as often as nursing does.

(1) We recommend to delete "or qualified therapist". We think it should read "hospice aides are assigned to a specific patient by a registered nurse. Written patient care instructions for a hospice aide must be prepared by a registered nurse who is responsible for the supervision of a hospice aide as specified under paragraph (h) of this section."

(2) Change home health to hospice.

(i) We recommend deleting this statement. It is our feeling that the IDT should have authority to decide when a patient needs hospice aide.

(3) (iv) We recommend adding, "as permitted by state law".

(4) Recommend deleting "or other appropriate licensed professional".

(h) Standard: Supervision of home health aides
Again, change home health to "hospice".

(1) Recommend deleting "or qualified therapist"
(2) Recommend deleting "or therapist"
(i) Delete "or qualified therapist"

WE RECOMMEND TO ADD:
(3) When an aide is permanently assigned to a licensed hospice facility, the every 2-week supervisory requirement does not apply, however, there must be evidence of an annual performance review in the aide's personnel file.

"ORGANIZATION AND ADMINISTRATION"

418.100 Organization and administration of services

(c) Standard: Services
(1) (vii) Please clarify "short term" i.e., respite vs. acute.
WE RECOMMEND TO ADD:
(ix) Continuous care
WE ALSO RECOMMEND TO ADD:
(3) Each hospice shall provide initial orientation for each direct employee that is specific to the employee's job duties.

(e) Standard: Professional management responsibility
Recommend to delete "of staff and". The hospice agency is not responsible for staff of another agency
(2) Recommend changing to "Furnished in a safe and effective manner by qualified personnel.

(g) Standard: In-service training
Recommend deleting "as necessary".

418.102 " MEDICAL DIRECTOR"

We recommend deleting the last sentence because this is the responsibility of the IDT, which include the medical director, attending physician and other health care professionals.

(a) Standard: Initial certification of terminal illness
The attending physician has been excluded from this initial certification. We recommend changing it to say, "The attending physician and medical director or physician designee reviews...."
(b) Standard: Recertification of the terminal illness
418.21(a) does this reference the BBA of 1997 (Aug 5, 1997)? Is this the correct recertification timeframes?

(c) Standard: Coordination of medical care

We recommend changing "patient's medical care in its entirety" to read "patient's medical and hospice care". We also recommend deleting the last sentence.

418.104 "CLINICAL RECORDS*"*

(a) Standard: Each patient's record must include the following:

(1) Explain. Why would you expect updated comprehensive assessment and not an updated plan of care? We recommend that it read: " The initial plan of care, revisions to plan of care, initial assessments, comprehensive assessments at recertification, clinical notes." As a surveyor team, we find that the progress notes is a repetition. If plans of care are updated appropriately there should be no need for progress notes.

"DRUGS, SUPPLIES, & DME"

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

(b) Standard: Controlled drugs in the patient's home

Recommend rewriting to say, "The hospice must have a written policy for delivery and disposing of controlled drugs maintained in the patient's home." It is our recommendation to delete the rest of the statement. We feel tracking and collecting does not apply to hospice. We do feel that education of patient and family regarding controlled medications needs to be done and documented but all the rest of the information stated here is not appropriate for hospice.

(c) Standard: Use and maintenance of equipment and supplies

(1) We recommend changing this entire paragraph to the "suggested language" in the comment column.

418.108 *"SHORT-TERM INPATIENT CARE"*

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

(2) Please clarify "nursing services". Is this RN or LPN?

(c) Standard: Inpatient care provided under arrangements

(3) We feel a copy of the medical record is not necessary. A copy of the discharge summary would be sufficient.

"INPATIENT CARE"

418.110 Hospices that provide inpatient care directly

(b) Standard: Twenty-four hour nursing services

Please clarify "nursing services".

(f) Standard: Patient rooms

(4) (v) We recommend to change to 100 sq feet for each residing patient whether it is a single or double room.

(m) Standard: Pharmaceutical services

We recommend deleting: "Drugs and biologicals must be obtained from community or institutional pharmacists or stocked by the hospice."

(o) Standard: ***"SECLUSION AND RESTRAINT"***

GENERAL COMMENT ON THE ENTIRE STANDARD:
It is our feeling that a "Hospice House" environment is so different than a nursing home or hospital. Other than for safety reasons we cannot fathom using restraints or seclusion on a hospice patient. Therefore, we feel we cannot comment on this section.

"RESIDENTS RESIDING IN A FACILITY"

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

(c) Standard: Core Services

We recommend adding medical director or physician designee.

(d) Standard: Medical Director

We recommend it to read, "The medical director or physician designee of the hospice must provide overall coordination of the medical care of the hospice resident that resides in an SNF, NF, or other facility." We recommend deleting the last sentence. We feel this leaves out the IDT team concept.

(e) Standard: Written agreement

(1) Why would this be part of a contract" Shouldn't it be part of the patient clinical record?

(4) (i) This would require a change in the plan of care

(ii) This says the same thing as (i). Why not combine?

(iii) Recommend to delete. Hospice takes care of the dying.

(g) Standard: Coordination of services

(1) Recommend to add " and updates of plan of care".

(h) Standard: Transfer, revocation, or discharge from hospice

Recommend changing "does not directly impact" to "may not directly impact".

(i) Standard: This standard needs to be **ALSO** added to subpart D 418.100 – Condition of Participation: Organization and administration of services. (DO NOT DELETE FROM THIS SECTION).

"PERSONNEL QUALIFICATIONS"

418.114 Personnel qualifications for licensed professionals

(b) Any place that states "home health aide" should state "hospice aide"

"SOCIAL WORK"

(c) (7) We recommend that a bachelor's degree in social work or related field (psychology, counseling, etc.) should be considered.

3

June 21, 2005
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3844-P

Dear Sirs:

GENERAL:

With commitment to interfaith ministry and the professional practice of pastoral care, the Association of Professional Chaplains serves chaplains in all types of health and human service settings. Almost 4,000 members are chaplains involved in pastoral care, representing more than 150 faith groups. As a national, not-for-profit professional association, the APC advocates for quality spiritual care of all persons in healthcare facilities, correctional institutions, long term care units, rehabilitation centers, hospice, the military, and other specialized settings. For more information about the APC or further information regarding our comments below, visit our website at http://www.professionalchaplains.org, or contact our Executive Director, Jo Schrader, at 847-240-1014.

SPIRITUAL NEEDS OF HOSPICE PATIENTS AND FAMILIES

We applaud CMS's awareness of and commitment to the inclusion of meeting the spiritual and emotional needs of hospice patients and families and a part of patient rights and the continuum of care. We would encourage the acknowledgement that spiritual needs, just as medical, social, physical, and psychosocial needs, depends upon the delivery of outcome-based, patient centered care by trained and certified professionals who are specialists in spirituality. While the proposed rules identify 'spiritual needs' and 'spiritual counseling', what is lacking is more specific standards regarding who is qualified to provide these services. The proposed rules, in the use of terms such as "clergy", which is a specifically Christian term, fails to acknowledge and provide care for the needs of patients of other religious and spiritual traditions, and we would encourage CMS to utilize language that is more inclusive. We would also encourage CMS to acknowledge the importance of providing for patient and family cultural needs, of which spiritual and religious needs are, while essential, only one part of a person's culture. There are no specific standards within the rules that require hospices to assess and be attentive and sensitive to cultural needs, such as dietary, space, and treatment.

LICENSED PROFESSIONAL SERVICES
PROPOSED 418.62

PROFESSIONAL SPIRITUAL CARE PROVIDERS

The proposed hospice rules contain specific standards for licensed professional services. We understand the rationale for basing these upon State standards for those in other healthcare

1701 E. Woodfield Rd., Suite 760, Schaumburg, IL 60173• Tel: 847/240-1014• Fax: 847/240-1015• E-mail: info@professionalchaplains.org

professions, such as physicians, nurses, therapists, medical social workers, home health aides, etc. However, professional spiritual care providers are board certified by national professional groups, and we would encourage that the proposed rules include this requirement of those providing spiritual care and counseling in all hospice settings. We have attached a copy of the Common Standards for Professional Chaplaincy, adopted by the Council on Collaboration in 2004, which provides a unified voice of the six primary professional spiritual care groups in the United States and Canada. The membership of these groups represents over 10,000 members who currently serve as chaplains, pastoral counselors, and clinical pastoral educators in specialized settings, including hospice and other healthcare organizations, counseling centers, prison, or the military.

In summary, Board Certified chaplains are required to possess:

- An undergraduate degree and a graduate-level theological degree from a college, university, or theological school accredited by a member of the Council of Higher Education Accreditation
- A minimum of 4 units (requiring 1600 hours of training) of Clinical Pastoral Education, which is nationally recognized clinical training in the provision of professional spiritual care
- Board certification by a national professional pastoral care cognate group by which the chaplain demonstrates competencies in pastoral theology and care, personal and professional identify and conduct, and commitment to a Code of Professional Ethics
- Continued professional development by active participation in membership of a cognate group through the payment of dues, professional continuing education, and peer review

In addition, professional spiritual care providers are required to abide by a Common Code of Ethics for Chaplains, Pastoral Counselors, Pastoral Educators, and Students, also a foundational document affirmed by the previously defined Council on Collaboration. We have also attached this document. By including standards that require the employment of Board Certified spiritual care professionals, the proposed CMS Rules would ensure that those providing spiritual care to hospice patients, families, and staff would be held accountable just as other professional, licensed staff are. This protects hospice patients, family, and staff with unwanted, intrusive, and potentially abusive spiritual interventions by those who are not professionally trained, certified, nor held accountable to professional standards of practice and ethics.

While community religious leaders provide gifts in the provision of religious care to hospice patients and families, professionally trained and certified spiritual care providers bring to the hospice environment the skills to provide spiritual assessment, an outcome-based spiritual plan of care and interventions based on professional spiritual care standards of practice, the ability to work effectively within an interdisciplinary team, and specialty in loss, grief, and bereavement care and counseling Board certified chaplains work with community religious leaders to facilitate their care to their religious community members, while also serving as an educator and

facilitator of the hospice environment and specialist in the unique spiritual and emotional needs of hospice patients and families.

We recommend that standards be included to require hospices to employ trained and certified professional chaplains in order to meet clearly and effectively the proposed rules including:

Proposed 418.52: PATIENT RIGHTS
Professionally trained and nationally certified spiritual care providers are advocates for patient rights, educators for patients, families, and hospice staff, and are trained to provide spiritual care to those seeking to make treatment and end of life decisions.

Proposed 418.54: COMPREHENSIVE ASSESSMENT OF THE PATIENT
Board certified chaplains are trained to provide spiritual assessments that identify issues, interventions, and specific outcomes to meet the unique needs of each hospice patient and their family. Additionally, board certified chaplains are trained in how to document in both clinical and progress notes in ways that articulate clearly to the entire interdisciplinary team what spiritual issues may impact the overall care of the patient and family. Professional chaplains are guided by and adhere to national standards of practice in assessment, interventions regarding spiritual distress, loss, bereavement, coping, and the use of religious and spiritual resources identified by the patient and family.

Proposed 418.56: PLAN OF CARE AND COORDINATION OF SERVICES
Professionally trained and nationally trained spiritual care providers have extensive training and experience in developing and writing an outcome-based written spiritual plan of care for patients and families and working with interdisciplinary group care planning and coordination of services.

Proposed 418.58: QAPI
Board certified chaplains not only have training in quality assessment and performance improvement, but also have shown value to organizations that they serve in actively participating and maintaining QI and PI planning and projects. All work of board certified chaplains is informed and guided by professional practice standards applicable to hospice care.

Proposed 418.78 VOLUNTEERS
Clinically trained and nationally certified professional spiritual care providers are skilled in the training and oversight of volunteers, particularly those who seek to provide emotional and spiritual care to hospice patients and families. Having a board certified chaplain in this role assures the hospice of maintaining patient rights and providing appropriate care by volunteers.

Proposed 418.100 ORGANIZATION AND ADMINISTRATION
Again, board certified chaplains are trained and professionally credentialed and follow national standards of practice in order to organize, manage, and administer spiritual services to patients, caregivers, and families within the hospice environment while maintaining dignity, comfort, and

advocacy for patient/family needs and desires. Board certified chaplains serve as educators to other professional staff and volunteers in areas of patient rights, advance care planning, end of life, and spiritual, religious, and cultural needs.

INCLUSIVE SPIRITUAL AND RELIGIOUS LANGUAGE

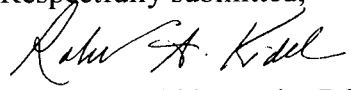
We strongly encourage the Proposed Rules be adapted to utilize language that is inclusive of persons of all spiritual and religious traditions. Rather than using the word 'clergy' in the Proposed Rules, we suggest the use of the word "Board Certified Chaplain" for those employed by the hospice and "community religious leaders" for those who serve as community support and/or volunteers.

CULTURAL ISSUES

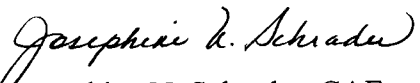
We also strongly encourage that the proposed rules be attentive in the inclusion of additional language addressing the cultural needs of patients and families. It is important to all patients, especially when dealing with the stresses of a terminal diagnosis and end of life, that their rights be respected in all areas of life. For many of differing cultural and spiritual backgrounds, the issues of diet, space for cultural, spiritual, and/or religious ritual, medication and other treatments, the inclusion of complementary therapies, and conversations around diagnosis, treatment, and death are essential dimensions of patient rights.

Thank you for this opportunity for us to comment on CMS-3844-P, the new proposed rules for hospice and for your consideration of our concerns. Do not hesitate to contact the Association of Professional Chaplains if we can provide more information regarding the training, certification, standards of practice, and work of professional chaplains.

Respectfully submitted,



Robert A. Kidd, M.Div. BCC
President



Josephine N. Schrader, CAE
Executive Director

ATT: Common Standards for Professional Chaplaincy
Common Code of Ethics for Chaplains, Pastoral Counselors, Pastoral Educators, and Students

Common Standards for Professional Chaplaincy

This document is one of four foundational documents affirmed by the constituent boards of the Council on Collaboration on November 7, 2004 in Portland, Maine. Collectively, these documents establish a unified voice for the six organizations that have affirmed them and describe what it means to these organizations to be a professional pastoral care provider, pastoral counselor or educator. The four documents are:

- Common Standards for Professional Chaplaincy
- Common Standards for Pastoral Educators/Supervisors
- Common Code of Ethics for Chaplains, Pastoral Counselors, Pastoral Educators and Students
- Principles for Processing Ethical Complaints

The membership of the participating groups represents over 10,000 members who currently serve as chaplains, pastoral counselors, and clinical pastoral educators in specialized settings as varied as healthcare, counseling centers, prisons or the military. The complete documents and information about each of the collaborating groups can be found on the following websites:

▪Association of Professional Chaplains (APC)
www.professionalchaplains.org
▪American Association of Pastoral Counselors (AAPC)
www.aapc.org
▪Association for Clinical Pastoral Education (ACPE)
www.acpe.edu
▪National Association of Catholic Chaplains (NACC)
www.nacc.org
▪National Association of Jewish Chaplains (NAJC)
www.najc.org
▪Canadian Association for Pastoral Practice and Education (CAPPE/ACPEP)
www.cappe.org

For more information on the foundations of professional pastoral care see "*Professional Chaplaincy: Its Role and Importance in Healthcare*" available at http://www.professionalchaplains.org/professional-chaplain-services-resources-reading-room-hc-role.htm

Qualifications of Professional Chaplaincy

The candidate for certification must:

QUA1: Provide documentation of current endorsement or of good standing in accordance with the requirements of his/her own faith tradition.

QUA2: Be current in the payment of the professional association's annual dues.

QUA3: Have completed an undergraduate degree from a college, university, or theological school accredited by a member of the Council for Higher Education Accreditation (www.chea.org); and a graduate-level theological degree from a college, university or theological school accredited by a

member of the Council for Higher Education Accreditation. Equivalencies for the undergraduate and/or graduate level theological degree will be granted by the individual professional organizations according to their own established guidelines.

QUA4: Provide documentation of a minimum of four units of Clinical Pastoral Education (CPE) accredited by the Association for Clinical Pastoral Education (ACPE), the United States Conference of Catholic Bishops Commission on Certification and Accreditation, or the Canadian Association for Pastoral Practice and Education (CAPPE/ACPEP). Equivalency for one unit of CPE may be considered.

Section I: Theory of Pastoral Care

The candidate for certification will demonstrate the ability to:

TPC1: Articulate a theology of spiritual care that is integrated with a theory of pastoral practice.

TPC2: Incorporate a working knowledge of psychological and sociological disciplines and religious beliefs and practices in the provision of pastoral care.

TPC3: Incorporate the spiritual and emotional dimensions of human development into the practice of pastoral care.

TPC4: Incorporate a working knowledge of ethics appropriate to the pastoral context.

TPC5: Articulate a conceptual understanding of group dynamics and organizational behavior.

Section II: Identity and Conduct

The candidate for certification will demonstrate the ability to:

IDC1: Function pastorally in a manner that respects the physical, emotional, and spiritual boundaries of others.

IDC2: Use pastoral authority appropriately.

IDC3: Identify one's professional strengths and limitations in the provision of pastoral care.

IDC4: Articulate ways in which one's feelings, attitudes, values, and assumptions affect one's pastoral care.

IDC5: Advocate for the persons in one's care.

IDC6: Function within the Common Code of Ethics for Chaplains, Pastoral Counselors, Pastoral Educators and Students

IDC7: Attend to one's own physical, emotional, and spiritual well-being.

IDC8: Communicate effectively orally and in writing.

IDC9: Present oneself in a manner that reflects professional behavior, including appropriate attire and personal hygiene.

Section III: Pastoral

The candidate for certification will demonstrate the ability to:

PAS1: Establish, deepen and end pastoral relationships with sensitivity, openness, and respect.

PAS2: Provide effective pastoral support that contributes to well-being of patients, their families, and staff.

PAS3: Provide pastoral care that respects diversity and differences including, but not limited to culture, gender, sexual orientation and spiritual/religious practices.

PAS4: Triage and manage crises in the practice of pastoral care.

PAS5: Provide pastoral care to persons experiencing loss and grief.

PAS6: Formulate and utilize spiritual assessments in order to contribute to plans of care.

PAS7: Provide religious/spiritual resources appropriate to the care of patients, families and staff.

PAS8: Develop, coordinate and facilitate public worship / spiritual practices appropriate to diverse settings and needs.

PAS9: Facilitate theological reflection in the practice of pastoral care.

Section IV: Professional

The candidate for certification will demonstrate the ability to:

PRO1: Promote the integration of Pastoral / Spiritual Care into the life and service of the institution in which it resides.

PRO2: Establish and maintain professional and interdisciplinary relationships.

PRO3: Articulate an understanding of institutional culture and systems, and systemic relationships.

PRO4: Support, promote, and encourage ethical decision-making and care.

PRO5: Document one's contribution of care effectively in the appropriate records.

PRO6: Foster a collaborative relationship with community clergy and faith group leaders.

Requirements for the maintenance of certification

In order to maintain status as a Certified Chaplain, the chaplain must:

MNT1: Participate in a peer review process every fifth year.

MNT2: Document fifty (50) hours of annual continuing education. (Recommendation that personal therapy, spiritual direction, supervision, and/or peer review be an acceptable options for continuing education hours.)

MNT3: Provide documentation every fifth year of current endorsement or of good standing in accordance with the requirements of his/her own faith tradition.

MNT4: Be current in the payment of the professional association's annual dues.

MNT5: Adhere to the Common Code of Ethics for Chaplains, Pastoral Counselors, Pastoral Educators and Students.

Common Code of Ethics for Chaplains, Pastoral Counselors, Pastoral Educators and Students

hereinafter referred to as: Spiritual Care Professionals

This document is one of four foundational documents affirmed by the constituent boards of the Council on Collaboration on November 7, 2004 in Portland, Maine. Collectively, these documents establish a unified voice for the six organizations that have affirmed them and describe what it means to these organizations to be a professional pastoral care provider, pastoral counselor or educator. The four documents are:

- Common Standards for Professional Chaplaincy
- Common Standards for Pastoral Educators/Supervisors
- Common Code of Ethics for Chaplains, Pastoral Counselors, Pastoral Educators and Students
- Principles for Processing Ethical Complaints

The membership of the participating groups represents over 10,000 members who currently serve as chaplains, pastoral counselors, and clinical pastoral educators in specialized settings as varied as healthcare, counseling centers, prisons or the military. The complete documents and information about each of the collaborating groups can be found on the following websites:

▪Association of Professional Chaplains (APC)
www.professionalchaplains.org
▪American Association of Pastoral Counselors (AAPC)
www.aapc.org
▪Association for Clinical Pastoral Education (ACPE)
www.acpe.edu
▪National Association of Catholic Chaplains (NACC)
www.nacc.org
▪National Association of Jewish Chaplains (NAJC)
www.najc.org
▪Canadian Association for Pastoral Practice and Education (CAPPE/ACPEP)
www.cappe.org

For more information on the foundations of professional pastoral care see "*Professional Chaplaincy: Its Role and Importance in Healthcare*" available at http://www.professionalchaplains.org/professional-chaplain-services-resources-reading-room-hc-role.htm.

The Code of Ethics for Spiritual Care Professionals:

- gives expression to the basic values and standards of the profession;
- guides decision making and professional behavior;
- provides a mechanism for professional accountability; and
- informs the public as to what they should expect from Spiritual Care Professionals.

Preamble

Spiritual Care Professionals are grounded in communities of faith and informed by professional education and training.

They are called to nurture their personal health of mind, body and spirit and be responsible for their personal and professional conduct as they grow in their respect for all living beings and the natural environment.

When Spiritual Care Professionals behave in a manner congruent with the values of this code of ethics, they bring greater justice, compassion and healing to our world.

Spiritual Care Professionals:

- affirm the dignity and value of each individual;
- respect the right of each faith group to hold to its values and traditions;
- advocate for professional accountability that protects the public and advances the profession; and
- respect the cultural, ethnic, gender, racial, sexual-orientation, and religious diversity of other professionals and those served and strive to eliminate discrimination.

1.0 Ethical Principles in Relationships with Clients

Spiritual Care Professionals understand clients to be any counselees, patients, family members, students or staff to whom they provide spiritual care. In relationships with clients, Spiritual Care Professionals uphold the following standards of professional ethics. Spiritual Care Professionals:

1.1 Speak and act in ways that honor the dignity and value of every individual.

1.2 Provide care that is intended to promote the best interest of the client and to foster strength, integrity and healing.

1.3 Demonstrate respect for the cultural and religious values of those they serve and refrain from imposing their our own values and beliefs on those served.

1.4 Are mindful of the imbalance of power in the professional/client relationship and refrain from exploitation of that imbalance.

1.5 Maintain relationships with clients on a professional basis only.

1.6 Avoid or correct any conflicts of interest or appearance of conflicting interest(s).

1.7 Refrain from any form of sexual misconduct, sexual harassment or sexual assault in relationships with clients.

1.8 Refrain from any form of harassment, coercion, intimidation or otherwise abusive words or actions in relationships with clients.

1.9 Safeguard the confidentiality of clients when using materials for educational purposes or written publication.

1.10 Respect the confidentiality of information entrusted to them by clients when communicating with family members or significant others except when disclosure is required for necessary treatment, granted by client permission, for the safety of any person or when required by law.

1.11 Understand the limits of their individual expertise and make referrals to other professionals when appropriate.

2.0 Ethical Principles in Relationships Between Supervisors/Educators and Students

Spiritual Care Professionals respect the integrity of students using the power they have as supervisors/educators in responsible ways. Spiritual Care Professionals:

2.1 Maintain a healthy educational environment free of coercion or intimidation.

2.2 Maintain clear boundaries in the areas of self-disclosure, intimacy and sexuality.

2.3 Provide clear expectations regarding responsibilities, work schedules, fees and payments.

2.4 Provide adequate, timely and constructive feedback to students.

2.5 Maintain a healthy respect for the personal growth of students and provide appropriate professional referrals.

2.6 Maintain appropriate confidentiality regarding all information and knowledge gained in the course of supervision.

3.0 Ethical Principles in Relationships with Faith Community

Spiritual Care Professionals are accountable to their faith communities, one another and other organizations. Spiritual Care Professionals:

3.1 Maintain good standing in their faith group.

3.2 Abide by the professional practice and/or teaching standards of the state/province, the community and the institution in which they are employed. If for any reason a Spiritual Care Professional is not free to practice or teach according to conscience, the Spiritual Care Professional shall notify the employer, his or her professional organization and faith group as appropriate.

3.3 Do not directly or by implication claim professional qualifications that exceed actual qualifications or misrepresent an affiliation with any institution.

4.0 Ethical Principles in Relationships with Other Professionals and the Community

Spiritual Care Professionals are accountable to the public, faith communities, employers and professionals in all professional relationships. Spiritual Care Professionals:

4.1 Promote justice in relationships with others, in their institutions and in society.

4.2 Represent accurately their professional qualifications and affiliations.

4.3 Exercise good stewardship of resources entrusted to their care and employ sound financial practices.

4.4 Respect the opinions, beliefs and professional endeavors of colleagues and other professionals.

4.5 Seek advice and counsel of other professionals whenever it is in the best interest of those being served and make referrals when appropriate.

4.6 Provide expertise and counsel to other health professionals in advocating for best practices in care.

4.7 Seek to establish collaborative relationships with other community and health professionals.

4.8 Advocate for changes in their institutions that would honor spiritual values and promote healing.

4.9 Provide other professionals with chart notes where they are used that further the treatment of the clients or patients, obtaining consent when required.

4.10 Communicate sufficient information to other care team members while respecting the privacy of clients.

4.11 Ensure that private conduct does not impair the ability to fulfill professional responsibilities or bring dishonor to the profession.

4.12 Clearly distinguish between statements made or actions taken as a private individual and those made as a member or representative of one of the cognate organizations.

5.0 Ethical Principles in Relationships with Colleagues

Spiritual Care Professionals engage in collegial relationships with peers, other chaplains, local clergy and counselors, recognizing that perspective and judgment are maintained through consultative interactions rather than through isolation. Spiritual Care Professionals:

5.1 Honor all consultations, whether personal or client–related, with the highest professional regard and confidentiality.

5.2 Maintain sensitivity and professional protocol of the employing institution and/or the certifying organization when receiving or initiating referrals.

5.3 Exercise due caution when communicating through the internet or other electronic means.

5.4 Respect each other and support the integrity and well being of their colleagues.

5.5 Take collegial and responsible action when concerns about or direct knowledge of incompetence, impairment, misconduct or violations against this code arise.

5.6 Communicate sufficient information to other care team members while respecting the privacy of clients.

6.0 Ethical Principles in Advertising

Spiritual Care Professionals engage in appropriate informational activities that educate the public about their professional qualifications and individual scopes of practice. Spiritual Care Professionals:

6.1 Represent their competencies, education, training and experience relevant to their practice of pastoral care, education and counseling in an accurate manner.

6.2 Do not use any professional identification (business cards, letterhead, Internet or telephone directory, etc.) if it is false, misleading, fraudulent or deceptive.

6.3 List and claim as evidence only degrees and certifications that are earned from educational institutions and/or training programs recognized by the certifying organizations of Spiritual Care Professionals.

6.4 Ascertain that the qualifications of their employees, supervisees and students are represented in a manner that is not false, misleading, fraudulent or deceptive.

6.5.1 Represent themselves as providing specialized services only if they have the appropriate education, training or supervised experience.

7.0 Ethical Principles in Research

Spiritual Care Professionals engaging in research follow guidelines and applicable laws that strive to protect the dignity, privacy and well-being of all participants. Spiritual Care Professionals:

7.1 Engage only in research within the boundaries of their competence.

7.2 In research activities involving human participants, are aware of and ensure that the research question, design and implementation are in full compliance with ethical principles.

7.3 Adhere to informed consent, including a clear and understandable explanation of the procedures, a description of the risks and benefits, and the duration of the desired participation.

7.4 Inform all participants of the right to withdraw consent and to discontinue involvement at any time.

7.5 Engage in research while being sensitive to the cultural characteristics of participants.

7.6 Maintain the confidentiality of all research participants and inform participants of any limits of that confidentiality.

7.7 Use any information obtained through research for professional purposes only.

7.8 Exercise conscientiousness in attributing sources in their research and writing thereby avoiding plagiarism.

7.9 Report research data and findings accurately.

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Hospice of the South Shore

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July 7, 2005

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

Dear Sir/Madam:

I appreciate this opportunity to comment on the Medicare and Medicaid Programs: Hospice Conditions of Participation; Proposed Rule, which appeared in the Federal Register on May 27, 2005. Hospice of the South Shore is a non-profit hospital based hospice serving 22 towns and approximately 450 terminally ill patients per year.

After reviewing the proposed changes there are several comments that I need to share along with the impact several of the proposed changes.

148.54 Comprehensive assessment of the patient-

The requirement for assessment within 24 hours is not a practical standard. With the short length of stay our acuity is high and the care intensive. Most of our patients require more nursing visits now than in previous years, and along with vacancies, diminishes the ability to meet the 24-hour standard. Our current practice is to contact every patient or family the day the referral is received to introduce ourselves and set up an appointment time. Often times the patient or family is not ready for the admission within 24 hours but welcome the phone contact as an initial step. I am requesting that the 24-hour comprehensive admission be removed and the language changed to "contact" within 24 hours which is a more reasonable and achievable standard. We make every effort to admit every patient in a rapid and timely manner and have more "same day admissions" requests which are done on a 24 hour basis. I ask for your consideration on the impact this standard would impose on hospices.

418.76 Home health aide and homemaker services-

Supervision of HHA standard is a bit confusing and I would appreciate some clarification on the intent. For hospices to physically supervise each HHA involved in the patient's care would be an operational challenge as many patients have multiple HHA's involved in their care.

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418.100 Organization and administration of services-

I am requesting a change in the language form " consistent with patient and family needs and desires to "consistent with the patient's goals." The proposed change suggests an opportunity for unrealistic treatment and interventions and, in addition, the patient's wishes and preferences should be the priority where there are conflicts in the family.

494.102 Medical Director-

Coordination of medical care- it is not a realistic expectation nor is it appropriate for a Medical Director to be responsible for directing the hospice's QA/PI programs. Many hospices, mine included, are very part time and do not have the knowledge to undertake this task. The medical director is utilized on a part time basis for IDT involvement, clinical consultations, and certifications.

418.108 Short term inpatient care-

General Inpatient level of care needs to have an RN on site 24 hours a day as this is a highly intense level of care. The 24-hour requirement should be removed from the Respite Care level.

418.112 Hospice in the SNF-

Medical Director-The proposed requirement for the hospice medical director attending physician SNF medical director and other physicians is not realistic, is time consuming and frankly would not occur. This requirement would restrict access for patients, as the physicians involved would find this burdensome. Physicians are always encouraged to be involved in patient care and communicate effectively as needed to all members of the team.

Thank you in advance for your time and willingness to revisit the proposed changes.

Sincerely,

Mary Beth Barry RN MSM CNPW

Mary Beth Barry RN, MSM, CHPN
Director
Hospice of the South Shore

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Northwest Healthcare Alliance, Inc.

July 16, 2005

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

Via Certified Mail
7002-0510-0003-6046-0383

Re: CMS-3844-P
Proposed Rule to 42 CFR Part 418

Hospice Conditions of Participation

This letter is respectfully submitted in response to the Proposed Rule regarding changes to the Hospice Conditions of Participation.

In this response, I will focus on one aspect of an area that appears to be neglected in this proposal but that needs to be addressed in order to prevent abuses to patients and to the Medicare Program, as well as, to achieve the desired quality improvement and that is **"patient choice."**

The Importance of this Rule

In the Introduction it was stated that CMS has historically adopted an *"approach that has been directed toward identifying health care providers that furnish poor quality care or fail to meet minimum Federal standards."* As providers, we never cease to be amazed by the lack of understanding at the Federal level of the abuses that go unchecked daily until they become so big that they can no longer be ignored and then the OIG takes action. That action is always late; long after the damage has been done to patients, providers, communities, taxpayers and the Program. The headlines of the past ten years of the billions assessed against hospital chains, therapy chains, home health chains, national hospice chains, not for profit providers and unscrupulous physicians attest to the unrelenting tide of greedy operators in the Medicare Program.

Many providers know of violations and abuses by other providers but don't want to get involved, the so called, "Good old' boys (or girls) club." Some of the national associations that depend on provider assessments and dues to pay their executives and employees salaries and benefits, are reluctant to take a position on **"patient choice"** or other potential abuse areas for fear of losing their income stream from the providers who rely on **"patient steering."**. And so we all regard the efforts of CMS and the OIG to chase down the rogues much like drivers gawking at the car accident on the side of the highway with several well lit police cars providing a barrier. A more humorous analogy

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is viewing CMS and the OIG as Wiley Coyote chasing but never catching the Road Runner, no matter what devilish instrument he employs. We do not understand the mentality of "catching them doing something wrong" and it appears from the words used in the introduction and the resultant rule changes and proposals that CMS is finally beginning to understand the problem. However, it does not go far enough.

Patients have a right to choose their providers in the Medicare Program. That right is fundamental to our American heritage and is guaranteed in the Social Security Act, Section 1802 (a) and the Medicare Conditions of Participation. Patients, in some settings are not given that option, but rather through coercion, fraud, neglect or more subtle manipulations are losing their protected health care rights.

The Problem

Nursing home chains have discovered **"hospice"** and the financial benefits it brings to their owners and shareholders. National hospice chains have discovered a rich source of referrals and revenues and have implemented plans to "milk" that resource through **"exclusive"** provider agreements that violate "patient choice." While seeking to *"focus on a patient-centered, outcome-oriented process that promotes patient care foremost rather than penalizing unproductive providers"* please don't underestimate the impact on human behavior of having to report quarterly results to market analysts. CMS still needs to utilize the "carrot and the stick" method to achieve its lofty goals.

These nursing home chains inherently can "influence" patients when they are most vulnerable -- at the point in their illness or when there is little or no resistance to a persuasive healthcare worker. Some patients may even be fearful of asserting their rights to choose a hospice provider (if they even know that they have that right!) for fear of retribution by the nursing home personnel.

Why is this an issue? In proposed 418.112, clarifying the relationship between nursing facilities and hospices there is the goal of ensuring *"that the resident meets all the same Medicare eligibility requirements as a patient who resides in his or her home.."* CMS pointed out in **"RESIDENTS RESIDING IN A FACILITY"** (page 30858 of the Federal Register) that the OIG's office has been very active in the "contractual arrangements between hospices and nursing homes." It appears that there is another initiative underway to deal with obligations regarding residents in LTC facilities receiving hospice services but we submit, additional strengthening of the Hospice COP needs to be included in these proposed rules.

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National nursing home chains who own their own hospice agencies, have developed exclusive relationships with their own captive agencies and so patients no longer have a "choice" of their Medicare hospice provider. This enables the nursing home chain to:

- Limit the oversight. There will be no "arms length" relationship to protect patients. One provider might be more inclined to cover for the other. If CMS only relies on Qui Tam reporting opportunities, the abuses will grow. If a nurse working for the nursing home division wants to run some errands and the hospice nurse who works for the same organization is available to cover for him/her, who will report it? Would this be viewed as a "gift" in order to secure referrals? How will CMS ever hear about it? Over the years, due to our agencies presence in several nursing homes, we reported several incidents of abuse by nursing home personnel and cooperated with the survey team to help them sanction those homes and personnel. We were another level of oversight and visa-versa. How will that happen when all the incentives are aligned against reporting violations? Will people report their friends, their fellow employees, their bowling team members? What if there is a problem patient who has no family, which is the typical nursing home patient, and the care is suspect, who will report it to the authorities? The employees of the same company who may have stock options in the parent organization? That didn't work at Enron, WorldCom and Tyco very well.
- The statement, *"It is not reasonable to expect the hospice to delegate any of its standard hospice core services to the nursing or residential facility staff"* sounds like someone at CMS still believes in the "tooth fairy!" Criminals don't do what is "reasonable." With no oversight because the nursing home has an "exclusive" relationship with its own company's hospice division, abuses will be guaranteed to make the news stories in the years ahead. And again, we will all gawk and shake our heads because we knew it was destined to happen.
- We attended a certificate of need hearing in our state recently and listened to a nurse who was the director of a local outlet of a national nursing home chain that was applying for a CON for hospice in the same area tell the audience, "I will not let my patients be taken care of by anyone other than my staff. That is why I want our own hospice agency." For emphasis, she stood and pointed her finger at the audience in a reproachful manner as she spoke. Does CMS think for one minute that this is an isolated response? While an argument could be made that she was simply passionate about the care they gave at her institution, she forgot one thing,

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IT IS NOT HER CHOICE, IT IS THE PATIENT'S! ***It is not her decision. It is the patient's. And who anointed her as the sole judge of the "quality" care that SHE allegedly gives.?*** By not stopping this dangerous trend in its tracks, CMS is dooming itself and the OIG to continued "chasing of the abusers," always one step behind. The sad part is that these patients are the last ones who should be abused. They will take their abuse to the grave and the very feature of hospice, its palliative, dignified care and compassion will be only a statement on a wall, not a practice protocol for the patient.

- National hospice chains have also developed a highly trained, professional sales force to get nursing homes to sign exclusive relationships with them with promises such as by giving the hospice access to **all** the patients, the hospice provider will automatically enroll more residents in hospice and when the census reaches 10 patients, the facility will have a full time hospice nurse on premises. This again helps the facility if they are short of staff. How will CMS or the OIG ever know that this is going on? Oh, I forgot, Qui Tam. Has CMS ever seen their sales manuals? Has the OIG? There is another way.

The Solution

How does CMS enforce the law against this kind of subtle but exceedingly effective manipulation? We believe the following considerations are appropriate:

- While we agree with CMS' stated goal of improving outcomes and patient care, that will be a futile exercise if the trend of "steering patients" continues. A recent Harris Interactive poll showed that only 1%-2% of consumers changed their decisions when presented with information on quality. How many patients are going to even fathom what CMS comes up with to validate quality while they are dealing with the most traumatic event of their lives? They will never hear it or see it. They will only be told, "Here is the hospice nurse."

- CMS would be better served if it followed a model similar to other government agencies protective and proactive models. **That includes properly trained surveyors who can act on short notice to respond to an alleged violation, as they do for a patient safety violation.** It includes working with affected agencies to identify violations and violators. It

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includes working with patients to help CMS identify violators.

- **Finally, there have to be teeth to the law**. Unless a hospice or nursing home is sanctioned and fined significantly, the practice of "steering" will continue and probably increase since publicly traded nursing home chains and hospice agencies have discovered the significant financial benefit of a symbiotic relationship between the two. If there is no punishment, there will be no change in behavior.

Specific Recommendations

I. Restriction on National Hospice Chains and National Nursing Homes:

We propose that CMS establish rules that restrict any "exclusive" relationships with nursing homes and hospices. Medicare Certified hospices should not be allowed to enter into exclusive relationships. Separately, nursing homes should be mandated to offer their residents in the Medicare Program a choice of hospice provider and should be made to give their residents a list of the Medicare Certified hospice agencies that serve the area, much like hospitals are required to do with home health agencies.

II. Additional Steps to Assure Compliance:

Nursing homes should be mandated to require that every employee be in serviced on the law as it relates to "patient steering." Each employee should sign a statement, similar to what is required now in sexual harassment policy documents, that they understand the law and recognize that if they "steer" a patient to the nursing homes hospice agency or to one agency, which has an exclusive contract with the nursing home, they could be subject to disciplinary action up to and including termination. Finally, each employee involved in the process should know that they are eligible for a cash award if they report corporate personnel to the OIG, who pressured them to violate patient's rights for the benefit of the nursing home's or the hospice's financial standing. These steps will go a long way towards assuring compliance through self-awareness at all levels.

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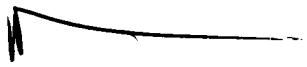
Conclusion

CMS has the duty to protect patient's rights and to ensure the fairness and strength of the Medicare system. In a free enterprise system, hospices should have equal ability to serve patients using the traditional methods of education, community service, quality outcomes and community outreach. None of that is effective if a nursing home's employees "persuade" a patient to use the facilities captive hospice agency when they are most vulnerable. What good is improved quality if there is no access because of "patient steering?"

Enhancing the provisions of the Medicare Conditions of Participation Proposed Rules to protect a patient's "right to choose" their own Medicare provider, will ensure the integrity of the Medicare Program and the achievement of the four measures for the outcome domains of **self –determination**, comfort, safety and effective grieving.

Sincerely,



Richard D. Block
President

Cc: R.J. Ruff, Jr., FAAMA, CHE-CMS Regional Administrator
Anne Keopsell, Executive Director, WSHPCO
Mark Rake-Marona, Western Regional Representative NHPCO

RDB: nbc

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6

June 30, 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: 2005 Proposed Medicare COPs for Hospice Programs

Dear Staff of CMS:

Both Sylvia Marcantel, RN and I attended NHPCO's Train the Trainer Session in Baltimore on June 9-10, 2005, where CMS presented in detail the new proposed Medicare COPs for Hospice Programs. We were very pleased with CMS's preparation and presentation of the training to aid us in reviewing the information with hospices in our states. We provided this information to all members of the Louisiana and Mississippi Hospice & Palliative Care Organization (LMHPCO) in both states. Members were given time to review the information before we held a conference call to discuss the proposed COPs. Members were then given another week to provide comment back to Sylvia and I, so we could formulate our member's responses into a single document to provide CMS our unified response. We feel comfortable that this document represents our member's consensus. The following represent our comments for the proposed Hospice COPs:

Preamble

1) Throughout the preamble the term "hospice industry" is used. We believe the correct terminology should be "hospice associations" in the context used, because the information cited has been provided by NHPCO. While NHPCO does represent a large amount of hospices across the country, it does not represent the entire "hospice industry".

2) On page 30842 of the federal register, discussion centers on "outcome-based measures". CMS cites the work of a Task Force that was convened by the National Hospice Work Group (NHWG) and NHPCO in 1999. We believe this work was relevant and necessary to advance the outcome-based studies hospice should be considering. However, there is a significant disconnect between the topics of these studies and the topics that CMS is suggesting that hospice track in 418.58. The Task Force created four measures for the outcome domains, including self-

determination, comfort, safety, and effective grieving. While all of these are certainly important outcomes, they do not all meet the requirements specified in 418.58(c), which specifies that "performance improvement activities must focus on high risk, high volume, or problem-prone areas." We understand the intent of what CMS is trying to indicate, but we believe both the preamble and section 418.58 needs some clarification. We recommend one Standard be created for Quality Assurance and one Standard be created for Performance Improvement Activities. The language in the preamble is really directed towards the Quality Assurance Standard, while language in 418.58(c) is directed towards the Performance Improvement Activities. Much of the confusion related to outcome-based measures during our meeting in Baltimore can be attributed to not talking about these two topics as separate Standards. Quality Assurance ensures high quality of care is being provided. Performance Improvement Activities are specifically initiated to fix problematic areas.

3) On page 30850 of the federal register, CMS describes how Medicare makes a distinction between providing services directly, as opposed to providing services under arrangement. CMS states the most common way is to utilize employees. Then Medicare cites a common law definition. CMS should clarify if its intent in citing the common law definition was to promote its use in determining whether or not an individual is considered an employee of a hospice.

4) On page 30850 of the federal register, CMS discusses the requirement of licensed professionals, such as PT, OT, and ST, participating in coordinating all aspects of care, including updating the IDT comprehensive assessment, developing and evaluating plans of care, participating in patient and family counseling, participating in the quality assessment and performance improvement plan, and participating in inservice training. First, CMS should clarify this is only appropriate when these licensed professionals are treating specific patients. Currently, the language implies licensed professionals would be involved in these activities for all patients. PT, OT, and ST are used infrequently in hospice, but are needed for some plans of care. They should not have to be involved in all activities. Second, we do not believe professionals, such as PT, OT, and ST, should be involved in the hospice quality assurance and performance improvement activities. These activities should be administered through the employees of the hospice.

5) Also on page 30850 of the federal register, CMS states that "contracted individuals would be required to actively participate in the coordination of care, including patient assessment and care planning, and in the primary hospice's inservice training and quality assessment and performance improvement process. We have the same concern here that we had in #4 above. Please clarify that these contracted individuals would only participate in these activities for patient's they were treating. We also do not believe contracted individuals should participate in the hospice's quality assurance and performance improvement activities.

6) Spiritual counseling is an important part of hospice. On page 30851 of the federal register, CMS states, "If a patient and family do desire spiritual counseling, then a hospice would be expected to facilitate visits by local clergy, pastoral counselors, or others <u>to the best of its ability</u>." We believe this lessens the importance of requiring these services. These services must be provided as part of the plan of care. Also, in this same paragraph, CMS using the term "desires". We suggest changing this term to "goals".

7) On page 30855 of the federal register, under section 418.104(e)(2), CMS is requiring the hospice to submit a copy of the patient's clinical record and discharge summary to the patient's attending physician, if the hospice patient revokes or if the hospice discharges the patient. We disagree with this requirement. This information can be provided to the attending physician, if he or she needs the information and requests it. Further, it is the patient's right to determine who should receive the information and when. We are concerned that a HIPPA violation would occur in this scenario, because the information is being provided without regard to need and without a direct request from the patient.

8) On page 30855 of the federal register, under section 418.104(e)(3), the term "patient's stay" is used. Since the vast majority of hospice care is not provided in a facility the hospice owns and operates, we suggest this be changed to "patient's service duration". "Patient's stay" is more appropriate for nursing facility or hospital COPs.

9) On page 30855 of the federal register, under section 418.104(f), Retrieval of clinical records, we would like to see some language that allows for cost recovery according to state law for the gathering and copying of records. The currently proposed language could imply that clinical records must be made available regardless of payment for gathering and copying services.

10) On page 30855 of the federal register, under section 418.106, CMS discusses the responsibility and accountability for maintaining controlled substances in the home. CMS indicates that primary responsibility rests with the hospice. We strongly disagree. The family takes responsibility for the controlled substances upon delivery to the home. Hospice provides intermittent care and in no way can protect the controlled substances 24 hours a day. Hospice should provide oversight and monitoring of the controlled substances, but hospice should absolutely not be primarily responsible for the controlled substances in the possession of the patient and/or family.

11) On page 30856 of the federal register, under section 418.108, we suggest CMS add "inpatient facility" after "...provided either in the hospice <u>inpatient facility</u> or in a participating Medicare or Medicaid facility."

12) On page 30856 of the federal register, under section 418.110, we suggest CMS add "whenever possible" at the end of the sentence, "We would require that each patient be kept comfortable, clean, well-groomed and protected from accident, injury, and infection, <u>whenever possible</u>." This is necessary, because hospice cannot not always prevent an accident or infection. By definition an accident is unexpected, and infections occur even when the best medical care is provided.

13) On page 30858 of the federal register, under section 418.112, we suggest CMS add "hospice" in this sentence, "Regardless of where the hospice patient resides, the responsibility for developing and implementing an appropriate <u>hospice</u> plan of care rests with the hospice."

14) On page 30858 of the federal register, under section 418.122(e), bullet (1), CMS states that "Written consent and documentation of the patient or the patient's representative that hospice services were desired" is required. This should not be part of the overall contract between a hospice and a facility. This is a consent from a patient to receive hospice services and it belongs in another section of the COPs. One agreement needs to govern the way the hospice and facility will work with each other for all patients, so the agreement should not identify specific patients.

15) On page 30860 of the federal register, under section 418.114, related to social workers, CMS states, "Later, the social worker's goal is to help family members during the bereavement process through in-depth counseling." While this is true sometimes, a hospice chaplain or bereavement counselor often provides this service. The proposed language seems to limit these services to a social worker. We do not believe this is appropriate.

418.3 Definitions

1) Clinical Note – The use of "or" should be used in this definition. The way it is written implies that all of the elements listed must be present in order for a document to be considered a "Clinical Note".

2) Drug Restraint – The use of the term "standard" in confusing, because most drugs that are administered to restrain a patient would be considered standard treatment for a patient's medical or psychiatric condition that would require restraint.

3) Employee – We do not believe that a Volunteer should be considered an Employee. Volunteers should have a separate definition. Legally, hospice does not have the same control of or obligations to Volunteers that it has to Employees. This definition could be problematic for hospice in the legal system.

4) Palliative Care – We question the use of the term "intellectual" and the phrase "to facilitate … access to information". These seem to be beyond the scope of Palliative Care.

5) Satellite Location – Can CMS provide a general definition to limit the distance a Satellite Location can be located from the main Provider # site? Some regional CMS memos have indicated that a Satellite location must be within the same "catchment" area as the main Provider # site. This should be specified in the COPs to give clear guidance to hospices.

Subpart C Patient Care

418.52(a) Standard: Notice of Rights
1) Regarding "in a language and manner that the patient understands during the initial evaluation visit in advance of furnishing care." We suggest you include language to cover "to the extent possible", since providing written materials may limit access to care. We also suggest you include language to meet this standard for minority languages that are most common in a given area, since it is impossible to cover all languages and dialects.
3) We believe the provision of all drug policy information upon admission is too much information for the patient and family to absorb immediately upon admission. We suggest changing to within the timeframe of the comprehensive assessment, which we believe should be within 7 days of admission and also upon the addition of new orders for additional controlled substances. Hospice should be able to provide information to the patient and family in a handbook upon admission, and then allow the patient and family to review. The hospice would then explain the policies in detail and answer any questions within 7 days of the admission to the patient and/or legal representative.
4) Please clarify the term "demonstrated" as meaning a signature of the patient or legal representative.

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

1) We believe (iii) should include language to include the right to refuse treatment such as, "The patient has the right to refuse treatment or to refuse to participate in experimental research." We also suggest adding (v) and including, "The patient has the right to formulate an advance directive."
3) We suggest adding "and practice." to the end of the sentence.
4) We suggest using the Home Health language from the HHA COPs, as this language is more appropriate for hospice than the language from the Nursing Facility COPs. We also suggest removing any language that would require a report of "alleged violations" to the State survey agency within 5 working days. This is language specific to Nursing Facilities.

418.52(e) Standard: Patient Liability
CMS has requested comment related to notification of expected payment from the patient and determining patient's liability related to nursing facility Medicaid Room & Board payments.

Hospices notify, to the extent possible, the patient or legal representative of any expected charges prior to admission. For standard Medicare/Medicaid hospice services this is not necessary, as no charges are passed on to the patient. There are often times we do not have the patient co-pay, co-insurance, or deductible information from commercial payors prior to admission. Requiring this information prior to admission can significantly delay the admission, thus affecting quality patient care for patient's in immediate need of care. We again believe that this kind of information should be provided to the patient and family within the 7 day timeframe of the comprehensive assessment. This allows the hospice to provide the immediate care needed and gives the hospice time to communicate with the commercial payor to determine any patient responsibility. Advance Beneficiary Notices (ABN) or notices of non-coverage are sometimes used to communicate this information.

Hospices often have difficulty obtaining patient's liability information related to nursing facility Medicaid Room & Board. Since the current pass-through law is legislated at the federal level for dually eligible Medicare and Medicaid beneficiaries, we would like to see some language in both the Hospice and Nursing Facility COPs that helps facilitate the coordination of this information between the Hospice, Nursing Facility, and Medicaid.

418.54(a) Standard: Initial assessment.
We suggest including the following language, "(unless ordered otherwise by the physician <u>or as requested by the family)</u>".

418.54(b) Standard: Time frame for completion of the comprehensive assessment.
Please clarify that "in consultation" does not mean the attending physician must be present in person. We believe the 4 day timeframe is too short and strongly suggest modifying to 7 day timeframe. Many times families request a later visit or deny the chaplain or social worker visits the first week while more immediate pain issues are addressed. It has been suggested that other IDT members could complete the initial assessment, such as a social worker. We believe that an RN should complete the initial assessment, since patients often have medical issues requiring immediate attention.

418.54(c) Standard: Content of the comprehensive assessment.
In (ii) Drug therapy we suggest adding a bullet that requires all drugs in the medication profile be listed and to designate which drugs hospice will be responsible for. We also suggest adding language of "drugs that are reasonable and necessary for the palliation or management of the terminal illness." Too often patients and families desire drugs with are proven not to be effective

in the terminal phase of an illness and only benefit in the early or mid stages. Usually these are cost prohibitive and have no benefit.

418.54(d) Standard: Update of the comprehensive assessment.
Some parties have commented that the comprehensive assessment should be updated every 15 days to tie into certification periods. We disagree with this suggestion. We believe the existing 14 day review is appropriate. We also do not believe it is necessary to have a timeframe specified to review the comprehensive assessment prior to recertification, since the review of the comprehensive assessment will likely take place on a different day than the recertification. The existing requirement allows hospices to review the comprehensive assessment as frequently as is necessary, which provides flexibility to provide the appropriate care to the patient and family.

418.54(e) Standard: Patient outcome measures.
We do not believe "patient outcome measures" are too burdensome for hospices. However, we would like the procedure to be clearly defined as it pertains to hospice, such as what is an adverse patient event? We do not want a certain number of quality improvement projects that have to be done each year, but rather issues that are discovered during normal program auditing should be documented on how they were improved to meet standards.
Examples of outcomes indicators are:

- Pain management (6 indicators relative to assessment and reassessment)
- Fall risk and prevention
- Adverse drug reactions
- Medication reconciliation
- Life closure
- Device-related urinary tract infection
- Management of documentation
- National Patient Safety Goals implementation
- Wound management

We do not want these prescribed in the regulations, but a list like this could be provided as an example. Some guidance should be given to allow new programs a foundation to start from; however, hospices should select their own measures depending on the risk factors determined in each program.

418.56(a) Standard: Approach to service delivery.
(1) Please add a provision to allow the hospice medical director to be the patient's attending physician. We believe that allowing the hospice to designate a qualified <u>hospice</u> professional that is a member of the interdisciplinary group is appropriate to coordinate the care of each patient and family. This person should not have to be an RN; however, we do believe the selection should be limited to an RN or social worker, since both have medical training and college education. Other disciplines may have more limited training and education and may not be best suited to coordinate this care. In bullet (iv) the IDT role was narrowed from the original COPs. We suggest, "a counselor, including pastoral, clergy, spiritual, or other counselor."
(2) We disagree with the proposed language. One IDT does not establish governing policies of the day-to-day care. An administrative team establishes policies and procedures and oversees the day-to-day provision of hospice care and services.

418.56(c) Standard: Content of the plan of care.
In (2) we would like a provision added to allow flexibility to increase the frequency upward to address changing needs, such as 2 X week and prn. In (6) we do not believe "agreement" is the most appropriate word to use. Patients and families may not agree with the entire plan of care,

but need to be knowledgeable of what is included in the plan. They may want more aggressive treatment than hospice was designed for or is covered by the Hospice Medicare Benefit. Also, the family may not be in agreement, but the patient is. We suggest using "knowledgeable" instead.

418.58(c) Standard: Program Activities.
In (2) please clarify "adverse patient event". We do not want a certain number of quality improvement projects that have to be done each year, but rather issues that are discovered during normal program auditing should be documented on how they were improved to meet standards.

418.58(d) Standard: Performance improvement projects.
We do not want a certain number of quality improvement projects that have to be done each year but rather issues that are discovered during normal program auditing documentation on how they were improved to meet standards.

418.58(e) Standard: Executive responsibilities.
In order to fulfill the Governing Body's responsibility for the quality of care and services provided, it must receive performance information regarding the results of outcome measurements, so that it can provide input and allocate resources for identified improvements.

418.64 Core services
We believe contracting for staff for continuous care should be allowed. Most hospices are small and cannot afford to hire full time continuous care staff, nor is it feasible to even find staff that will be able to stay continuously with a patient in the middle of the night at a moments notice. Disallowing contracting of staff basically eliminates the possibility of providing continuous care when a patient desperately needs it. The consequence of this is likely an ER admission to a hospital, which is significantly more expensive and is not the best course of treatment for the patient and family. CMS should definitely consider these issues before disallowing contract staff for continuous care. Disallowing this option is not in the best interests of the patient and it is more costly to the Medicare system.

418.64(d) Standard: Counseling services.
Hospice provides counseling services to patients and families in their homes and in a nursing home setting in the same manner. No denigration of services occurs. Bereavement services are provided through memorial services and private or group sessions for staff or other residents in nursing facilities. Unfortunately, not all nursing facilities take advantage of these services, but neither do all families.

418.72 Condition of participation: Physical therapy, occupational therapy, and speech-language pathology.
We believe the dietitian should be moved to the list of non–core services. The dietitian serves more like a therapy provider than a counselor.

418.76 Condition of participation: Home health aide and homemaker services.
We believe "home health" aide should be changed to "hospice" aide. Most hospices do not provide home health.

418.76(g) Standard: Home health aide assignments and duties.
In (2)(i) an aide should not need an MD or nurse practitioner order to perform duties. The RN Case Manager assigns aides duties, and includes these duties in the plan of care, which a

physician signs. Home Health needs orders for these services, because Home Health is administered in a very different fashion and its staff and goals are also very different. It needs to be assumed that all services are available for the hospice patient, and the RN may assign as needed. This information is documented in the plan of care, if the IDT needs to coordinate this information. Hospices need to be able to defer to state law (such as the nurse practice act), especially with regards to medications. Most allow delegation to the aide or unlicensed staff the task of assisting the patient to take their own medications, as long a judgment is not required. They can physically move the medication to the mouth and give the patient water or liquid to aid in swallowing.

418.76(h) Standard: Supervision of home health aides.
COPs should specify that supervisory visits assessing the aide services may be conducted when the client is admitted, recertified or during a prn visit. We agree that the RN should make an onsite visit to the patient's home no less frequently than every 14 days to assess the aide's services. We absolutely disagree that an RN should be onsite with the aide no less frequently than 28 days. We believe onsite visits should be made at least every 90 days. This should not be for every patient. The intent of this standard is to assess the aide's competency. This can be accomplished sufficiently by having each aide visit one of their patients, while an RN assesses the aide's competency.

418.76(i) Standard: Individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit.
It is very important that CMS add language that it is not a duplication of services to have a waiver aide-only service and the Medicare/Medicaid Hospice Benefit at the same time. In Louisiana the waiver is denied, if hospice services have been elected. This most often prevents the patient from accessing the Hospice Medicare Benefit at the time they need it the most. The waiver aide does not provide clinical care. The waiver aide is simply a sitter. Terminally ill patients must have access to professional clinical care at the end of their lives.

418.78(e) Standard: Level of activity.
A major point of revising these regulations is to make the regulations less prescriptive and "to focus on a patient-centered, outcome-oriented process that promotes patient care foremost", according to the preamble associated with these revisions. We believe that setting a 5% volunteer hour minimum is simply a prescriptive method to ensure volunteer utilization that has absolutely nothing to do with providing quality patient care. The 5% target is an arbitrary percentage that has no basis to ensure quality patient care. It is interesting that our existing regulations prescribe this minimum percentage to require volunteers, yet require no minimum number of visits for patient care staff. Ensuring a minimum number of patient visits would have had a significantly larger affect upon quality patient care that designating a specific number of volunteer hours. We would like this prescriptive 5% minimum removed from the regulations, since it is not a statutory requirement. In order to ensure volunteer continuity, the volunteer program should document recruiting, educating, and retention of volunteers and the process of assigning appropriate volunteers to patients with needs that can be met by volunteers.

Subpart D Organizational Environment

418.100(a) Standard: Serving the hospice patient and family.
Substitute "promote" in place of "ensure", since you cannot ensure patient/family experiences. Also, in (2) substitute "goals" in place of "desires", since desires may actually be significantly

more than what is needed to accomplish goals and interventions of a plan of care. Finally, we suggest adding (3) "When the patient and family are not in agreement with the election of hospice care and/or the plan of care, the hospice will honor the patient's needs and goals."

Section 418.100(e) Standard: Professional management responsibility.
Requiring hospice agencies to supervise the staff and services provided pursuant to independent contracts probably will result in the IRS concluding the entity or person providing the service is an employee of the agency and not an independent contractor. One of the critical factors distinguishing employees from independent contractors is whether the employer significantly controls and supervises the work. The hospice should not be required to supervise staff and services for all arranged services. Further, in section (e)(2) of this Section, personnel of arranged services are not likely to have the same qualifications as hospice employees. Hospice employees perform their jobs routinely every day, which provides them certain skills that outside contracted personnel would have difficulty achieving without the same experience. This requirement should be changed to require the hospice to ensure that arranged services are provided by qualified personnel.

Section 418.100(f) Standard: Hospice satellite locations.
The preamble states that CMS is "accepting comment on applying the Medicare Appeals Procedures that affect participation in the Medicare program." We are not sure how this relates to the approval of hospice satellite locations. We would recommend continuing to use the CMS Form 855A to establish new satellite locations with CMS. Please elaborate on how the Medicare Appeals Procedures affects hospice satellite locations.

418.102 Condition of participation: Medical Director
The proposed addition should be changed to "When the medical director is not available, a physician designated by the medical director or the hospice assumes the same responsibilities and obligations as the medical director. The medical director or physician designee coordinate with other physicians and health care professionals to ensure that each patient experiences medical care that reflects hospice policy." Also, please specify that a hospice may contract with an entity (such as a hospital) to allow a physician to serve as a hospice medical director. Many hospitals control physician's time, since the hospitals pay physicians a salary. Consequently, many contracts have to be made with the hospitals directly to allow the physicians to devote some of their time to medical director activities.

418.102(c) Standard: Coordination of medical care.
The Medical Director should be a "participant" in the QAPI Committee/Program, but should not be responsible for directing the hospice QAPI Committee/Program. The hospice Governing Body should be responsible for the QAPI Committee/Program and the hospice Governing Body should be able to designate a member of the hospice staff to direct the QAPI Committee/Program.

418.104 Condition of participation: Clinical records

Advantages of using an EHR:
1. Access from any computer anywhere in the world at any time of the day.
2. Easily portable.
3. Clean copy that is legible, if notes are typed vs. scanned.

Disadvantages of using an EHR:

1. Must have very computer literate clinical staff, which is often unavailable in today's environment.
2. Must carry laptop from house to house. This causes many issues, including the appearance of a "cold machine" between the clinical staff and the patient/family, breakage caused by dropping laptops (occurs often), theft out of cars (laptops are targets for thieves), potential cross contamination between households (laptops are not sterile medical instruments, nor are they disposable items that are only used in one household).
3. Significantly increased costs of infrastructure, software, maintenance, training, data entry staff, etc.
4. If laptops are not used, and handwritten notes are used instead and then entered at the office to become part of the EHR, several issues arise: 1) gaps in time between handwritten note and entry into EHR puts patients at risk, if information is not immediately transcribed. Under any circumstance, there would always be a gap in time which puts the patient at risk. 2) double entry / double time to complete a medical record caused by handwriting the note and then entering the note in the computer. 3) transcription errors are possible by taking a handwritten note and transcribing into the EHR. Transcription errors associated with medications could especially put a patient at risk.
5. Increased time devoted to EHR, instead of patient care. EHRs tend to work well in facilities such as hospitals, nursing facilities, or doctor's offices. This is due to the nature of the care provided and the location. For example, hospitals and doctor's offices bill hundreds, if not thousands of codes for different procedures. EHRs have been created to help these entities bill appropriately and efficiently. Hospice only uses 4 billing codes, and 1 code is used 90%+ of the time. Consequently, hospice gains no efficiency by implementing an EHR system. Hospitals, nursing facilities, and doctor's offices are all physical locations where an EHR system can be placed for easy access. The system is always on and ready to be used. Since hospice provides care in hundreds of homes across a given community, the only logical way to implement an EHR is to use a laptop system for portability. These systems would be turned on and off all day long as they are transported from one home to the next. This process of booting a machine and shutting it down takes time, and forces a clinical staff member to spend more time working with the computer than the patient/family. A clinical note can be written by the time a laptop is turned on, so this is definitely an added burden.
6. Unless hospices provide laptops to every staff member and volunteer (this is not practical), hospices would still have handwritten notes from certain disciplines that would have to be entered by a new data entry employee in order to have a complete EHR. Due to this practicality issue, we have seen some providers in our states try to implement an EHR by only providing laptops to nurses. All other disciplines retained using the process of handwritten clinical notes. This system is not a true EHR, because more than half of the IDT is not included in the EHR. However, this is as far as these providers were willing to go to implement an EHR due to the practicality of providing laptops to every staff member and volunteer.
7. One of our largest hospice providers that serves multiple states across the country abandoned a trial run of implementing an EHR due to the same problems mentioned above. This is an organization that has the resources and infrastructure to take on a task like this, but reported that due to the model of providing hospice services throughout the community, the cost-prohibitive nature of providing laptops to all staff and volunteers, the extensive training, and the very long learning curve, they decided to go back to handwritten clinical notes. It was just too difficult to fully implement outside of a facility, and the hospice failed to recognize any positive patient

outcomes. In fact time devoted to patient care was decreased as a result of the implementation of the EHR.

Barriers/Issues with electronic medical records:
1. Learning curve of computer program is long.
2. Staff available is often poorly trained in use of computers.
3. Decrease in number of hours spent providing patient care in order to utilize the EHR system.
4. Security of computer devices.
5. Maintenance of devices and system; troubleshooting on a daily basis.
6. Increase in staff numbers.
7. Cost.

418.104(b) Standard: Authentication
Hospice is simply too broad to implement this newly proposed regulation. Too many physicians and nursing facility staff are included in our coordination of care to implement this across all persons connected to a clinical record. We suggest removing this requirement, as this is onerous and does not provide for better patient outcomes.

418.106(b) Standard: Controlled drugs in the patient's home
We believe that education of the "potential dangers" of controlled substances must be taught for patient, family, and staff safety. However, "potential dangers" is misleading and we would like "side-effects" substituted in its place.

418.106(c) Standard: Use and maintenance of equipment and supplies.
This Section should be rewritten to specify that when DME is provided by a contracted vendor, the vendor assumes the responsibility to ensure internal or manufacturer policies exist for repair and routine maintenance of equipment. The hospice should be required to verify these policies are in place with the vendor the hospice chooses.

418.108 Condition of participation: Short-term inpatient care.
We suggest that you include a description of short-term inpatient care and when it can be utilized. General Inpatient care is designed to be provided intermittingly and can be used to 1) to provide pain and symptom management that cannot be provided in the patient's home either due to the staff required or the equipment necessary to provide the care, 2) ensure appropriate care due to the inability of the hospice and or the patient's caregivers to provide services in a safe and effective manner in the home, or 3) ensure continuity of care in the event of a psychosocial or family problem. Inpatient Respite care is limited to a five day duration and is used to give the family/caregiver a break during the care of the patient.

418.108(a) Standard: Inpatient care for symptom management and pain control.
We agree with removing the 24 hour nursing coverage requirement for Inpatient Respite care. However, we believe the 24 hour nursing coverage requirement should remain in effect for General Inpatient care.

418.112(d) Standard: Medical Director
Medical directors of hospices and nursing facilities should not have to be the primary designees coordinating care for a hospice patient. Instead, the IDT should be allowed to designate a team member to coordinate care. Also, we do not agree that it is necessary for the hospice medical

director to communicate with the SNF/NF medical director, the patient's attending physician, and other physicians in the provision of care for the terminal condition to ensure quality care for the patient and family. The hospice medical director needs to be able to provide services with some autonomy to make decisions for the patient and family. The attending physician can request to receive communication related to updates to the patient and family care, but the hospice medical director is ultimately responsible for this care. Some attending physicians want to be more involved in care planning than others, but this is an individual preference that varies by physician. Most attending physicians develop a relationship with the hospice medical director and become comfortable with the medical director's assumption of the responsibility to participate in the IDT care planning process.

418.112(f) Standard: Hospice plan of care.
We would prefer the 14 day interval to review the plan of care to remain in place. Some providers have suggested maybe moving to a 15 day interval to tie in with recertification periods. However, leaving the standard as 14 days allows the IDT to have regular meetings on specific days of the week (i.e. every other Tuesday). This logistically works well with hospice medical directors too, because they can block out their clinic days on Tuesdays, for example. Recertifications that come due can be anticipated and can be reviewed at the IDT meeting immediately preceding the recertification.

418.112(i) Standard: Orientation and training of staff.
This proposed Section would inundate facilities with an overflow of inservices that likely couldn't be accommodated in the facilities schedules. We suggest modifying the language to state, "Hospice staff must assure orientation of facility staff."

418.114 Condition of participation: Personnel qualifications for licensed professionals.
This Section seems to indicate that a non-degreed social worker can be hired to fulfill the duties of a hospice social worker, because they are "licensed" by the State. This is a lower qualification level than is currently in place. We strongly believe that a degreed social worker remain the standard for hospice care. Section 418.114(c)(7) specifies a baccalaureate degree requirement, but only when no State licensing requirements exist. In a state where State licensing requirements exist, a non-degreed social worker could fulfill the duties of a hospice social worker under the proposed condition of participation. This needs to be modified to correct this problem.

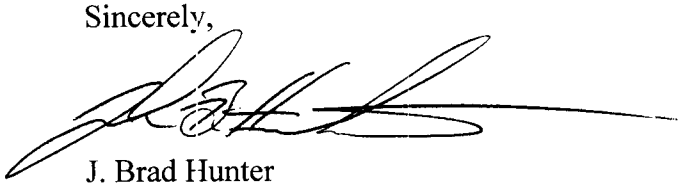
418.114(c) Personnel qualifications when no State licensing, certification or registration requirements exist.
CMS has requested comment on (7) social worker related to the possibility of requiring an MSW to fulfill the hospice social worker duties. The BSW curriculum is obviously not as rigorous as the curriculum for an MSW. We believe an MSW is often better prepared to fill the role of a hospice social worker, but MSWs are often difficult to find in many states, especially rural states. We would propose that the MSW requirement be imposed, but a waiver should be given to hospices that show cause why they cannot hire an MSW. CMS should keep in mind that many hospices will not be able to hire MSWs due to the location of the hospices and local availability of MSWs. CMS should also consider that while one MSW may exist in a small rural area, the hospice may not be able to afford the MSW due to price competition for the limited supply of MSWs in that area. Also, if an MSW requirement is imposed, existing hospice social workers must be grandfathered in to allow them to continue practicing as hospice social workers. We

believe one year of experience as a social worker is appropriate before becoming a hospice social worker. It is not necessary to have this one year of experience in a health care setting. This would significantly limit the pool of new social workers entering hospice, as they are more likely to remain in the health care setting they were originally hired in.

418.114(d) Standard: Criminal background checks.
States already require specific criminal background checks that vary by state. We would suggest removing this Section from the proposed conditions of participation. If the condition remains, there must be some guidance as to what law violations prevent staff from being hired and what response or action is to be taken when a criminal background check reveals violations of the law.

Thank you for the opportunity to comment on the proposed hospice COPs. If you have any questions or comments related to this response, please contact me at your convenience at (205) 970-8888, ext.102 or via email at brad@chahospice.com.

Sincerely,



J. Brad Hunter
President

To: Department of Health and Human Services

Re: Medicare requirements for Masters in Social Work (MSW): file code CMS-3844-P

Date: June 29, 2005

I'm responding to your request for comments concerning the Medicare requirement for MSWs in the hospice setting. The Federal Register article cited several reasons for changing this requirement. Additional reasons include:

1) In order to receive a MSW, students are required to have about two years of clinical internship in different settings where they are supervised by another MSW. Clinical experience enables the student to gain real life experience, which can't be duplicated in a classroom situation. People with a bachelor's degree or Masters in Counseling don't receive these intense clinical experiences.
2) Most hospitals require social workers to have a MSW as cited in Social Work Today, March 24, 2003. MSWs are trained to ask questions, which encompass the holistic approach. Hospice social workers tend to follow people longer than in a hospital setting. We interact with clients and their family and friends in a different way, have a better understanding of community resources, and since we work primarily with people in their homes don't have the immediate back up of co-workers in difficult situations. Thus hospice social workers should have the minimum requirements for hospital social workers.
3) Incorporating the requirement of one-year experience in a medical setting enables the MSW to better understand the medical terminology and abbreviations often used in documentation. However, due to the shortage of MSWs, this could be more of a recommendation than a requirement.
4) Rural areas do present a challenge in meeting the MSW standard. The HHS department's suggestion of having assistant social workers supervised by an MSW is a viable one.

Social workers are called in to deal with difficult and complicated situations, which often occur when people are in emotional and/or psychological pain. Without the necessary training and expertise, well-intentioned people can do more harm. Raising the standard of care for hospice social workers will better insure that patients and their families and friends will receive the necessary support and resources at a very vulnerable time in their lives.

Thank you for soliciting comments on this very important issue.

Respectively,

Marla Karow, MSW

Marla Karow, MSW
Samaritan Evergreen Hospice
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mkarow@samhealth.org

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HOME HEALTH & HOSPICE
COLUMBUS COMMUNITY HOSPITAL

June 22, 2005

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

To whom it may concern,

I attended an information session on June 20th, where I had the opportunity to be educated on the 2005 Proposed Medicare Conditions of Participation for Hospice Programs. I feel that strongly that I need to comment on the proposed issues of Social Work qualifications (418.114 (7))

I have worked as a Medical Social Worker, in the area of Hospice for the last eight years, with a bachelor's degree. Up until the last couple of years I would have defended the issue that a BSW was perfectly capable to serve in this capacity. I have been in the process of pursuing my Master's Degree in Social Work for the last two years; I have found that I do not believe that I have done my past clients justice. I feel that I have had the skills to listen and do case management, but the assessment and counseling skills were not as effective as needed. With many Hospices using the Social Worker and Counselor as a duel role I now believe that it will be imperative to have a Master's level person in that position. When there is the possibility of having both the BSW and a professional counselor, the skills of the Social Worker is used to determine if the counselor is needed.

With a BSW, you are taught the basics in community resources, case management, advocacy, and, limited assessment skills. As a MSW, you are intensively educated on assessment of individuals and family functioning, and how to counsel them. This is very important when working with Hospice patients.

A good example of this would be in the area of grief versus depression. So many times we see in IDG's a patient being put on an anti-depressant because of depression. Since taken masters classes I have been able to do some assessments and determine that is was grief, and grief cannot be treated with medication. Treating grief with medication can lead to unnecessary medication reactions, and cost. Where as the treatment for grief is communication, and counseling.

Coming from a smaller community I can see the impact that this could have on the smaller rural hospice organizations. But I firmly feel that a Master's level person should somehow be involved with each Hospice patient. Being in the position that I am in I can see both sides of this issue.

Please feel free to contact myself if any further input or comments are needed, (402) 562-4496

Sincerely,

Lisa Weber DeVoll

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ACPE

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ASSOCIATION FOR
CLINICAL
PASTORAL
EDUCATION, INC.

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Associate Director

June 30, 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

Dear CMS:

This is in response to the proposed rule to revise the existing conditions of participation that hospices must meet to participate in the Medicare and Medicaid programs. Specifically, we are supportive and appreciative of CMS's commitment to have requirements that focus on the care delivered to patients and their families by hospices, including attention to spiritual care.

The Association for Clinical Pastoral Education, Inc. is a professional association committed to advancing experience-based theological education for seminarians, clergy and lay persons of diverse cultures, ethnic groups and faith traditions. We establish standards, certify supervisors [faculty] and accredit programs and centers in varied settings. Clinical Pastoral Education (CPE) is the requisite training for board certification as a professional chaplain. ACPE programs promote the integration of personal history, faith tradition and the behavioral sciences in the practice of spiritual care. We have nearly 350 accredited programs and over 800 certified faculty nationwide. For further information about ACPE, Inc. please visit our website at www.acpe.edu, or contact our Executive Director, Rev. Dr. Teresa E. Snorton at 404-320-1472.

We would like to offer this response to the proposed rule:

PROPOSED 418.62: LICENSED PROFESSIONAL SERVICES

The proposed hospice rules contain specific standards for licensed professional services. We understand the rationale for basing these upon State standards for those in other healthcare professions, such as physicians, nurses, therapists, medical social workers, home health aides, etc. However, **professional spiritual care providers** are first extensively training and then board certified by national professional groups. We would encourage that the proposed rules include this requirement of training and board certification for those providing spiritual care and counseling in all hospice settings.

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In addition to undergraduate and graduate theological degrees, a Board Certified chaplain must complete a minimum of 4 units (requiring 1600 hours of training) of Clinical Pastoral Education, which is nationally recognized clinical training in the provision of professional spiritual care. Clinical Pastoral Education is an outcomes-based educational program, recognized by the United States Department of Education. Our standards focus on the development of pastoral formation, pastoral competence and pastoral reflection.

Pastoral formation aids the professional spiritual care provider in self-awareness, values assessment, and use of consultation. Pastoral competence leads the student in skill development, i.e. pastoral care skills (listening, empathizing, conflict resolution, crises management) counseling, spiritual assessment, multidisciplinary teamwork, multicultural concepts of religion, spirituality and care, care to the grieving, leadership, management, positive use of power and authority, responsible boundaries to name a few. Pastoral reflection directs the student in the use of collaboration with other professionals, and self and peer evaluation in providing ministry to others.

The ACPE, Inc. maintains rigorous standards for its educational programs, all of which are reviewed in one-year, five-year and ten-year cycles to assure quality, integrity and consistency. Our standards are reviewed annually for adequacy and relevance to the field. Further, they are revised every five years in conjunction with our application for re-recognition by the United States Department of Education.

A copy of the ACPE training standards (which includes our objectives and outcomes for Clinical Pastoral Education) is included with this response. We are also including a copy of the Common Standards for Professional Chaplaincy and our Code of Ethical Conduct adopted by the Council on Collaboration in 2004, which provides a unified voice of the six largest professional spiritual care groups in the United States and Canada. The membership of these groups represents over 10,000 members who currently serve as chaplains, pastoral counselors, and clinical pastoral educators in specialized settings, including hospice and other healthcare organizations, counseling centers, prisons, or the military.

By including standards that require the employment of a trained and Board Certified spiritual care professionals, the proposed CMS Rules would ensure that those providing spiritual care to hospice patients, families, and staff would be held accountable just as other professional, licensed staff are. This protects hospice patients, family, and staff with unwanted, intrusive, and potentially abusive spiritual interventions by those who are not professionally trained, certified, nor held accountable to professional standards of practice and ethics.

While community religious leaders provide gifts in the provision of religious care to hospice patients and families, professionally trained and certified spiritual care providers

bring to the hospice environment the skills to provide spiritual assessment, an outcome-based spiritual plan of care and interventions based on professional spiritual care standards of practice, the ability to work effectively within an interdisciplinary team, and specialty in loss, grief, and bereavement care and counseling Board certified chaplains work with community religious leaders to facilitate their care to their religious community members, while also serving as an educator and facilitator of the hospice environment and specialist in the unique spiritual and emotional needs of hospice patients and families.

We recommend that standards be included to require hospices to employ trained and certified professional chaplains in order to meet clearly and effectively the proposed rules including:

Proposed 418.52: PATIENT RIGHTS
Professionally trained and nationally certified spiritual care providers are advocates for patient rights, educators for patients, families, and hospice staff, and are trained to provide spiritual care to those seeking to make treatment and end of life decisions.

Proposed 418.54: COMPREHENSIVE ASSESSMENT OF THE PATIENT
Board certified chaplains are trained to provide spiritual assessments that identify issues, interventions, and specific outcomes to meet the unique needs of each hospice patient and their family. Additionally, board certified chaplains are trained in how to document in both clinical and progress notes in ways that articulate clearly to the entire interdisciplinary team what spiritual issues may impact the overall care of the patient and family. Professional chaplains are guided by and adhere to national standards of practice in assessment, interventions regarding spiritual distress, loss, bereavement, coping, and the use of religious and spiritual resources identified by the patient and family.

Proposed 418.56: PLAN OF CARE AND COORDINATION OF SERVICES
Professionally trained and nationally trained spiritual care providers have extensive training and experience in developing and writing an outcome-based written spiritual plan of care for patients and families and working with interdisciplinary group care planning and coordination of services.

Proposed 418.58: QAPI
Board certified chaplains not only have training in quality assessment and performance improvement, but also have shown value to organizations that they serve in actively participating and maintaining QI and PI planning and projects. All work of board certified chaplains is informed and guided by professional practice standards applicable to hospice care.

Proposed 418.78 VOLUNTEERS
Clinically trained and nationally certified professional spiritual care providers are skilled in the training and oversight of volunteers, particularly those who seek to provide emotional and spiritual care to hospice patients and families. Having a board certified chaplain in this role assures the hospice of maintaining patient rights and providing appropriate care by volunteers.

Proposed 418.100 ORGANIZATION AND ADMINISTRATION
Again, board certified chaplains are trained and professionally credentialed and follow national standards of practice in order to organize, manage, and administer spiritual services to patients, caregivers, and families within the hospice environment while maintaining dignity, comfort, and advocacy for patient/family needs and desires. Board certified chaplains serve as educators to other professional staff and volunteers in areas of patient rights, advance care planning, end of life, and spiritual, religious, and cultural needs.

INCLUSIVE SPIRITUAL AND RELIGIOUS LANGUAGE
We strongly encourage the Proposed Rules be adapted to utilize language that is inclusive of persons of all spiritual and religious traditions. Rather than using the word 'clergy' (which is a Christian term) in the Proposed Rules, we suggest the use of the word "Board Certified Chaplain" for those employed by the hospice and "community religious leaders" for those who serve as community support and/or volunteers.

CULTURAL ISSUES
We also strongly encourage that the proposed rules be attentive in the inclusion of additional language addressing the cultural needs of patients and families. It is important to all patients, especially when dealing with the stresses of a terminal diagnosis and end of life, that their rights be respected in all areas of life. For many of differing cultural and spiritual backgrounds, the issues of diet, space for cultural, spiritual, and/or religious ritual, medication and other treatments, the inclusion of complementary therapies, and conversations around diagnosis, treatment, and death are essential dimensions of patient rights.

Thank you for this opportunity for us to comment on CMS-3844-P, the new proposed rules for hospice and for your consideration of our concerns. Do not hesitate to contact the Association for Clinical Pastoral Education, Inc. if we can provide more information regarding clinical pastoral education or the training of professional chaplains.

Respectfully submitted,

Arthur Schmidt, D. Min, BCC
ACPE President

Joan Hemenway, D. Min.
ACPE President-Elect

Teresa E. Snorton, D. Min., BCC
ACPE Executive Director

ATT: ACPE Standards (2005)
Common Standards for Professional Chaplaincy
Common Code of Ethics for Chaplains, Pastoral Counselors, Pastoral Educators, and Students

ACPE

Standards of the Association for Clinical Pastoral Education, Inc.

2005

Standards Committee
Association for Clinical Pastoral Education, Inc.
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STANDARDS of the Association for Clinical Pastoral Education, Inc.

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Preface

Richard C. Cabot conceived of **clinical pastoral education** (CPE) as a method of learning pastoral practice in a clinical setting under **supervision**. Anton T. Boisen enlarged the concept to include a case study method of theological inquiry -- a study of "living human documents." William S. Keller began supervising theological **students** in case study methods, believing pastoral practice was complete only as it addressed contributing social conditions. As CPE developed, other leaders opened the doors to integrating knowledge from medicine, psychology and other behavioral sciences into pastoral practice.

The Association for **Clinical Pastoral Education**, Inc. (ACPE) formed in 1967 after some forty years of experience, development and practice of **clinical pastoral education** by several organized but uncoordinated groups. The groups merging to form ACPE included the Institute of Pastoral Care, Inc., the Council for Clinical Training, Inc., the Association of Clinical Pastoral Educators, and the **certification** and **accreditation** functions of the Lutheran Council in the U.S.A.

Thus ACPE became the **standard** setting, accrediting, certifying resource agency in the field of **clinical pastoral education**. It accredits institutions, agencies and parishes as **clinical pastoral education** centers to offer programs of **clinical pastoral education** and certifies **supervisors** to conduct these programs.

ACPE accredited centers offer **clinical pastoral education** as: part of theological education; training for pastoral ministry; training for institutional chaplaincy; training for pastoral counseling; training for **certification** as a **supervisor** of **clinical pastoral education**; and training for other specialized ministries. Theological schools give academic credit for **clinical pastoral education** according to the credit system of each school.

NOTE: Throughout the manual, bold text indicates a term defined in the glossary; text in italics is for emphasis.

STANDARDS
of the
Association for Clinical Pastoral Education, Inc.

Part One -- Introduction

I. Mission of the Association for Clinical Pastoral Education, Inc. (ACPE)

The Association for **Clinical Pastoral Education**, Inc. (ACPE) is a professional association committed to advancing experience-based theological education for seminarians, clergy and lay persons of diverse **cultures**, ethnic groups and faith traditions. ACPE establishes **standards**, certifies **supervisors** and accredits centers to provide programs of **clinical pastoral education (CPE)** in varied settings. ACPE approved programs promote the integration of personal history, faith tradition and the behavioral sciences in the practice of spiritual care.

II. Philosophy for Promulgation of Standards

As a professional association, ACPE has responsibility to the public to define **standards** of conduct for **members** and promulgate **standards** for education and **certification** in **clinical pastoral education** to safeguard the public and to help assure quality education for and competence of practitioners.

III. Standards Committee

A. Function and authority

The **Standards** Committee, responsible to the ACPE Board of **Representatives**, recommends to the Board **standards** for ethical conduct of **members, clinical pastoral education (CPE), accreditation** of centers to offer programs of CPE, and **certification** of **supervisors**. The Board, after considering the recommendations of the **Standards** Committee, sets the **standards** for ethical conduct, **clinical pastoral education, accreditation** of programs to provide CPE, and **certification** of **supervisors**.

The **Standards** Committee develops recommendations for **standards** based on input from the ACPE **Accreditation, Certification** and Professional Ethics **Commissions**, ACPE **members**, constituents, cognate groups, care recipients, and the public. The **Standards** Committee also develops mechanisms for feedback and review of the respective **Commissions'** manuals every five years.

B. Composition

The **Standards** Committee is comprised of ten **members**, a **representative** from each of the nine regions and a chair. **Members** are elected for a three year term, with one-third elected each year. **Members** are elected by the Board of **Representatives** upon nomination by the Representation and Nomination Committee from the candidate(s) suggested by each region.

Part Two -- Standards

Standard 100 Code of Professional Ethics for ACPE Members

Maintenance of high **standards** of ethical conduct is a responsibility shared by all ACPE **members** and **students**.

ACPE **members** agree to adhere to a **standard** of conduct consistent with the code of ethics established in ACPE **standards. Members** are required to sign the *Accountability For Ethical Conduct Policy Report Form* (Appendix 1) and to promptly provide notice to the ACPE Executive Director of any **complaint** of unethical or felonious conduct made against them in a civil, criminal, ecclesiastical, employment, or another professional organization's forum.

Any ACPE **member** may invoke an ethics, **accreditation** or **certification** review process when a **member's** conduct, inside or outside their professional work involves an alleged abuse of power or authority, involves an alleged felony, or is the subject of civil action or discipline in another forum when any of these impinge upon the ability of a **member** to function effectively and credibly as a CPE **supervisor**, chaplain or spiritual care provider.

Standard 101 In relationship to those served, ACPE **members**:

101.1 affirm and respect the human dignity and individual worth of each person.

101.2 do not discriminate against anyone because of race, gender, age, faith group, national origin, sexual orientation, or disability.

101.3 respect the integrity and welfare of those served or supervised, refraining from disparagement and avoiding emotional exploitation, **sexual exploitation**, or any other kind of exploitation.

101.4 approach the religious convictions of a person, group and/or CPE **student** with respect and sensitivity; avoid the imposition of their theology or cultural values on those served or supervised.

101.5 respect confidentiality to the extent permitted by law, regulations or other applicable rules.

101.6 follow nationally established guidelines in the design of research involving human subjects and gain approval from a recognized institutional review board before conducting such research.

Standard 102 In relation to other groups, ACPE **members**:

102.1 maintain good standing in their faith group.

102.2 abide by the professional practice and/or teaching **standards** of the state, the community and the institution in which they are employed. If, for any reason they are not free to practice or teach according to conscience, they shall notify the employer and ACPE through the regional director.

102.3 maintain professional relationships with other persons in the **ACPE center**, institution in which employed and/or the community.

102.4 do not directly or by implication claim professional qualifications that exceed actual qualifications or misrepresent their affiliation with any institution, organization or individual; are responsible for correcting the misrepresentation or misunderstanding of their professional qualifications or affiliations.

Standard 103 In relation to ACPE, **members**:

103.1 continue professional education and growth, including participation in the meetings and affairs of ACPE.

103.2 avoid using knowledge, position or professional association to secure unfair personal advantage; do not knowingly permit their services to be used by others for purposes inconsistent with the ethical **standards** of ACPE; or use affiliation with ACPE for purposes that are not consistent with ACPE **standards**.

103.3 speak on behalf of ACPE or represent the official position of ACPE only as authorized by the ACPE governing body.

103.4 do not make intentionally false, misleading or incomplete statements about their work or ethical behavior when questioned by colleagues.

Standard 104 In collegial relationships, ACPE **members**:

104.1 respect the integrity and welfare of colleagues; maintain professional relationships on a professional basis, refraining from disparagement and avoiding emotional, sexual or any other kind of exploitation.

104.2 take collegial and responsible action when concerns about incompetence, **impairment** or misconduct arise.

Standard 105 In conducting business matters, ACPE **members**:

105.1 carry out administrative responsibilities in a timely and professional manner.

105.2 implement sound fiscal practices, maintain accurate financial records and protect the integrity of funds entrusted to their care.

105.3 distinguish private opinions from those of ACPE, their faith group or profession in all publicity, public announcements or publications.

105.4 accurately describe the **ACPE center**, its pastoral services and educational programs. All statements in advertising, catalogs, publications, recruiting, and academic calendars shall be accurate at the time of publication. Publications advertising a center's programs shall include the type(s) and level(s) of education offered, and the ACPE address, telephone number and website address.

105.5 accurately describe program expectations, including time requirements, in the **admissions** process for **CPE programs**.

Standard 200 Complaints

ACPE encourages persons to work out concerns or **grievances** informally, face-to-face, and in a spirit of collegiality and mutual respect. If differences are not resolved, a **complaint** involving an alleged violation of the ACPE ethical or professional **standards** may be registered in accordance with the procedures set forth in the manual *Processing Complaints of Ethics Code Violations.*

The Professional Ethics **Commission** has final authority to determine whether violations of ACPE **standards** have occurred and to determine final disposition of **complaints**. Policies and **procedures** for registering a **complaint**, conducting mediation and hearings, and disposing of **complaints** are found in *Processing Complaints of Ethics Code Violations.*

Standard 300 Accreditation

The **Accreditation Commission** establishes **procedures** and guidelines, detailed in the ACPE *Accreditation Manual*, for granting and maintaining the **accreditation** of an **ACPE center** and its programs. The **Accreditation Commission** has authority to take action on all **accreditation** matters, including granting, deferring, denying, suspending, or withdrawing **accreditation** for any center, subject to the ACPE **appeal** process.

301-306 ACPE Accredited Centers

All ACPE Accredited Centers shall:

Standard 301 develop and maintain a written plan which:

301.1 describes the administrative structure and lines of authority within the center.

301.2 provides for compliance with ACPE **standards.**

301.3 describes how commitments to **students** will be met in the event of substantial change within the institution or center.

Standard 302 provide at least the following **components:**

302.1 financial, human and physical resources sufficient to support the units of CPE offered by the center.

302.2 a population that provides **students** with opportunities for ministry and **clinical pastoral education**.

302.3 a written agreement that specifies the relationship and operational details between the center and any agency(ies) whenever a program uses elements from any agency(ies) external to itself.

Standard 303 provide these educational resources:

303.1 a **faculty** of sufficient size to fulfill program goals and comprised of persons **authorized** by ACPE. A center's **faculty** must include at least one **supervisor** certified by ACPE as **Associate Supervisor** or **ACPE Supervisor**.

303.2 a **faculty** development plan.

303.3 interdisciplinary **consultation** and teaching within the program(s) provided by adjunct **faculty** and/or guest lecturers.

303.4 individual and group **supervision** by a person **authorized** by ACPE.

303.5 a **peer group** of at least three CPE (Level I/II) **students** engaged in small group process and committed to fulfilling the requirements of the educational program.

303.6 access to library and educational facilities adequate to meet the the ACPE **standards**.

303.7 access to current ACPE **standards** and **commissions'** manuals.

303.8 **student** support services including, but not limited to, orientation, a process for **educational guidance** and recommendations for counseling resources, resume preparation and employment search.

Standard 304 provide all policies and **procedures** in writing and inform all **students** and **ACPE program** staff of their content. These include, but are not limited to:

304.1 an **admission policy** that clearly states the ACPE accredited center does not discriminate against persons because of race, gender, age, faith group, national origin, sexual orientation, or disability.

304.2 a financial **policy** that clearly states fees, payment schedules, refunds, stipends, and benefits.

304.3 a **complaint procedure** consistent with ACPE **standards** and the ACPE manual *Processing **Complaints** of Ethics Violations*.

304.4 a **procedure** for maintaining **student records** for ten years, which addresses confidentiality, access, content, and custody of **student records** should the center be without a **supervisor** and/or **accreditation**. (See *Guidelines for **Student Records***, Appendix 12, ACPE *Accreditation Manual.)*

304.5 a **procedure** for providing **consultation** for CPE **students**.

304.6 a **procedure** for discipline, dismissal and withdrawal of **students**.

304.7 a policy for ethical conduct of **students** and program staff consistent with the ACPE Code of Ethics.

304.8 a statement of **student** rights and responsibilities.

304.9 an agreement for training at the ministry site that includes, but is not limited to:

- authorization to visit patients, parishioners or clients;
- access to appropriate clinical records and informed consent with regard to use of **student** materials; and
- agreement by the **student** to abide by center polices protecting confidentiality and rights of clients/patients/parishioners.

304.10 a **policy** and **procedure** that provides for completion of a unit or program in process if the **supervisor** is unable to continue.

Standard 305 have **consultation** and program evaluation, including:

305.1 an on-going process of **consultation** with a designated professional advisory group.

305.2 on-going program evaluation sufficient to promote the continuous quality improvement of the educational program(s) including:

- course content and materials;
- success with respect to **student** achievement, including course completion, **certification** rate and job placement;
- educational methods and **supervisory** relationship;
- **student** to **supervisor** ratio;
- appropriate level of challenge in individual learning contracts;
- assessment of **students'** use of CPE.

Standard 306 accurately describe the center, its pastoral services and educational programs.

- All statements in advertising, catalogs, publications, recruiting, and academic calendars shall be accurate at the time of publication.
- Publications that advertise a center's programs shall include the type(s) and level(s) of education offered and the ACPE mailing address, telephone number and website address.

<u>307-308 ACPE Accredited Programs</u>

Standard 307 An applicant's suitability for **admission** to any **CPE program** is a matter of judgment by the ACPE accredited center in accordance with its **admission** policies. Requirements for **admission** to **CPE programs** include, but are not limited to:

307.1 a completed ACPE application.

307.2 an **admission interview** with a **qualified interviewer** for persons applying for an initial **unit of CPE** to determine readiness for clinical learning.

307.3 either graduation from high school/completion of a GED or ordination by a faith community or **commission** to function in ministry by an appropriate religious authority as determined by ACPE.

307.4 fulfillment of education or experience requirements established by the ACPE accredited center.

307.5 acceptance by an **ACPE accredited center** accredited for appropriate program type.

307.6 Additional requirements for **admission** to Supervisory CPE include, but are not limited to:

307.6.1 previous ministry experience in which the applicant demonstrated ability to function pastorally.

307.6.2 successfully meeting **CPE Level II** outcomes.

307.6.3 **consultation for readiness** for the **student** and **supervisor** as specified in the ACPE ***Certification*** *Manual,* Part Two, IV. A.

307.6.4 ACPE membership.

Standard 308 Program **standards** include:

308.1 a specific time period for a **program unit** of **clinical pastoral education** or a half unit of **clinical pastoral education.**

- A unit of CPE is at least 100 hours of structured group and individual education. Each unit shall be accompanied by the supervised, clinical practice in ministry. The combined time shall be no less than 400 hours.

- A half unit of CPE is at least 60 hours of structured group and individual education. Each half unit shall be accompanied by the supervised, clinical practice in ministry. The combined time shall be no less than 240 hours.

308.2 supervised clinical practice of ministry to persons and the detailed reporting and evaluation of that ministry.

308.3 **supervision** by a person **authorized** by ACPE.

308.4 an individual **contract** for learning developed collaboratively by the **student** and **supervisor**.

308.5 a relational learning environment that fosters growth in pastoral formation, pastoral reflection and pastoral competence; such an environment involves mutual trust, respect, openness, challenge, conflict, and confrontation.

308.6 an instructional plan that employs a **process model of education** and **clinical method of learning** including:

308.6.1 delineation and use of **students'** goals.

308.6.2 core **curriculum** appropriate to the CPE setting.

308.6.3 clearly written syllabus.

308.6.4 evidence of congruence between program goals and the mission of the institution.

308.6.5 program evaluation by the **students.**

308.7 presentation and use of literature and instruction appropriate to the **students'** learning goals and needs.

308.8 final evaluations written by the **student** and **supervisor.**

308.8.1 **Supervisor's** evaluation will be available to the **student** within 45 calendar days of the completion of the unit.

308.8.2 **Supervisor's** assessment reflects professional judgment about **student's** work, abilities, strengths, weaknesses.

308.8.3 **Supervisor** certifies completion of a unit or half unit of **CPE (Level I/II).**

308.8.4 **Student** may attach a written response to the **supervisor's** evaluation, which then becomes part of the **student's** record.

309-319 Objectives and Outcomes of ACPE Accredited Programs

CPE provides theological and professional education using the **clinical method of learning** in diverse contexts of ministry. ACPE accredits two types of **clinical pastoral education** programs: **CPE (Level I/Level II)** and Supervisory CPE. ACPE accredited programs provide a progressive learning experience through a two level **curriculum**. Level I curriculum outcomes must be satisfactorily addressed prior to admission to Level II. Completion of **CPE (Level I/Level II)** curriculum outcomes is prerequisite for **admission** to Supervisory CPE.

308.6 an instructional plan that employs a **process model of education and clinical method of learning** including:

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Pastoral Reflection

309.9 to develop **students'** understanding and ability to apply the **clinical method of learning**.

309.10 to develop **students'** abilities to use both individual and group **supervision** for personal and professional growth, including the capacity to evaluate one's ministry.

Standard 310 Where a pastoral care specialty is offered, the CPE center designs its **CPE Level II curriculum** to facilitate the **students'** achievement of the following additional objectives:

310.1 to afford **students** opportunities to become familiar with and apply relevant theories and methodologies to their ministry specialty.

310.2 to provide **students** opportunities to formulate and apply their philosophy and methodology for the ministry specialty.

310.3 to provide **students** opportunities to demonstrate **pastoral competence** in the practice of the specialty.

Standard 311-312 Outcomes of CPE (Level I/Level II) Programs

Standard 311 Outcomes of **CPE Level I**

The **curriculum** for **CPE Level I** addresses the fundamentals of **pastoral formation**, **pastoral competence** and **pastoral reflection** through one or more **program units**. Satisfactory achievement of Level I outcomes must be documented in the **supervisor's** evaluation(s).

At the conclusion of **CPE Level I students** are able to:

Pastoral Formation

311.1 articulate the central themes of their religious heritage and the theological understanding that informs their ministry.

311.2 identify and discuss major life events, relationships and cultural contexts that influence personal identity as expressed in pastoral functioning.

311.3 initiate **peer group** and supervisory **consultation** and receive critique about one's ministry practice.

Pastoral Competence

311.4 risk offering appropriate and timely critique.

311.5 recognize relational dynamics within group contexts.

311.6 demonstrate integration of conceptual understandings presented in the **curriculum** into pastoral practice.

311.7 initiate helping relationships within and across diverse populations.

Pastoral Reflection

311.8 use the clinical methods of learning to achieve their educational goals.

311.9 formulate clear and specific goals for continuing **pastoral formation** with reference to personal strengths and weaknesses.

Standard 312 Outcomes of **CPE Level II**

The **curriculum** for **CPE Level II** addresses the development and integration of **pastoral formation, pastoral competence** and **pastoral reflection** to a level of competence that permits **students** to attain professional **certification** and/or **admission** to Supervisory CPE. The Level II **curriculum** involves at least two or more program units of CPE. **Supervisors** must document satisfactory completion of **CPE Level** II curriculum outcomes in the **supervisor's** final evaluation(s).

At the conclusion of **CPE Level II students** are able to:

Pastoral Formation

312.1 articulate an understanding of the pastoral role that is congruent with their personal values, basic assumptions and personhood.

Pastoral Competence

312.2 provide pastoral ministry to diverse people, taking into consideration multiple elements of cultural and ethnic differences, social conditions, systems, and justice issues without imposing their own perspectives.

312.3 demonstrate a range of pastoral skills, including listening/attending, empathic reflection, conflict resolution/confrontation, crisis management, and appropriate use of religious/spiritual resources.

312.4 assess the strengths and needs of those served, grounded in theology and using an understanding of the behavioral sciences.

312.5 manage ministry and administrative function in terms of accountability, productivity, self-direction, and clear, accurate professional communication.

312.6 demonstrate competent use of self in ministry and administrative function which includes: emotional availability, **cultural humility**, appropriate self-disclosure, positive use of power and authority, a non-anxious and non-judgmental presence, and clear and responsible boundaries.

Pastoral Reflection

312.7 establish collaboration and dialogue with peers, authorities and other professionals.

312. 8 demonstrate self-supervision through realistic self-evaluation of pastoral functioning.

Standard 313 Objectives of Supervisory CPE

Through Supervisory CPE, qualified persons who have demonstrated pastoral, professional, and clinical competence will develop competence in the art, theory and practice of **supervision** of **clinical pastoral education**.

The objectives of Supervisory CPE define the scope of the Supervisory CPE **program** curriculum. Outcomes define the competencies that result from a **supervisory student**'s participation in Supervisory **CPE programs**.

Standard 313 The Supervisory CPE center designs its Supervisory CPE **curriculum** to facilitate achievement of the following objectives:

313.1 to develop supervisory **students'** knowledge in theories and methodologies related to CPE **supervision** drawn from theology, professional and organizational ethics, the behavioral sciences, and adult education.

313.2 to provide **students** practice in the **supervision** of CPE under the **supervision** of an ACPE **Supervisor**.

313.3 to facilitate **students'** integration of the theory and practice of CPE **supervision** in their identity as a person, pastor and educator.

314- 319 Outcomes of Supervisory CPE

Standard 314 Outcomes achieved by Supervisory CPE **students** accrue in six areas of competency derived from the Supervisory CPE objectives. A successful candidate for **certification** as ACPE **Associate Supervisor** demonstrates the following:

Standard 315 Competence as a pastoral **supervisor**:

315.1 maintains personal integrity and a deepening pastoral identity.

315.2 demonstrates emotional and spiritual maturity.

315.3 forms meaningful pastoral relationships.

315.4 self-supervises own on-going pastoral practice.

315.5 refines one's professional identity as a clinical pastoral educator.

315.6 demonstrates awareness of how one's **culture** affects professional and personal identity, pastoral practice, the supervisory relationship, and **student** learning.

Standard 316 Competence in the theories of **supervision**:

316.1 articulates understanding of and methodology for clinical pastoral **supervision** based on a critical grasp of the professional literature relating to the field of clinical **supervision**.

316.2 articulates and implements a philosophy of CPE based on an educational model integrating the theory and practice of CPE, which is based on and congruent with one's theology.

316.3 articulates rationale for multicultural competence, integrating the theory and practice of CPE, which is based on and congruent with one's theology.

Standard 317 Competence in the practice of CPE **supervision** including:

317.1 individual **supervision**

317.1.1 assesses an individual **student's** learning patterns, personality, and religious history as a basis for supervisory strategies.

317.1.2 supervises **students'** pastoral work, giving attention to unique patterns of personal and professional development, including the ability to assist **students'** movement toward pastoral identity.

317.1.3 defines and evaluates **students'** pastoral and personal resources, and uses supervisory strategies and

interventions to facilitate **students'** learning and development in pastoral care.

317.1.4 assists **students** in taking responsibility for formulating a learning process and evaluating the results of the learning experience.

317.1.5 uses one's personality and personal, religious and cultural history as a teaching resource in shaping a personal supervisory style.

317.2 group CPE **supervision**

317.2.1 facilitates development of group interpersonal interaction.

317.2.2 enables **students** to use their responses to the program as a learning experience.

Standard 318 Competence in **CPE program** design and implementation:

318.1 develops and organizes programs of CPE based on program educational principles appropriate to experiential learning .

318.2 manages **CPE programs** effectively.

318.3 develops a variety of **CPE program** resources.

318.4 uses diverse clinical educational methods.

318.5 works with the theological implications of the ministry context.

318.6 understands and applies professional organizational ethics as they relate to CPE and pastoral practice.

318.7 uses appropriate clinical skills and teaching methods that integrate the role of context and **culture** in pastoral practice and education.

318.8 advocates for students based on awareness of how persons' social locations, systems and structures affect one's ministry, learning and the educational context.

318.9 considers cultural factors in the use of learning assessments, educational strategies, **curriculum** resources, and evaluation procedures.

Standard 319 Competence in pastoral education:

319.1 integrates educational theory, knowledge of behavioral science, professional and organizational ethics, theology, and pastoral identity into supervisory function.

319.2 demonstrates awareness of the cultural contexts of diverse **student** groups and clinical populations, that integrates and articulates **ethnic identity** development and its implications for pastoral practice and supervisory relationships.

320 Appeal of Adverse Accreditation Decisions

Informal discussion and **consultation** are available when adverse **accreditation** decisions are rendered. Applicants seeking **accreditation** have a right to request a review of an adverse decision and a right to an orderly presentation of views when a decision is appealed.

320.1 The **procedures** for filing an **appeal**, designed to insure the right of fair process as defined by ACPE, are found in the ACPE ***Accreditation*** *Manual,* Appendix 7 ***Appeal*** *of Adverse* ***Accreditation*** *Decision(s).*

320.2 An **appeal** must be based on the grounds that such decision was:

- arbitrary, capricious or otherwise in violation of ACPE **standards** or the ACPE ***Accreditation*** *Manual*; or
- not supported by substantial evidence in the record on which the adverse decision was based.

Standard 400 Certification

Certification by ACPE is granted by the **Certification Commission**. The **Certification Commission** establishes **procedures** and guidelines, detailed in the *ACPE Certification Manual*, for granting and maintaining **certification** of **CPE Supervisors.**

The **Certification Commission** has authority to take action on all **certification** matters, including: granting, denying or continuing **certification**; defining and implementing **procedures** by which **certification** may be withdrawn; and determining the limits and conditions under which a person in training may practice **supervision**. All **Certification Commission** decisions are subject to the ACPE **appeal** process.

Entry into the formal certification process requires successful completion of at least four units of **CPE (Level I/Level II)** and demonstration of having met **CPE (Level I/Level II)** outcomes. (See ACPE ***Certification Manual.)***

401-404 Certification as Supervisory Candidate

Standard 401Formal requirements include:

401.1 ACPE membership.

401.2 college graduation.

401.3 **Master of Divinity degree or its equivalent.**

401.4 **ordination** or **commission** to function in ministry by an appropriate religious authority as determined by ACPE.

401.5 **faith group endorsement.**

401.6 pastoral experience.

401.7 completion of at least one unit of Supervisory CPE.

Standard 402 **Pastoral competence:**

Demonstrates

402.1 personal integrity and pastoral identity.

402.2 emotional and spiritual maturity.

402.3 ability to form meaningful pastoral relationships.

Standard 403 Conceptual competence:

403.1 is familiar with diverse conceptual frameworks in pastoral theology and the behavioral and social sciences as they relate to pastoral functioning.

403.2 integrates knowledge, skill, theory, and practice to the end that one functions creatively, flexibly and imaginatively in pastoral ministry.

Standard 404 Potential for **certification** by ACPE as an **ACPE Supervisor:**

404.1 demonstrates an understanding of CPE **supervision** that is congruent with ACPE **standards**.

404.2 integrates personal and professional strengths and weaknesses and understands how these factors influence **supervision.**

405-408 Certification as Associate Supervisor

Standard 405 Formal requirements:

405.1 **certification** as **Supervisory Candidate.**

405.2 ACPE membership as a **Supervisory Candidate.**

405.3 completion of at least two units of supervised **supervision** of CPE as a **Supervisory Candidate.**

405.4 approval of all required theory position papers.

Standard 406 Supervisory competence:

406.1 completes the objectives and outcomes of Supervisory CPE.

406.2 chooses among methods of individual and group **supervision**.

406.3 plans, organizes and implements a **unit of CPE.**

406.4 relates to and uses interdisciplinary teaching resources.

406.5 critiques one's supervisory methodology based on feedback.

Standard 407 Conceptual competence:

407.1 is familiar with diverse conceptual frameworks in pastoral theology, personality theory, learning theory, group process theory, cultural anthropology, social organization, and change.

407.2 is able to articulate and integrate one's theory, skill and art of **supervision.**

407.3 knows the ACPE **standards** and the history of CPE.

407. 4 is able to affirm and/or modify one's **supervision** in response to self-reflection, self-evaluation and the **consultation** of one's **supervisors**, peers and **students**.

Standard 408 Continues to demonstrate **pastoral competence** as defined in **Standard** 402.

409-410 Certification as ACPE Supervisor

Standard 409 Formal requirements:

409.1 **certification** as **Associate Supervisor.**

409.2 ACPE membership.

409.3 having conducted at least two independent units of CPE following **certification** as **Associate Supervisor.**

Standard 410 Professional competence:

Demonstrates

410.1 supervisory competence and conceptual competence as defined in **Standards** 406-407.

410.2 autonomy in CPE **supervision** that is both responsible and collegial.

411 Continuation of Supervisory Status

Standard 411 Continuation of supervisory status is contingent upon:

411.1 adhering to the ACPE Code of Professional Ethics.

411.2 demonstrating spiritual and educational growth.

411.3 supervising **students** in an ACPE accredited program at least once every three years or participation in other CPE-related educational activities.

411.4 maintaining ordination or **commission** to function in ministry by an appropriate religious authority.

411.5 maintaining **faith group endorsement.**

411.6 participating in peer review at least every five years in accordance with regional **procedures**.

411.7 maintaining membership in ACPE.

412 Reciprocity for CPE Supervisor Status

Procedures and guidelines for **reciprocity** shall be included in the ACPE *Certification Manual* (Part Two, IV. K). Organizations with which **reciprocity** exists are published in the **ACPE Directory**.

413 Appeal of Certification Decisions

Applicants seeking **certification** have a right to request a review of a negative decision and a right to an orderly presentation of views when a decision is appealed. **Members** of sub-committees rendering a negative **certification** decision are prohibited from discussing the dynamics of the review process with the applicant or anyone outside the committee until the time for filing an **appeal** has passed.

413.1 The **procedures** for filing an **appeal**, designed to insure the right of fair process as defined by ACPE, are found in the ACPE *Certification Manual,* Appendix 7, ***Appeal** of Negative **Certification** Decisions.*

413.2 An **appeal** must be based on the grounds that such decision was:

- arbitrary, capricious or otherwise in violation of ACPE **standards** or the ACPE ***Certification** Manual;* or
- not supported by substantial evidence in the record on which the negative decision was based.

PART THREE -- GLOSSARY

ACPE center -- an administrative structure (or entity) **authorized** by the ACPE **Accreditation Commission** to conduct programs of **CPE (Level I/Level II)** and/or Supervisory CPE. A center is responsible for providing (or contracting for) and coordinating those **components** identified by ACPE **standards** as necessary for clinical pastoral learning to occur. The term applies to such structures with Candidacy or Accredited Member status.

ACPE Directory -- The official ACPE listing of accredited **ACPE centers** and their designated programs and **supervisors**: member seminaries; denomination, faith group and agency members; network members; and international affiliate members. **Supervisors (Associate Supervisors. ACPE Supervisors**, retired **supervisors, Supervisory Candidates)** and clinical **members** are listed on the ACPE website at www.acpe.edu.

ACPE Supervisor -- person **authorized** by ACPE to function autonomously to conduct **CPE (Level I/Level II)** and Supervisory CPE.

Accreditation -- authorization, granted by the ACPE **Accreditation Commission**, to conduct programs of **CPE (Level/ Level II)** and/or Supervisory CPE, based on demonstrated ability to meet ACPE **standards**. **Accreditation** ordinarily consists of two stages: Candidacy (pre-accreditation) and Accredited Member status. A separate **accreditation** is required to offer Supervisory CPE.

Accreditation review -- formal process for examining a proposed CPE center's or ACPE accredited center's compliance with ACPE **standards** and **procedures**, and for taking action on the **accreditation** of the center and/or its CPE **program(s).**

Admission -- acceptance of an applicant into a designated **CPE program**.

Admission interview -- the meeting of an applicant to a **CPE program** with a **qualified interviewer** to discuss the application, provide information, assess the applicant's readiness for CPE, and discuss the suitability of the center to the educational goals of the applicant. A face-to-face meeting is strongly recommended.

Appeal -- formal request for reconsideration of a decision made about ACPE **certification** by the **Certification Commission** or ACPE **accreditation** by the **Accreditation Commission** or formal challenge of a decision by a panel in the professional ethics process.

Associate Supervisor -- person **authorized** by ACPE to function as an autonomous CPE **supervisor** for a limited period of time and who has demonstrated to the **Certification Commission**: (1) successful integration of theoretical positions with supervisory practice; and (2) supervisory identity and skills sufficient to allow autonomous functioning that is responsible and collegial.

Authorized -- authority given by ACPE for specific persons to serve as primary **supervisor** for a unit of CPE, i.e. **ACPE Supervisor, Associate Supervisor**, or National Association of Catholic Chaplains **Supervisor** in a center dually accredited by the U.S. Catholic Conference and ACPE. A **Supervisory Candidate** may only supervise under the **supervision** of an **ACPE Supervisor** and may sign **students'** evaluations in conjunction with the **supervisor**, but may not sign the ACPE **student** unit report form.

Certification -- action by the ACPE **Certification Commission** to grant the time-limited status of **Supervisory Candidate** or **Associate Supervisor** or the status of **ACPE Supervisor** to persons affirmed in a review as having satisfied ACPE **standards** for the respective status.

Clinical method of learning -- an educational model that uses data from the actual practice of ministry as the content for reflection.

Clinical Pastoral Education (CPE; clinical education, clinical pastoral learning) -- a method of learning ministry by means of pastoral functioning under **supervision** as developed by ACPE. It is a **process model of education**, predicated on **students'** individual needs that are compatible with program objectives. ACPE distinguishes two types of CPE programming: **CPE (Level I /Level II)** and Supervisory CPE.

Commission -- a **representative** group given authority to make decisions on behalf of ACPE.

Complaint -- a **grievance**, presented in writing and signed, involving an alleged violation of the ethical criteria established by ACPE **Standards** 100 Code of Professional Ethics. A **complaint** must identify the specific **standard** alleged to have been violated.

Component -- one of the structured elements that comprise a **CPE program.**

Consultation -- a meeting of persons in which an individual or group seeks feedback and non-binding advice about functioning, progress and/or plans in CPE.

Contract for learning -- an agreement developed cooperatively by a **student** and CPE **supervisor** which establishes the learning goals of the **student** and the means to achieve those goals in a **unit of CPE**.

CPE Level I -- a program consisting of CPE unit(s) in which the **student** focuses on meeting the outcomes established in ACPE **Standard** 311.

CPE Level II -- a program consisting of CPE unit(s) in which the **student** focuses on meeting the outcomes established in ACPE **Standard** 312.

CPE program(s) -- structured system of **components** (e.g., **supervisor, curriculum,** clerical services, consultants, **student peer group**, experiences in ministry to clients,

multi-disciplinary personnel, evaluation process, specific time frames, learning contract, etc.) in which clinical pastoral learning can occur and is accredited by ACPE.

Cultural humility -- an attitude of respect when approaching people of different cultures, which entails engagement in a process of self-reflection and self-critique requiring an ability to move beyond one's own biases.

Culture -- A symbolic system of meanings, attitudes, feelings, values and behaviors that is shared by a group of people, a particular society or population, and is communicated from one generation to the next via language and/or observation. **Culture** regulates and organizes what a group feels, thinks or does, but may be expressed individually in a variety of ways. **Culture** includes: familial roles, patterns of social and interpersonal communication, affective styles, values and ideals, spirituality and religion, habits of thinking and artistic expressions, customs and norms, rituals and celebrations, and geographical and historical location.

Curriculum -- the total educational program of CPE, including its methodology (program **components**, i.e., conceptual/didactic sessions, ministry practice, clinical critique, seminar types, written materials, bibliography, other creative experiences, etc.), appropriate to the center's **CPE programs**.

Educational guidance -- timely provision of, or referral to, educational resources appropriate to the needs of the **student** in addressing the **student's** goals or the objectives and outcomes of the **CPE program**.

Ethnic Identity -- refers to people who share a common nationality, culture or language. Race refers to differences due to observable physical features, such as skin color, hair type and color, stature, head shape and size, and other facial features. Both are socio-cultural constructs, defined communally and contextually.

Faculty -- person(s) employed or contracted by the **ACPE center** to provide clinical instruction and/or direct **supervision** of **students'** pastoral or **supervisory** formation and function. A **faculty** member must be certified as **ACPE Supervisor, Associate Supervisor** or **Supervisory Candidate**. A **Supervisory Candidate** functioning as a clinical educator must work under the **supervision** of a person with current credentials as **ACPE Supervisor**. In a center dually accredited by the U.S. Catholic Conference and ACPE, a National Association of Catholic Chaplains **Supervisor** may be a **faculty member**.

Faith group endorsement -- formal recognition by a faith group that a person is a **member** in good standing of that group and affirmation of that person for **admission** to the status of **Supervisory Candidate** and/or **certification** as **Associate Supervisor** or **ACPE Supervisor**.

Grievance -- an alleged violation of ethical/and or professional conduct believed to afford reason for a **complaint**. (See definition of **complaint**.)

Impairment -- state of reduced professional functioning wherein a practitioner fails to provide safe, ethical, competent service due to organic illness, excessive use of alcohol and/or drugs, stress related disorder, mental or emotional disability, or deterioration through the aging process.

Master of Divinity degree or equivalent -- graduation from an accredited theological school with a Master of Divinity degree; or ordination from a recognized Jewish seminary; or three academic years of full-time (or equivalent part-time) post-baccalaureate accredited, theological education; or a post-baccalaureate theological degree with such additional study and vocational formation experience as may be evaluated by an appropriate ACPE regional **certification** committee to constitute equivalent level of study; or a Master's degree in a related field with such additional post-baccalaureate theological course work and vocational formation experience as may be evaluated by an appropriate ACPE regional **certification** committee to constitute an equivalent level of study.

Member -- for purposes of the ACPE **Standards**, individuals holding the class/type of membership in ACPE as **ACPE Supervisor**, **Associate Supervisor**, **Supervisory** Candidate, **Supervisor** on Leave, Retired **Supervisor**, Clinical **Member**, **Student** Affiliate **Member**, and Retired **Member** as defined in the ACPE Bylaws.

Multicultural -- a society made up of peoples of many **cultures**, in which there is cross-cultural interaction and intercultural engagement.

Pastoral Competence -- the discovery and use of skills necessary for the intensive and extensive practice of ministry.

Pastoral Formation -- the exploration and development of one's pastoral identity and practice through integrating one's heritage, theology and knowledge of behavioral and social sciences.

Pastoral Reflection -- the process of increasing awareness and understanding of, and ability to articulate, the meaning and purpose of one's experience in ministry.

Pastoral Specialization -- development of **pastoral competence** in an area of ministry with an identified focus in a particular setting or context.

Peer group -- small group of at least three **CPE (Level I/II) students** engaged in small group process and committed to fulfilling the requirements of the educational program.

Policy -- a set of rules and/or directions on a designated subject, congruent with ACPE **standards**, **procedures** and guidelines, by which decisions are made.

Procedure -- a set of steps to be followed in a regular and definite order to accomplish a designated purpose. **Procedures** for **accreditation** of centers, **certification** of

supervisors, and dealing with **complaints** of ethics code violations can be found in the respective manuals, available from ACPE or at www.acpe.edu.

Process model of education -- an understanding of growth and change (in behavior, beliefs, ideas, awareness, etc.) as taking place gradually or in on-going modifications, and as never being finished or perfected.

Professional advisory group (professional **consultation** group, committee, etc.) -- group of interdisciplinary professional resource persons used by the **ACPE center** at regular intervals over time to provide advice and **consultation** on center and program planning, development and program evaluation. **Members** of this group are qualified in their fields and knowledgeable about CPE.

Program unit -- a unit of CPE, as defined in ACPE **standard** 308.1. The **curriculum** of a program unit is at least 100 contact hours of structured group and individual education. Each unit shall be accompanied by the supervised clinical practice in ministry. The combined time shall be no less than 400 hours.

Qualified interviewer -- **ACPE supervisor** or other person meeting these criteria:

- knowledgeable about current ACPE **standards**, **procedures**, practices, and objectives,
- objective as to the interests of the applicant, church, seminary, center, and CPE,
- able to recognize those qualities of well being, personality and faith which will enable an applicant to develop in CPE,
- able to dynamically engage the applicant and assess readiness for CPE,
- able to assess the applicant's potential to benefit from CPE in the center(s) to which application is being made,

and who may prepare an **admission interview** report that becomes part of the applicant's CPE application.

Reciprocity -- mutual exchange of the status of **certification** of CPE **supervisors** as **authorized** by the ACPE Board of **Representatives**.

Representative -- person appointed, elected or employed, who serves in an ACPE regional or national office or position or chairs a committee or **commission.**

Sexual exploitation -- any sexual advance, request for sexual favors, or physical contact of a sexual nature, even if by mutual consent, between persons in situations of unequal power. **Sexual exploitation** is inclusive of the terms sexual harassment, sexual abuse and sexual misconduct. Sexual contact with those served pastorally or supervised, even if by consent, is considered a violation of the ACPE Code of Professional Ethics.

Social location -- a person's position in the world in relation to accessing resources; location is in reference to social groups; complex arrangements determined by economics, class structure, **culture**, etc.

Standards-- adequate and relevant parameters of educational quality that define and advance practice and provide a framework for evaluation.

Student -- person admitted to and participating in a program of CPE.

Student record -- confidential file maintained by a CPE center that may contain **admissions** material, reports, evaluations, individual **contract for learning,** and other material related to a **student's** CPE experience. (See ACPE ***Accreditation*** *Manual,* Appendix 12 *Guidelines for* ***Student Records.)***

Supervision (CPE **supervision,** pastoral **supervision**) -- an educational method by which a **supervisor**, through a face-to-face relationship, enables **students** to learn about self, others, the spiritual, and ministry from clinical experience and examination of that experience so that **students** integrate their learning in their professional identity and functioning.

Supervisor -- a clinical pastoral educator who satisfies ACPE requirements for **certification**, either an **ACPE Supervisor** or **Associate Supervisor.**

Supervisory Candidate -- an **admission** status into the **certification** process granted to **students** in Supervisory CPE who demonstrate readiness to supervise **students** in programs of CPE under the **supervision** of a person with current credentials as an **ACPE Supervisor**; may supervise **students** under **supervision**, but without direct observation, as further supervisory competence is gained.

Types of CPE programs -- CPE (Level 1/LevelI) and Supervisory CPE, with **standards**, objectives and **admission** requirements specific to each type.

PART FOUR -- APPENDICES

APPENDIX 1 Accountability For Ethical Conduct Policy Report Form 28

APPENDIX 1

ACCOUNTABILITY FOR ETHICAL CONDUCT POLICY REPORT FORM

*For the purposes of this Policy, "**member**" refers to: **ACPE Supervisors, Associate Supervisors, Active Retired Supervisors, Supervisory Candidates, and Clinical Members.***

I certify that (a) no discipline or corrective action arising from a **complaint** of unethical or felonious conduct has been imposed on me, and no **complaint** against me for unethical or felonious conduct is pending in a civil, criminal, ecclesiastical, employment or another professional organization's forum; and, (b) I have never resigned, been transferred or terminated, nor negotiated a settlement from a position for reasons related to unethical or felonious conduct.

Date_____/_____/_____

Signature_____

If the above cannot be certified, please provide an account of the **complaint** including the forum, the charges, and the final outcome. Provide the names of people involved in the process whom you authorize to provide full information to ACPE **representatives. Prior actions are not an automatic bar to ACPE membership. Each situation will be evaluated on its own merits by an Accountability Review Committee composed of the Executive Director, the Chair of the Professional Ethics Commission (PEC), the Chair of the Certification Commission, the PEC legal consultant, and a designated Board member.** ACPE has the right to extend or deny candidacy status or membership regardless of previous **complaints**, other forum's findings or subsequent remedial actions according to the judgment of the named **representatives** to the Accountability Review Committee on behalf of the Association. If denied, the applicant may resubmit an application at a later time. Decisions are final and binding on ACPE. *(Attach pages if necessary.)*

I understand that as a condition of membership in the Association for **Clinical Pastoral Education** I will provide to the Association timely notice of any **complaint** of unethical or felonious conduct filed against me. I agree to provide to the ACPE Professional Ethics **Commission** in a timely fashion the information it requests regarding the investigation, adjudication, dismissal or settlement of such **complaint**. Failure to report or provide accurate, full and truthful information may be grounds for discipline including removal of membership in the Association for **Clinical Pastoral Education**, Inc.

Date_____/_____/_____

Signature_____

Printed
Name_____

Current Membership
Category_____

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VNA

VNA of Greater Lowell

Care You Can Trust

VNA Hospice of Greater Lowell
336 Central Street
Lowell, MA 01852-2609

Mail: P.O. Box 1965
Lowell, MA 01853-1965

Phone: 978-458-3123
978-459-9343
800-349-8585

Fax: 978-458-3116
Intake Fax: 978-459-0981

www.vnalowell.org

July 8, 2005

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

Dear Sir/Madam:

I appreciate the opportunity to comment on the Medicare and Medicaid Programs: Hospice conditions of Participation; Proposed Rule which appeared in the Federal Register on May 27, 2005.

The proposed CoP's offer many revisions, which should serve to enhance quality and continuity of care in hospice, reflecting the growth and development of hospice and palliative care in the years since the first CoP's were promulgated in 1983.

There is one area of comment I would like to address in this letter.

Core Services (Proposed 418.64)

- **Allows the primary hospice to enter into arrangement with another Medicare certified hospice to obtain core services under extraordinary or other non-routine circumstances.**

This is an excellent provision to accommodate the referenced circumstance of temporary travel of a patient outside the hospice's service area.

However, for the other types of circumstances referenced, where the patient would remain in the hospice's own service area, the limiting of arrangements to contracting only with another certified hospice would present a number of difficult issues.

- In states with no determination of need/condition of need requirement, this would put hospices in the position of needing to contract with competing hospices and thus raise many conflict of interest issues.

- Hospices servicing the same or overlapping service areas would not be likely to have staff available to assist a competing hospice.

Allowing hospices to contract for core services in extraordinary or non-routine circumstances from a broader range of local resources (e.g., home health agencies, nursing staffing agencies, counseling agencies, etc), with the provision that the hospice be required to ensure that competency/skill of contracted staff and maintain professional responsibility of all care provided, would help address this issue.

Thank you for the opportunity to submit this comment.

Sincerely,

Amba Coltman LICSW

Amba Coltman, LICSW
Interim Hospice Program Director

11

July 13, 2005

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

Dear Sir/Madam:

Thank you for this opportunity to comment on the Medicare and Medicaid Programs: Hospice Conditions of Participation; Proposed Rule which appeared in the Federal Register on May 27, 2005. The Hospice & Palliative Care Federation is a non-profit organization, established in 1980, whose membership includes 45 licensed hospices in Massachusetts as well as other organizations and individuals who share our mission of advancing and promoting excellence in end of life care.

In general, hospice providers have found the new organization of the proposed CoPs helpful and more user friendly. For the most part, new standards are consistent with the hospice community's interest in assuring quality and encouraging a greater degree of uniformity among hospice programs. We will provide comment on those standards which we feel need further clarification or where the standards may pose implementation problems for hospices in Massachusetts. In addition, we have **highlighted our priority issues in bold type.**

Other General Comments

- Well-organized with new structure -- Patient Care followed by Administrative Standards
- The Nurse Practitioner's role as an attending physician should be included and clarified throughout
- The impact analyses appears to minimize time and cost on most activities
- Palliative Care was not focused upon enough to help move hospice "upstream"
- Concern that the Interpretative Guidelines falling from the CoPs be clear so that differences in interpretation and enforcement by regions is minimized
- The greater flexibility to choose appropriate practices is appreciated

418.3 Definitions

Clinical note - Change to include *spiritual* changes

Drug restraint - Clarification needed. At end of life (EOL), certain medications can be standard treatment to manage terminal agitation or to induce sedation for those experiencing intractable suffering. Surveyors who are not expert in EOL care may view this as a drug restraint rather

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than as acceptable practice. Surveyors and hospices will have to agree to the definition of "standard treatments" used at end of life in order to assure that there are options for controlling symptoms not responsive to conventional treatment.

***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 hospice philosophy of providing care across all settings wherever the patient's home may be and is a risk to potential fraud and abuse.**

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

418.52 Patient's rights

(a) *Notice of rights*

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

(3) *Information about tracking and disposal of controlled substances* - Informing families about drug policies at the time of admission will be confusing and potentially terrifying to families already concerned about having controlled substances in the home. Given how much information is already conveyed during the admission visit, information about drug policies may be better provided during the assessment visit rather than admission. Explanations in a patient handbook should suffice until further explanation is appropriate. Language should consistently state "controlled substances" rather than "narcotics."

(b) *Exercise of rights and respect for property/person*

(1) Should include right to refuse treatment

(4) Should use language from Home Health CoPs more appropriate to home setting

(e) *Patient liability* - Use of ABN form for hospice is still confusing.

418.54 Comprehensive assessment of the patient

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

We also recommend that the CoPs allow the initial assessment of the patient to be carried out by other than an RN, such as by the social w orker, as long as the nursing assessment be done by the RN within 24 hours. Many hospices currently allow this practice.
(b) Time for completion of comprehensive assessment - 4 calendar days is a realistic time frame and necessary given that 1/3 of hospice patient die within 7 days.
***(e) Patient outcome measures* - While it is a desirable goal to have "systematic and retrievable" data for each patient, implementation will be very difficult for hospices without computerized clinical record systems. Many hospices in Massachusetts do not have the financial resources to purchase these expensive computerized systems. Since EOL/hospice outcomes have not been accepted to date by the National Quality Forum, it will take leadership and research on the part of CMS and the National Hospice & Palliative Care Organization to identify, test, and standardize a reliable set of indicators to determine quality. A phase-in period for this standard is recommended.**

418.56 Interdisciplinary group care planning
(a) (1) *Approach to service delivery* - There was consensus that a qualified licensed professional could coordinate a patient's plan of care, thus lessening the burden on RN responsibilities. However, in many hospices, this would require a significant culture shift.
(c) (6) *Content of the PoC.* - There should be **no** requirement that the **family** agree with the PoC as the patient's wishes should prevail. Further clarification is needed if the patient is not competent and there is disagreement among family members. In Massachusetts, the patient's appointed health care proxy makes the health care decisions.
(d) *Review of the PoC* - The requirement for the Hospice Medical Director to collaborate with the attending physician is desirable but not always practical given time, interest of the attending and the resources of the hospice program. "To the extent possible" is acceptable language.

418.58 Quality assessment and performance improvement
Performance measures for hospice and EOL are not agreed upon or uniformly used within the provider community and computerized systems are not consistently available for efficient collection and summary of data.
(c) (2) *Program activities* - An adverse event is sometimes defined as an "unexpected death or an incident that has serious consequences. " An example would be the unlawful diversion of medication leading to the death of other than the patient outside the home.
(e) (2)*Executive responsibility* - QA/PI outcomes should be shared on a regular basis with the governing body of the hospice program.

418.64 Core Services
(a) Allowing the primary hospice to enter into arrangement with another Medicare certified hospice to obtain core services out of area for routine travel is very helpful. However, when the patient remains in the hospice's own service area or when a hospice has extraordinary staffing needs due to unusual vacancies, a number of difficulties may be presented. For instance, in non-CON/DON states, the limiting of arrangements to contracting only with another certified hospice, would put hospices in the position of being required to contract with competing

hospices and thus may raise conflict of interest concerns. In addition, since hospices in non-CON/DON states have overlapping service areas. Recruitment problems for one hospice program may extend to other hospices in the same area. Hospices should be allowed to contract with other staffing resources such as home health agencies, nursing staff agencies, or counseling agencies as long as they ensure that competencies and skills of contracted staff and maintain professional responsibility for the care they provide.
(d) (3) (iii) *Spiritual counseling* - Revise language "hospice need not go to extraordinary lengths to do so." If spiritual care is important enough to be a core service, the hospice should try hard to arrange it.

418.66 Nursing services
(a) For purposes of waiver, what is the definition of a non-urbanized area?

418.76 Home health aide and homemaker services.
(h) *Supervision of HHA* -this standard requires clarification. Is this a Human Resource function such that EACH HHA must be supervised for job performance or is it the patient's Plan of Care that is being supervised? If the former, this will pose a substantial coordination and operational challenge since there may be more than one HHA caring for the patient's length of stay in hospice care.
Further, it is not clear whether the requirement for on-site supervision of the HHA every 28 days is in addition to the requirement for supervision every 14 days.

418.100 Organization and administration of services
(a) (2) *Serving the hospice patient and family* - Change language from "consistent with patient and family needs and desires"to "consistent with the patient's goals." The former language leaves the door open to futile and unrealistic treatment and interventions. Patient preferences should have priority in situations where there are conflicts in the family. In addition, the limited availability and reliability of outcome measures to date to satisfy this requirement should be considered as well as the challenges of auditing the family's satisfaction.
(e) *Professional management responsibility* - The hospice should have professional oversight responsibility for the services provided but not the staff. That responsibility belongs to the SNF.
(f) *Satellite locations* - With the growing number of corporations with multiple entities opening hospice programs using the same provider number, the definition of satellite should be clarified so that it is consistent across regions and not subject to interpretation. The process for determining approval of the satellite needs to be further clarified.

418.102 Medical Director
(c) *Coordination of medical care* - It is neither realistic nor appropriate for a medical director to be responsible for directing the hospice's QA/PI program. The average hospice medical director has not the time, the training or the interest in administering such a program. In Massachusetts, there are only two full time HMDs in the state. All other hospice programs use the services of a medical director on a part time basis and those

hours are used for clinical consultation, IDT involvement and direct patient care.

For the QA effort, the Hospice Medical Director should have involvement but not primary responsibility.

418.104 Clinical records

(b) *Authentification* - this is not practical for home hospice care and the financial impact would be significant.

(e) *Discharge and transfer of care* - facilities do not want to receive a complete copy of the patient's clinical record. This is not done in any other aspect of health care. A detailed discharge summary is acceptable and consistent with HIPAA standards to provide the minimum information necessary.

418.105 Drugs, controlled substances ....

(b) *Controlled drugs in the patient's home* - language should be revised to "safety of controlled substances" rather than "potential dangers" of their use. It is challenging enough to have the family comfortable with controlled substances in the home without reinforcing social stigmas. The hospice policy for the use of the drugs and their disposal should be stated in the hospice's printed materials but not necessarily discussed at the initial visit.

(c) (1) *Use of DME* - the DME vendor, not the hospice, should be responsible for the repair and routine maintenance policies and procedures with the hospice responsible for the professional management of the contract.

418.108 Short-term inpatient care

General inpatient care should be appropriate and available to families who are experiencing a short-term crisis of a psychosocial nature as well as for an acute symptom condition that requires 24 hour skilled nursing care. Criteria for the use of GIP and respite should be clearly defined and separate in their requirements as this is a point of misunderstanding by professionals and the public.

(a) *Inpatient care for symptom management and pain control* - The CoPs should retain the requirement that an RN be on-site 24/7 at facilities providing the GIP either as freestanding units or as contracted facilities. GIP, as the most acute level of hospice care, warrants the expertise and care of an RN to monitor pain and symptoms deemed unmanageable at the routine home level of care.

(b) *Respite* - for this level of care, we agree that an RN providing direct care 24/7 is not needed on-site in the facility as respite care is primarily for care giver relief and the patient is usually stable.

(c) (3) A copy of the entire medical record is not needed, only a discharge summary.

418.110 Hospice providing inpatient care directly

(b) *Staffing* - an RN should be on-site 24 hours a day to provide direct patient care.

(o) *Seclusion and restraint* - As stated in *Definitions,* clarification and mutual understanding is needed here. At end of life (EOL), certain medications can be standard treatment to manage

terminal agitation or induce sedation for those experiencing intractable suffering. When certain drugs are used to manage the treatment of a single symptom, it is not the same as using the drug for "restraint." Surveyors who are not expert in EOL care may view such treatment as a drug restraint rather than acceptable practice. As an example, Mrs. S. has advanced cancer and a prognosis of just a few days. She is being treated with high doses of Resperidol for terminal agitation as she has become severely agitated, exhibiting violent behavior toward her family. Her family was extremely distressed by this unusual behavior from such a gentle person. Mrs. S' medication was titrated to treat the terminal agitation and its resulting violent behavior, the symptom was eliminated and she died peacefully with her family at her side.

Surveyors and hospices will have to agree to the definition of "standard treatment" in end of life care in order to assure there are adequate options for symptoms not responsive to conventional treatment.

418.112 Hospice in the SNF

(d) *Medical director* - the requirement for communication between the hospice medical director, attending physician, SNF medical director and other physicians is burdensome and may restrict access to hospice for nursing home residents. The coordination with the SNF medical director, attending physician and other consulting physicians should be encouraged where feasible and when the parties have expressed a desire to be directly involved in the patient's care.

(I) *Orientation and training of staff* - Training of SNF staff by hospice is critical to the care of the nursing home resident in hospice care. However, depending on the number of hospice contracts held by the SNF, it may be impractical for all hospices to be required to provide training without overwhelming SNF staff. Wording should be " 'must assure' orientation of facility staff."

418.114 Personnel qualifications

(c) *(7) Social worker* - there was consensus that the minimum education requirement for a direct care social worker should be a MSW degree as the level of clinical judgement and independence required in the culture and environment of a person's home comes only through experience, education and training. However, a waiver exemption should be afforded where the hospice can show undue difficulty in recruiting a master's prepared social worker.

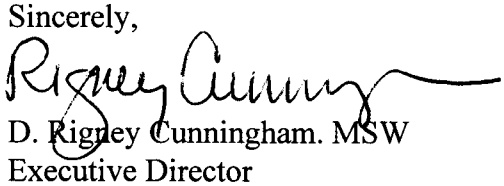
(d) *Criminal background checks* - CORI checks should be required for all direct care hospice staff and volunteers. This is already required by Mass. statute for all direct care staff and volunteers in health care settings.

418.116 Compliance with Federal, State and local laws

(b) *Multiple locations* - see comments on satellites in Definitions (418.3) and Organization and Administration of Services (418.100)

We appreciate the opportunity to offer these comments to CMS on behalf of Massachusetts hospices and hope that the implementation process will move ahead to provide updated, fresh and clear rules to guide care to individuals at the end of life.

Sincerely,



D. Rigney Cunningham. MSW
Executive Director

Comments for CMS-3844-P

Medicare and Medicaid Programs:
Hospice Conditions of Participation

July 13, 2005

"II. Background (pg 30840)
A. The Medicare Hospice Benefit
Hospice care is an approach to caring for the terminally ill individual that provides palliative care rather than traditional medical care and curative treatment. Palliative care is treatment for the relief of pain and other uncomfortable symptoms through the appropriate coordination of all aspects of care needed to maximize personal comfort and relieve distress. **Hospice care allows the patient to remain at home as long as possible by providing support to the patient and family, and keeping the patient as comfortable as possible while maintaining his or her dignity and quality of life.**" (Proposed Hospice Conditions of Participation as published on May 27, 2005)

This explanation of the hospice benefit is designed to set the framework that the rest of the legislation is to build upon. The emphasis placed on patient comfort and dignity resonates through out the entirety of the Conditions of Participation with the exception of the way that outside staffing is handled when dealing with continuous care.

"We believe that the new MMA provision authorizes us to propose that hospices may not routinely contract for a specific level of care (e.g., continuous care) or for specific hours of care (e.g., evenings and week-ends), as these are regularly occurring situations that hospices are able to plan staffing for." Pg 30850

Unfortunately the authors of this passage are incorrect about a hospice's ability to "plan staffing for" continuous care for two main reasons.

Continuous Care Patient Census are Extremely Unstable
According to previous regulations continuous care is only to be given to patients in crisis that need eight or more hours of nursing care per day to be maintained at home. By their very definition continuous care patients are critical unstable patients. It has been our experience that continuous care patients survive an average of three to four days before passing on, and have the habit of going into a periods of crisis which necessitates continuous care at very inconvenient times for their hospice provider. Hence, ***Continuous Care Patient Census Are Not Stable and Are Not Predictable***. A hospice can literally have 6 continuous care patients on Friday, 10 by Saturday, and 3 by Tuesday. Exactly how is a hospice supposed to plan staffing for continuous care patients if they cannot predict how many continuous care patients they are going to have?

Continuous Care Shifts are Generally 12 Hour Shifts
In order to maintain consistency of staff with a patient and their family that is facing immanent death, Continuous Care Shifts normally last 12 hours. In contrast the average routine visit lasts a little longer than an hour making it easy for a hospice to request a staff member to take on an

extra routine visit when the hospice is running short on staff. Obviously it is not possible to request a staff member to take on an extra 12 hour continuous care shifts on top of their previously scheduled routine care visits.

If a hospice is going to "provide support to the patient and family, and keep the patient as comfortable as possible while maintaining his or her dignity and quality of life", they need to be allowed to use any experienced qualified nurses they can find, otherwise you are holding them to a standard that is impossible to live up to unless they use the tools (staffing agencies) that you have forbidden them to use. If the reason for this restriction on the use of staffing agencies stems from anxiety regarding the quality of staff provided by staffing agency than why include the following in the conditions of participation?
"As with all other contracting arrangements, the hospice would be required to maintain professional management responsibility for the service(s) being provided under arrangement as well as the individual(s) providing them. " pg3085
If there is still a question of the quality of care provided by staffing agencies who care for hospice patients, the answer to ensuring quality of patient care is not banning legitimate and needed uses of outside agency such as in the realm of continuous care, but instead overseeing them. Why not survey staffing agencies for the right to see hospice patients? If the staffing agency is enforcing the standards set for in the conditions of participation than your anxieties are eased with a survey, if a staffing agency is not living up to those standards than they can be forced to shape up or stop seeing hospice patients. Either way quality of care for hospice patients is improved and more patients gain access to the care that they need.

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

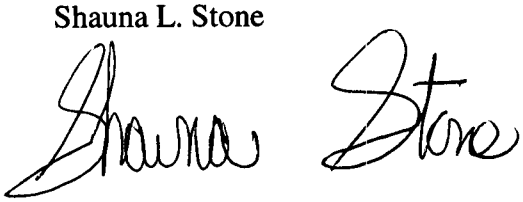
(a) Standard: Serving the hospice patient and family. The hospice must ensure--

- *(1) That each patient receives and experiences hospice care that* ***optimizes comfort and dignity; and***
- (2) ***That each patient experience hospice care that is consistent with patient and family needs and desires.*** " (Sec 418.100)

Unfortunately nurses do not take turns being sick or having family emergencies, and patients do not wait their turn to enter into a period of crisis. If you truly want a hospice to live up to the standards quoted above for all their patients, continuous care patients included, you must find a way to allow hospices access to the quality nurses that they need when they are short on staff, otherwise those standards are simply unobtainable.

Thank you for your time.

Shauna L. Stone



Comments for CMS-3844-P

Medicare and Medicaid Programs:
Hospice Conditions of Participation

July 8, 2005

Patient's Rights – Proposed §418.52
As advocates for hospices and the patients they serve, we continue to be concerned with a disregard for patients in distress. Specifically, the continuous care provisions in the regulations are in dire need of attention, and must be adjusted to become centered on the best needs of the patient.

Regulation 418.80 continues to utilize language so unfortunately vague, that there is a total absence of consistency enforcing the regulation. While we certainly understand the need to insure quality of care when in the patient's home, and most certainly at such a critical time as the last few days/weeks/months of an individual's life, it seems to be incumbent upon us all to always err on the side of patient advocacy.

Therefore, in regards to the above referenced regulation, please allow us the opportunity to address certain terminology contained within.

This specific regulation has always been quoted as the determining guidance for interpretation of extant regulations regarding the ability to utilize outside staffing agencies by a hospice. There are no less than five (5) inconsistencies and poorly defined terminologies involved which create significant confusion resulting in an eventual absence of consistent appropriate care.

418.80 reads as follows:

> *Except as permitted in 418.83, a hospice must ensure that substantially all[1] the core services described in this sub-part are routinely[2] provided directly by hospice employees. A hospice may use contracted staff if necessary to supplement hospice employees in order to meet the needs of patients during periods of peak patient loads[3] or under extraordinary circumstances[4]. If contracting is used, the hospice must maintain professional, financial, and administrative responsibility for the services and must assure that the qualifications of staff and services provided meet the requirements specified in this sub-part[5].*

1. There is a tendency for this provision to be completely ignored. While we will later contend there is no viable reason whatsoever for the majority of core services to be rendered by hospice employees as the remainder of the regulation states clearly the hospice retains full responsibility for patient care regardless of the care-giver's origination, who determines "substantially all"? By any definition imaginable, when a hospice is capable of providing 75, 85, or 95% of all core services, this would meet the level of the greater majority, thus "substantially all". Therefore, when contract is used

for the remaining 5-25%, this burden appears to have been met rendering most of the remainder of the burden irrelevant.

2. The presence of the word "routine" suggests that a hospice be in the practice of providing the levels of care on a constant basis, which is entirely appropriate, and acknowledges the need for extraneous assistance when "routine" is not possible in specific instances. "Routinely", as described in #1 above, can easily be determined to be a majority of patient care, leaving the remainder to whatever means necessary to satisfactorily meet the needs of the patient.
3. "Peak patient loads" cannot be anything less than whenever a hospice has the responsibility to render care to their patients and lack sufficient staff to do so. Many circumstances may contribute to this scenario, including but not limited to in-house staff not being available for personal or professional reasons, family emergencies, personal inability to arrange schedules outside the norm by staff, lack of success in hiring enough staff, staff not accepting the work because it does not fit their understanding of their roles in the organization, the possibility of contributing to extreme overtime which the staff member is unwilling to accept and the hospice is unable to impose, the possibility of abusing a salaried employee's workload, and many other potential situations. It is a substantial difficulty for a hospice to plan for any specific number of patients on any given day, as censuses vary wildly at times. Sometimes when a hospice is successful in admitting additional patients, they can be penalized for being good at what they do. By the nature of the terminology, "peak patient load" seems to indicate there is simply at least one patient need the hospice is unable to staff through their own available in-house staff at that moment. If that situation continues, the hospice is mandated to continue to render services, and yet they are being hindered at being able to procure outside resources to meet the need.
4. "Extraordinary circumstance" has also met with a variety of interpretations, which further lends itself to subjectivity. In a true "patient oriented" definition, this could easily mean a hospice has met with any need it is unable to fulfill within its own ranks. Extraordinary simply means not ordinary. If a hospice can meet 90% (substantially all) of its needs, but on a couple of days a week or a month, the needs exceed the means, "extraordinary circumstance" should be available as an appropriate determination.
5. We all want to ensure the safety and best efforts care rendered to a patient in the last days, weeks, and months of their lives. Listed here are appropriate provisions mandating that a hospice retain responsibility for the level of care provided. A hospice must be held accountable and fully culpable for the actions of anyone placed in a patient's home regardless of the origin of that care-giver. Likewise, a staffing agency providing care to a hospice's patients must adhere to the hospice's policies and procedures, meet all regulatory demands, and provide the hospice with those assurances in the process. This becomes a matter of self-policing on a higher level than even within a hospice's own ranks as a hospice must interview and hire outside agencies with additional care knowing they (the hospice) are accepting responsibility for indirect staff. A hospice is very likely to enter into such an agreement with greater care than if no such precautions were mandated.

Page 30850 of the proposed conditions of participation state:

We believe that the new MMA provision authorizes us to propose that hospices may not routinely contract for a specific level of care (e.g., continuous care) or for specific hours of care (e.g., evenings and week-ends), as these are regularly occurring situations that hospices are able to plan staffing for.

We object to this item on two levels. First, it is addressed in an exceptionally unlikely environment whereas a hospice is expected to be willing to enter into a contract whereby they would be forced to utilize another hospice's assistance to render care. Except as in a circumstance constituting invocation of a hospice's contingency plan, hospices are understandably unwilling to share such information as patient base, referral base, staffing shortages, etc. with another hospice in order to attain this assistance. Secondly, continuous care is a level of care that is significantly more difficult to staff that routine, inpatient, or even respite due to the logistics involved. Therefore, planning ahead for continuous care patients are exceptionally unrealistic in any certain terms. As a former administrator, I tried very hard to always have adequate staff for any continuous care needs, but the fact that on any given day we could have twice as many, half as many, or no patients compared to the previous day made it an ***absolute impossibility*** to maintain a sufficient pool of staff available for this level of care when needed. We can conceivably understand trends in admissions that would lead us to prepare for influxes in overall census, but the fragile nature of continuous care patients, and the appropriate designation of those patients who qualify, versus those who would not, as well as those who would qualify and not accept the care make this prediction impossible.

Page 30851 excludes continuous care from specialized care
because, while time intensive, such care does not require highly specialized nursing skills.

By this exclusion, it is indicated that none of the potential relief offered by the new conditions of participation apply to the needs of continuous care patients when outside staffing is otherwise called for. As described above, continuous care presents an almost insurmountable difficulty in planning and eventual staffing, and must therefore NOT be excluded from any possible relief arising from new conditions of participation. In fact, the argument by experienced hospice administrators is easily made that continuous care should have its own provisions allowing this level of care at any time a hospice is willing to accept the need and the incumbent responsibilities that accompany the necessity.

Page 30874 states:

Core Services (Sec. 418.64)
The proposed rule would allow core services to be provided under contract with another Medicare certified hospice in certain extraordinary or other non-routine circumstances as described, allowing hospices more flexibility. ***In addition, it would allow hospices to contract for highly specialized nursing services, allowing for even more flexibility. The option to contract out for highly specialized nursing services would allow hospices to provide such highly specialized services at a lower cost than if the hospice directly employed individuals to perform such services. We are proposing that hospices that choose to contract for core services or highly specialized***

nursing services must have a contract with the entity providing the contracted services. Negotiating, documenting and signing a business contract is a standard business practice and does not impose a burden.

We are confused with the language here. As written, this CoP indicates that a hospice can contract for core services with another hospice, but later seems to indicate it can contract core services with an "entity" that is not specifically identified here as another hospice. Is it the intent to allow a hospice to contract with an entity other than another hospice for core services, including continuous care (as it is not specifically excluded here) as long as the contract meets standards already declared in previous regulations?

On page 30883 Sec. 418.64 is actually worded as follows:

Sec. 418.64 Condition of participation: Core services.

A hospice must routinely provide substantially all core services directly by hospice employees. These services must be provided in a manner consistent with acceptable standards of practice. These services include nursing services, medical social services, and counseling. The hospice may contract for physician services as specified in Sec. 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.**

It appears the intent is to create a relationship between hospices for assistance with core services. What would be the level of difficulty in allowing a hospice to contract with outside staffing agencies who are also capable and willing to meet all standards of compliance and with whom the hospice is willing to accept the responsibility for the agency's actions as dictated in earlier (and subsequent) notes? Should the hospice be limited where they can obtain trained and qualified assistance needed when they must also accept the liabilities, accountabilities, and culpabilities for a staffing agency's actions?

Page 30887 reiterates the standards relating to the host hospice's responsibility in a contractual arrangement:

(e) Standard: Professional management responsibility. **A hospice that has a written agreement with another agency, individual, or organization to furnish any services under arrangement, must retain**

administrative and financial management, and supervision of staff and services for all arranged services, to ensure the provision of quality care. Arranged services must be supported by written agreements that require that all services be--

(1) Authorized by the hospice;

(2) Furnished in a safe and effective manner by personnel having at least the same qualifications as hospice employees; and

(3) Delivered in accordance with the patient's plan of care.

We continue to support the need for the hospice to retain ultimate responsibility for the care and case management of the patient, and these provisions are entirely sufficient to create an environment of careful selection of outside resources by a hospice.

The following items must be addressed due to their conspicuous absence in the proposed conditions of participation;

There exists a contradiction in who may provide contracted care-givers within the medical community. For instance, an automobile accident victim may enter the emergency room and be tended by contracted registered nurses. An emergency room physician on contract may determine surgery is necessary, whereby the patient is moved to the operating room to have surgery performed by another contracted physician, more contracted nurses, and even possibly an anesthetist who is not an employee of the facility. The **entire process** is conceivably carried out by staffing agency personnel. However, when a terminally ill patient is on his or her death bed and palliative care is necessary, there are regulations preventing qualified nursing staff (from a staffing agency) from rendering that care. Also, there are provisions wherein many cases volunteer nursing staff may perform services such as continuous care, but not trained nurses hired from an established staffing agency. At present, there are holes whereby the volunteers are not even scrutinized by full background and criminal history checks. Staffing agencies must meet standards the hospice must adhere to, and these checks will be performed. We continue to encourage CMS to consider that allowing staffing agencies to assist allows in the process much greater and more direct observation, supervision, and regulatory consistency by the governing and surveying entities involved.

Additionally, it must be remembered that a hospice has little or nothing to gain financially by employing a staffing agency for care. In fact, the point can be made that staffing agency costs are prohibitive, and will be used sparingly and only after all attempts to locate in-house (and less expensive) staff has failed.

We implore CMS to consider the needs of the patient to include the utilization of qualified staff wherever they may originate from. We would gladly offer ourselves as available for scrutiny if CMS would like to appoint some form of inspection/survey on our own program. We want to offer only care that meets standards of quality the terminally ill patient deserves, and have spent many, many hours refining policies, orientation, and training that generally far exceeds that of the host hospice themselves. We welcome the survey process perhaps as part of the

survey on the host hospice, and indeed many times surveyors have requested quite specific items related to our services in continuous care. If we are deficient, we expect to be held accountable, and would earnestly endeavor to improve when necessary. As patient advocates, we strongly urge CMS to grant us (and other qualified agencies) the opportunity to prove the value of such a service as ours, and not simply dismiss this program without first giving us an honest prospect of proving the benefits we offer the patient and the hospice.

July 22, 2005

Response to New Cops for Hospice Care

Subpart A- definitions
No comment.
Subpart C- Patient Care
418.52 Condition-Patient's rights
418.53 Standard (a)(1) Notice of rights
Pts Rights should be in a language they understand. As far as an interpreter the family or caregiver usually are too distraught to interpret, they are learning at the same time. Repeating of rights through out the care process and recorded as verbal understanding would be more effective. Of course leave a copy of the rights and have them sign on admission that they received it. A brief summary should be the extent on admission. There is too much information and questions for anyone in these circumstances to retain everything.
(3) I agree the hospice should inform the patient and family of their drug policy and procedures on admission packet/Plan of Care.
(b) a person should be allowed to refuse treatment.
(e) The patient should be warned of their liability.
418.54 Condition – Comprehensive assessment of patient

(a) Initial Assessment- The Hospice RN must make an initial assessment within 24 hrs after the hospice receives an order. This is not enough time. This would create a difficulty in coordinating times with some family members involved with decision making . There should be a 2-3 day window. If over 2 days documentation of why so long maybe. (Such as the example above).
(b) The only other discipline that could do an initial assessment could be a Social Worker due to the expertise of the grieving process and coordination of Durable Medical Equipment and other resources she is familiar with. The problem with this is a Social Worker is not as familiar as the Nursing staff with pain regimes and can't do the physical assessment.
(c) To request a date from the family could be a simple request in time that meets the constraint of everyone involved.

Standard © content of the comprehensive assessment. CMS should not require a specific form.
Standard (d) Update of the comprehensive assessment. Each hospice can design their own form.
Standard (e) Patient outcome measures- a good idea more thought needs to be put into this to for take the outcome measuring system.
418.56 Condition- Interdisciplinary group care planning and coordination of services
Standard (a)Again the RN should be the one for the medical assessment and the Social Worker for the psychosocial alone or with the RN.
Standard (b) Plan of care- Hospice must include the family in the plan of care. Yes
Standard © Content of plan of care. I think the word understanding is better.
Standard (d) Review of the plan of care-Added language is unnecessary.
Standard (e) Suggestion. An interdisciplinary meeting once every 28 days with all of team members and family invited. Once a week smaller meetings with two to three members of the team once a week.
418.58 Condition- Quality assessment and performance improvement-
Standard (a) Program scope- I agree
Standard (b) Program data- More thought needs to be put into how to measure.
Standard ©- Program activities. I agree that hospices should continue to prepare to meet this requirement but is not quite ready yet.
Standard (d) Would have to tract hours after implementing. May have to add more Quality Improvement staff.

418.58 condition
Standard (e) Executive responsibilities- They should delegate and monitor and provide feedback to the QI person or persons on the projects.
418.64 Condition-Core Services
Standard (d)(1) The families are provided in the Nursing Homes the same as in the patients home. As far as the staff of the Nursing Facilities, it depends on how receptive that facility is. There could be support groups or time set aside with the Hospice team for individual discussion.
(2) Nutritional counseling has been expanded. Good!
418.72 condition-PT,OT speech-language pathology. Dietitians be added to this section as a non-core service. I agree.
418.74 Condition-waiver of requirement- I agree
418.76 Condition – Home health aide and homemaker services.
Standard (g)(2)(i)I agree, no need for a separate order.
(h) Supervision of Home Health Aides. Good change here! 28 days is better, yet the Nurse and Supervisors can have a handle on what the aide is doing.
Standard (j) Homemaker qualifications-I agree with the standard.
SUBPART D – ORGANIZATIONAL ENVIRONMENT
418.100 Condition Organization and administration of services
Standard (a) Serving the hospice patient and family –
Standard (e)I agree with "by qualified personnel
Standard (f) Hospice satellite locations- I agree
418.102 Condition- Medical director. No
Standard (b) Recertification-Expectations of family may not be realistic but identified.
Standard © Coordination of medical care . I agree it would be too difficult.
418.104 Condition-Clinical records
Standard (a) Content. (Electronic Health Record) Has advantage of information being transported quickly. It will be expensive and some employees are not receptive to computers yet. It is the way to go though.
Standard (b) Authentication. I think it can be implemented. I think it should include physicians, Not necessarily Nursing Homes, they may not be computerized yet or infusion vendors.
Standard © Protection of information. Has to be followed.
Standard(d)- Retention of Record- Records to be kept 6 years-ok
Standard(e)Discharge or transfer of care. The whole medical record it too cumbersome. The H&P or discharge summary, (initial assessment and last assessment), all medication. Maybe a Summary from each discipline of the team.
418.106 Controlled drugs in the patient's home- The word collecting could be interchanged with dispensing.
Standard © use and maintenance of equipment and supplies. I agree with re-writing it.
418.108 Condition_ Short-term inpatient care I agree it should be available for psychosocial/family crises.
Standard (a) Inpatient care for symptom management and pain control. I believe the verbage should be certified and an RN on duty requirement and LPN/LPN.(for inpatient not respite)
418.110 condition- Hospice that provide inpatient care directly .
Standard (a) I agree with standard
Standard (b) Twenty-four hour nursing service. Not for respite
Standard (f) Pt rooms. No comment
Standard (l) I agree with standard

Standard (o) I think Hospices should be an exception WHEN USED FOR TERMINAL RESTLESSNESS. All of the Hospice patients are terminal, death on these meds are likely to happen frequently.
418.112 Condition
Standard (d)- Medical director No , the facility medical director does not always provide the care to hospice patients. The primary MD does also.
418.114 Condition
Standard(b) ?
Standard © I agree
(7) Social Worker. I think one year of experience in the health setting should be required and with a baccalaureate.
Standard (d) Criminal background checks . Don't remove.

Thank you,

Sandra E. Miller, RN

July 18, 2005

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

Dear CMS Representative,

I fully support the CMS's move toward quality initiatives and related accountability. I share the vision of quality care provided by accountable professionals at the lowest possible cost to all Americans. After all, I may need that care some day and the CMS, through quality initiatives, creates the base from which I will be advocated for.

Relying on my ten years as a hospice field worker and manager, I have created the following comments to point to where proposed changes are contradictory to our shared vision. Based on my experience and where applicable, I have not simply criticized, but have offered alternatives to proposed changes. I consider these alternatives to be more supportive of the Conditions in their practical application because they strengthen rather than detract from essential elements of quality hospice care.

Thank you for consideration of my comments. Keep up the good work.

Respectfully Submitted,

Steve Janes
P.O. Box 361
Gallatin Gateway, MT. 59730

Comments Re: CMS-3844-P (Hospice Conditions of Participation)

CMS introductory statements paraphrased and numbered for reference in comments:

1. "...focus on the care delivered to patients and their families."

2. "...reflect an interdisciplinary view of patient care and allow hospices flexibility in meeting patient standards."

3. "...efforts to achieve broad-based improvements in the quality of health care."

4. "...to focus on a patient-centered, outcome oriented process that promotes patient care foremost, rather than penalizing unproductive providers."

5. "...to achieve a balanced regulatory approach by ensuring that hospice furnishes health care that meets essential health and quality standards."

6. "All of the revised requirements are directed towards improving patient outcomes of care and satisfaction."

7. "...this problem focused approach has inherent limits. Ensuring quality through the enforcement of prescriptive health and safety standards, rather than improving the quality of care for all patients, has resulted in our expending much of our resources on dealing with marginal providers, rather than on stimulating broad-based improvements in quality care."

8. "...adequate to protect the health and safety of individuals under hospice care and to promote the effective and efficient use of Medicare funds."

9. "Use a patient-centered, interdisciplinary approach that recognizes the contributions of various skilled professionals and other support personnel and their interaction with each other to meet the patient's needs."

10. "Use performance measurement systems to evaluate and improve care."

418.54 COMPREHENSIVE ASSESSMENT OF THE PATIENT

(a) A "within 24 hours" requirement is made in disrespect of patient rights. Many patients, after their physician requests hospice services, do not want a visit from hospice within 24 hours due to a number of reasons, from simple convenience to wanting other family members present (who otherwise cannot be present within that time frame) during the initial hospice visit. In the latter example, having family members present helps the patient garner needed support and helps the hospice do a

comprehensive assessment, the basis for formulating an adequate care plan and thereby meeting the patient's and family's needs. Also, many hospices, due to practicalities, may not be able to adequately meet this requirement (i.e. a small rural hospice with one RN who has received 2 or more orders for hospice on one day. It does happen). **Alternative:** Have hospices monitor a quality standard around timeliness in meeting patient needs at the start of care, with the expectation that hospices having problems in these areas be able to demonstrate improvement in providing hospice services to beneficiaries in a timely fashion. Refer to CMS introductory statements 4, 6, 7 and 10.

(b) A "no later than 4 calendar days" requirement would cause hospices to push patient assessments through the system at a rate that would not allow for adequate interdisciplinary team (IDT) processes. If CMS is truly supporting the interdisciplinary approach that works so well in the provision of hospice care, it will take a closer look at this requirement. Weekly IDT meetings are usual within hospices because of practical scheduling reasons. This standard and the CoP's in general should reflect the practical matter of calendars and scheduling, otherwise splintering of the holistic approach to hospice care is likely to occur. **Alternative:** Replace the 4-day requirement with a standard of 7 days. Refer to introductory statements 2, 5, 7 and 9.

(c)(3)(ii) Some hospices have suggested that this only refer to medications related to the hospice diagnosis. This should include distinguishing language to make it clear that *all* medications are reviewed to be consistent with professional standards as well as management and oversight language found elsewhere in the Conditions. Refer to introductory statements 1, 3 and 8.

(d)(1) The 14-day requirement is again a digression from a CMS stated goal to move away from "Enforcing structure and process requirements," that have "...been inadequate to meet the growing challenges associated with the changing hospice care environment." For practical reasons, the ultimate effect of this requirement would be a detriment to our highly valued and effective team functions in the care of hospice patients. It would likely result in rubberstamping of assessments by team members and the fragmenting of team processes. If CMS is going to realistically move toward ..."outcome-oriented standards," they are going to have to rely on quality measures and provide reasonable time frames that support rather than detract from team processes and patient-centered care. **Alternative:** Require that hospices maintain ongoing documentation of comprehensive assessments at frequencies based on patient needs and in respect of patient rights, that care planning be based on ongoing comprehensive assessment, and that care plans are reviewed by the IDT within 7 days of a change in condition warranting changes in the plan of

care and no less than every 30 days. This allows for adequate interdisciplinary processing and leeway for holidays that can bump IDT meetings by a day or two. Refer to introductory statements 2, 4, 6, 7, 8, 9 and 10.

418.56 IDG PLANNING AND COORDINATION OF SERVICES

(a)(1)(iv) The CMS should leave this language alone. I agree with the narrowing of the counselor definition to spiritual care because it was too broad previously. The members listed here represent the core concepts in providing holistic hospice care. The only other addition could possibly be Bereavement Counselor, to be in line with the comprehensive assessment requirement that includes ongoing bereavement assessment, but only under a condition of when that role is *not* being filled by one of the disciplines already listed.

(d) An alternative to the 14-day requirement is already stated above. I agree with the language about collaboration with the patient's attending physician, *if* that is what the patient wishes. The maintenance of this relationship can be important for the physician as well as the patient.

418.58 QUALITY ASSESSMENT AND IMPROVEMENT PROCESS

Quality Improvement is an important process no matter what the latest acronym for it is and I whole-heartedly support the CMS movement towards it and outcomes and away from rules that don't always make practical sense.

(e) I am comfortable with the Governing Body's role in Quality Improvement and outcome measurement.

418.76 HOME HEALTH AIDE AND HOMEMAKER SERVICES

(g)(2)(i) This process should be more fluid and require IDT approval vs. physician order for these services. This would allow more efficient and timely provision of hospice services to beneficiaries. See introductory statements 2 and 9.

(h)(i) The CMS is moving toward quality measurement and improvement. If Home Health Aide quality indicators for a hospice are favorable, the hospice is assessing Home Health Aide competency, and the patient is satisfied with Home Health Aide services, why would point of care assessments of aides be necessary much less have a time frame associated with them? The CMS appears to once again be drifting from its vision of moving from structure to quality measurement in regards to this standard. **Alternative:** Require hospices to measure home health aide outcomes and

patient satisfaction, and demonstrate improvement when there are substandard results. See introductory statements 1, 3, 4, 5, 6, 7, 8 and 10.

418.100 ORGANIZATION AND ADMINISTRATION OF SERVICES

(a)(2) What patients and their families "desire" are often contradictory with one another (i.e. the Schiavo case). Because of this I suggest striking "and desires" from this language. Hospices can assess and address the needs of patients and their families and work toward (as we often do) aligning "desires" when they are different.

(e)(2) I can think of several examples where this would be impossible to fulfill, from a practical point of view, especially in rural settings. I suggest these proposed language changes: supervisory responsibility for "services" (vs. "staff") and "by qualified personnel," vs. "personnel having at least the same qualifications as hospice employees."

418.102 MEDICAL DIRECTOR

(c) I have no issues with having the medical director in charge of the hospice quality program. With movement of the CMS and health care in general towards quality initiatives, I think the medical director quality association is logical and necessary. If CMS and hospice is going to move in this regard, the effort of hospices to incorporate *involved* medical directors, even in rural settings, will be a worthwhile effort in the long run.

418.104 CLINICAL RECORDS

(b) With advances in technology for communication of orders, prescriptions, etc. this is a reasonable standard. The question I have is: even with signature files, how do we realistically accomplish it?

418.106 DRUGS, CONTROLLED DRUGS AND BIOLOGICALS, MEDICAL SUPPLIES, AND DURABLE MEDICAL EQUIPMENT

(c)(1) When under contract, the vendor must assume responsibility for repair and routine maintenance. Language here should reflect that.

418.108 SHORT-TERM INPATIENT CARE and
418.110 HOSPICES THAT PROVIDE INPATIENT CARE DIRECTLY

General Comments: I think there should be a revision of these standards and established levels of care and associated reimbursement to distinguish between inpatient care that, 1) is required for symptom control or, 2) is required when the care needs are too complex or otherwise beyond that routinely provided at SNF's, and care that can be routinely provided in SNF's. In my community, SNF placement is not appropriate for most symptom management issues, or when care needs are great or complex.

Nursing requirements should follow suit. For care described in 1) and 2) above, the nursing requirement should be 24-hour RN, regardless of location. Anything else is a substandard level of care. Reimbursement should be commensurate.

The 24-hour "nursing" requirement, RN or LPN/LVN, would be appropriate for a lower level of care and should be associated with a lower level of reimbursement, but not that of the Respite level of care. Why do you think hospices rarely use this level of care and contract with nursing homes for GIP?

CMS should take a closer look at hospice practice in regard to GIP and Respite level of care utilization. I think too many hospices are drawn toward contracting with SNF's for General Inpatient level of care, and I am skeptical in regards to whether or not the level of care provided is worthy of the reimbursement. Therefore, I think the terms "General Inpatient" and "Respite" and their associated reimbursement should be re-evaluated and a more adequate system of identifying levels of care be developed.

In regards to the newly proposed Conditions, I believe the 24-hour "nursing" vs. 24-hour RN is a lowering of the standard that should not be implemented.

418.112 HOSPICES THAT PROVIDE HOSPICE CARE TO RESIDENTS OF A SNF/NF, ICF/MR, OR OTHER FACILITIES

(e)(4)(iii) I suggest changing "life threatening condition" to "a change in condition," to more adequately reflect the hospice care situation.

418.114 PERSONNEL QUALIFICATIONS FOR LICENSED PROFESSIONALS

(a) This proposed change is good in concept, but not in practicality when considering variations in state law. The State of Montana only requires licensure at the MSW level for social workers. Therefore, implementation of this rule would require Montana hospices to hire only masters prepared social workers. This would put an undue strain on hospices in rural parts of the state where MSW's are not readily available and is therefore impractical. Other states allow licensure of non-School of Social Work graduates. Therefore, under the proposed rules, these inadequately prepared individuals could practice hospice social work, lowering the standard of care for beneficiaries. **Alternative:** remove licensure language in regard to social work and retain the current standard that requires at least a Bachelors prepared social worker from an accredited school of social work.

Comments for CMS-3844-P

Medicare and Medicaid Programs:
Hospice Conditions of Participation

June 27, 2005

Patient's Rights – Proposed §418.52
Proposed **§418.52** states:

> © *Standard: Pain management and symptom control.* The patient has a right to receive effective pain management and symptom control from the hospice.
>
> It is also stated on page 30844 of the explanation section that, "We are proposing to specify that the patient must also be informed about factors that affect palliation and comfort."

I am very glad that you are addressing the very real concern that critically ill hospice patients and their loved ones have about pain management and patient comfort, especially in the last stages of a terminal illness. I think this is a wonderful concept, but I do have some concerns. Does it go far enough to ensure that all hospice patients are informed of their continuous care benefit rights? Also, will it guarantee that all patients who qualify for and want their continuous care hospice benefit receive the care they need?

Since the purpose of hospice is to allow the terminally ill patient the ability to die with dignity at home, surrounded by loved ones, is seems to be contradictory to force hospices into a no-win situation. If a dying patient as a condition that warrants continuous care, and the hospice does not have the staff to provide that level of care, the hospice must (1)- deny continuous care, and force the patient's loved ones to try to deal with the critical situation alone (2)- force the patient into the hospital to die – away from friends and family; or (3)- use qualified agency nurses to provide the care, which the new CoPs clearly state is not allowed.

Conditions of Participation: Core Services
Proposed §418.64

Why not? Why can the hospice contract almost every other specialty nursing service except for continuous care? According to the explanation on page 30851 of proposed CoPs §418.64(b), continuous care nursing "does not require highly specialized nursing skills". I must respectfully disagree with that statement. To be able to sit for 12 hours at a time, with a terminally ill and probably actively dying patient, probably need to assess the pain level of an unconscious patient and administer appropriate pain medication, help the patient's friends and family handle the emotional stress and grief of watching a loved one pass away, and be calm, caring and professional throughout – that is not something every nurse can do. It is not even something every hospice nurse can do. It requires a special person, with very specialized nursing skills. Continuous Care nursing should be

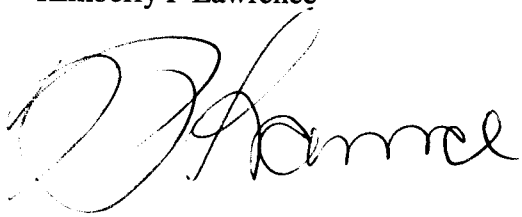
classified as the specialized skill that it is, and thusly allow hospices to use contract nurses to fill this vital role.

Also at issue in the explanation of Proposed §418.64 is the statement, "We believe that the new MMA provision authorizes us to propose that hospices may not routinely contract for a specific level of care (*e.g.*, continuous care) or for specific hours of care (*e.g.*, evenings or week-ends), as these are regularly occurring situations that hospices are able to plan staffing for." I do not understand how a hospice can plan for continuous care. Since continuous care is warranted only when a patient's symptoms become uncontrolled, for example, severe pain, unrelenting nausea and vomiting, acute respiratory distress, etc., continuous care, by its very nature, is unpredictable. How can a hospice be expected to predict when a patient will experience break-though pain or go into repertory distress? How can they predict how many of their patients might have these issues at the exact same time? While I agree that the hospice can and should have staff available to handle their AVERAGE continuous care patient load, it is unreasonable to expect them to be able to plan for and schedule patient crisis situations. The costs of maintaining employees on staff to handle potential peak patient load situations is simply too cost prohibitive. Is it really reasonable to ask a hospice to pay 2-4 extra permanent staff nurses every day for a situation that may only happen once or twice a week, or a month?

By agreeing that continuous care nursing is a specialized skill and allowing hospices to use contract staff when they experience peak patient loads, you will take great strides in insuring that all hospice patients receive the level and quality of care that they deserve. After all, it's all about allowing these terminally ill patients the right to die with dignity, in their own homes, surrounded by the one's they love.

Thank you for your time and consideration.

Kimberly P Lawrence



617-637-8556

Kimberly@ccsnationw.de.com

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Calvert Hospice

Life, healing, hope.

July 22, 2005

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Ave., S.W.
Washington, D.C. 20201

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

Dear Administrator McClellan:

Calvert Hospice appreciates that the Centers for Medicare and Medicaid Services (CMS) has published proposals for revisions of the Conditions of Participation for hospice and takes this opportunity to comment on the Notice of Proposed Rulemaking, 70 *Fed. Reg.* 30840. Calvert Hospice endorses the comments of the National Hospice and Palliative Care Organization (NHPCO) and the Hospice Network of Maryland (HNM). Nonetheless, as a small hospice in a rural county in Southern Maryland, we would like to point out that some of the proposed conditions would impose significant hardship on our operations.

1. DEFINITIONS
   (a) ***Attending Physician*** - We strongly urge CMS to include specifically include in the definition of Attending Physician that the Hospice Medical director may serve at the patient's Attending Physician. Our patients in Calvert County receive care from many physicians through the Washington, D.C. metropolitan area, the Baltimore metropolitan area, Annapolis, and surrounding counties. Often they do not have a conveniently located local physician that the Hospice team may contact for orders and to sign the death certificate. Given that the number of physicians in the county is limited, it can be very useful if the Hospice Medical Director, a local internal medicine practitioner, can be named as the patient's Attending Physician.

   (b) ***Drug Restraint*** – We support the comments of NHPCO on this point. Appropriate treatment of a terminal condition may include therapies that, in other contexts, might be viewed as "drug restraint." We urge CMS to modify this definition as recommended by NHPCO.

2. PATIENT'S RIGHTS

P.O. Box 838 • 238 Merrimac Court Prince • Frederick, MD 20678
(410) 535-0892, (301) 855-1226 • (410) 535-5377 (fax) • 1-800-735-2258 for the hearing impaired
www.calverthospice.org

(a) ***Exercise of rights and respect for property and person*** - We encourage CMS to adapt the regulatory language currently used for home health agencies in place of the formulation proposed which has been adapted from the skilled nursing facility regulations.

3. COMPREHENSIVE ASSESSMENT

(a) ***Initial assessment*** - The proposed regulations prescribe that the "hospice registered nurse must make an initial assessment within 24 hours after the hospice receives a physician's admission order for care (unless ordered otherwise by the physician). . . ." Because the notion of "admission order" is new to hospice, Calvert Hospice suggests that this provision be re-cast to prescribe an initial nursing assessment within 24 hours of the patient's admission to hospice, thereby encompassing the physician's certification of the patient as appropriate for hospice care and the process of admitting the patient at a time convenient for the patient and family.

(b) ***Time frame for completion of the comprehensive assessment*** – The proposed conditions establish at best a confusing process, and, at worst, an unworkable one. The assessment process leading to the development of a plan of care should consist of patient-centered, face-to-face assessments by a nurse, social worker and other hospice team members as appropriate. The four day time limit is insufficient to accomplish this most important task.

4. INTERDISCIPLINARY GROUP

(a) ***Approach to service delivery*** – Calvert Hospice would note again its comment at Item 1(a) above regarding the patient's Attending Physician. It is often not the case where the patient's Attending Physician and the hospice Medical Director are different individuals. Thus, Calvert Hospice urges CMS to eliminate the parenthetical phrase in proposed §418.56(a)(1)(i).

Calvert Hospice would also request that CMS return to the statutory language in §418.56(a)(1)(iv), so that the regulation would require a "pastor or other counselor."

5. VOLUNTEERS

(a) ***Level of Activity*** – Calvert Hospice urges CMS to adopt the revisions recommended by NHPCO and delete the addition of the phrase "day-to-day" in modifying "administrative" volunteer activity. The addition of "day-to-day" is confusing and should be eliminated.

6. ORGANIZATION AND ADMINISTRATION OF SERVICES

(a) ***Professional Management Responsibility*** – As proposed, the obligation to ensure supervision of staff of agencies with which hospices have a written agreement is

unworkable. The hospice should be responsible for the oversight of the services provided and not the direct supervision of staff. This responsibility should be included in the written agreement with contracting agency, so that it, not the hospice, is directly responsible for the overall supervision of staff and the hospice remains responsible to the patient and to Medicare for the provision of the service.

7. MEDICAL DIRECTOR
   (a) ***Coordination of Medical Care*** – Calvert Hospice opposes the proposal to make the Medical Director responsible for directing the hospice's quality assessment and performance improvement program. The Medical Director has no special expertise regarding the identification of appropriate outcome measures, data elements, collection strategies or aggregation techniques. As the Medical Director is, in our hospice, a volunteer, it is surely an inappropriate utilization and waste of valuable resources to require that this member of the team perform this administrative role.

8. CLINICAL RECORDS
   (a) ***Authentication*** – CMS appears, once again, to be using an inappropriate model in crafting the proposed language. Hospice patients are cared for directly by hospice staff and by staff of agencies with which hospice has a written agreement. It should be sufficient for the contracting agency to have verified the signature and certify to that verification by contract rather than imposing the extraordinary administrative burden on the hospice to verify the signature of every physical therapist, respiratory therapist, nursing home aide or nurse who may offer treatment to the patient while he or she is under hospice care.

   (b) ***Discharge or transfer of care*** – Sending a complete copy of a patient's record to the Attending Physician or to the next facility is an extraordinarily onerous requirement for both the originating hospice and the receiving entity. Discharge orders, history and physical and medication profile should be sufficient. Even if all hospices had the funds to invest in electronic recordkeeping (as CMS is aware most do not), such duplication of data is unnecessary.

9. SNF/NF
   (a) Calvert Hospice has spent many years working with the two local SNFs in our service area to achieve a workable relationship integrating the roles of the staffs of both agencies to provide hospice care for the facilities' residents. The proposed regulations, without corresponding changes in the SNF/NF regulations, will virtually ensure that these efforts will have been for naught. Unfortunately, these provisions elevate hospice in an inappropriate way over the staff of the facility and, because there is no requirement that SNFs refer dying patients to hospice, will succeed in denying nursing home patients the services of hospice in their last days. Hospices

and SNFs are partners in the care of their patients, jointly developing care plans, jointly ensuring the best care for the patients and families. The proposed regulations should ensure that this equal partnership can be maintained.

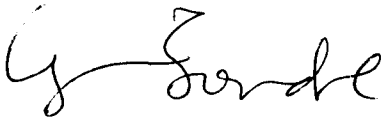
(b) ***Written Agreement*** – Calvert Hospice would note that it is inappropriate for the written agreement between hospice and the facility to include the written consent of the patient or patient's representative. Perhaps it would be appropriate for CMS to require that the contract to include a provision that the hospice obtains the written consent of the patient or patient's representative as required by the conditions of participation.

In addition, rather than specify the conditions under which the facility immediately notify the hospice, it would be more appropriate for the contract to include a provision that the facility and hospice to develop and document a plan of communication that would ensure that the hospice is notified regarding any change in the patient's condition that would require alteration of the plan of care (including a transfer of the patient from the facility).

CONCLUSION

As noted, Calvert Hospice endorses the comments submitted by the NHPCO and urges CMS to incorporate the changes recommended by NHPCO, as well as those few additional suggestions we have offered, into the final version of the regulations.

Sincerely,



Lynn Bonde
Executive Director

18

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Email: hospice@hospiceslv.org

July 22, 2005

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

Dear CMS:

I am writing to comment on the proposed rules for the Hospice Conditions of Participation.

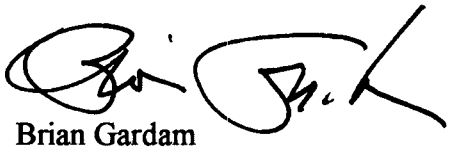
I am supportive of the intent of many of the proposed changes, but have concerns about some areas.

1. It would be a positive step to allow for a "qualified health care professional who is a member of the interdisciplinary group" to coordinate a patient's care, rather than restricting this role to a registered nurse, as under the current Conditions of Participation (Section 418.56). For many patients, psychosocial issues are paramount, and it would be appropriate to assign case management to a social worker rather than a nurse.
2. The emphasis on quality assessment and performance improvement is in accord with efforts taken by the National Hospice and Palliative Care Organization and hospices throughout the country. As described in your proposal, hospices would have flexibility in designing their particular performance improvement approach. I urge the standards be designed so that they can be scaleable to the size of the hospice (Section 418.58).
3. The requirement for hospices to track and collect controlled drugs would be unduly burdensome and risky for hospice nurses serving patients at home. Our nurses do oversee the amount of drugs being used, and take steps to reduce the possibility of diversion. However, the drugs belong to the patients, and we cannot monitor them 24 hours a day. Moreover, it would be dangerous for it to become known that Hospice staff sometimes collect and transport controlled substances. (Section 418.106(b)).
4. Throughout the proposed rules, there are increased duties proposed for the medical director. Most smaller hospices have part-time medical directors, who are in some cases volunteers. The requirement for the assumption of responsibilities currently carried out by other members of the IDG, such as communication with the attending physician for all patients in an SNF

(Section 418.112(d)) would pose problems for smaller hospices in recruiting and paying for additional hours of the time of a medical director.

Thank you for your attention to these concerns.

Very truly yours,



Brian Gardam
Executive Director

Sharon Mezzina RN
6130 60th Court
Vero Beach, Fl. 32967
smezzrn@yahoo.com
July 16, 2005

Center for Medicare & Medicaid Services—file CMS-3844-P,

I am a Certified Hospice and Palliative Care nurse and a Registered Nurse. I work at the Visiting Nurses' Association (VNA) Hospice House in Vero Beach Florida. Our unit is a free standing, 12 bed in-patient unit that serves the residents of Indian River County. I am also a student at Florida Atlantic University pursuing by advanced degree to become a nurse practitioner.

I am writing about the Proposed Rule: Medicare Hospice Benefit Conditions for Participation. I would like to encourage CMS to adopt the proposed definition of "attending physician" as stated in the proposal which includes the nurse practitioner. It is my understanding that the newly adopted definition will be listed in Section 418.114 under personnel requirements.

Nurse practitioners are uniquely qualified to be Primary Care Providers. Most people trust nurses and it is this trust that creates a strong relationship between the patient and the nurse practitioner. Nurse Practitioners have the caring perspective as nurses to see the patient as a whole being and they have the expertise to be the Primary Care Provider.

The Primary Care Provider is in an excellent position to discuss and obtain advance directives from patients signing onto hospice services. Securing these documents early in the patient's illness allows the Nurse Practitioner and nurses to maintain patient's rights through the illness and the dying process. Once these decisions are made, the patient can transition through a "good death" which is the backbone of the hospice philosophy.

Instating the nurse practitioner under the definition of "attending physician" allows them to provide continuity of care. For some citizens in rural areas, the nurse practitioner is the only practitioner they have available. They are highly skilled, qualified, knowledgeable and superb patient advocates. The proposed rule has clearly stated it wants the Conditions of Participation to be patient-centered, patient oriented; a job for patient advocates and nurse practitioners.

Please adopt the proposed definition of "attending physician" to include Nurse Practitioners.

Thank-you for time and consideration.

Respectfully,
Sharon Mezzina RN, CHPN
Sharon Mezzina RN, CHPN

20

A nonprofit organization dedicated to patients and families facing serious illness and loss

July 21, 2005

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

Dear Sir/Madam:

Thank you for this opportunity to comment on the Medicare and Medicaid Programs: Hospice Conditions of Participation, Proposed Rule that appeared in the Federal Register on May 27, 2005. Hospice Care, Inc. is a non-profit organization, established in 1978, serving over 40 communities in the greater Boston area. We are an affiliate of the Visiting Nurse Association of Boston Foundation.

I would like to say that I appreciate the amount of time and energy that has gone into this effort. And I commend Mary Rossi-Coaju and Danielle Shearer for all their work. Their presentation in Baltimore was well done and very comprehensive. I give them a lot of credit for facing an audience of 100+ hospice managers/executives with such poise.

In general, I have found the new organization of the proposed CoPs helpful and more user friendly. For the most part, the new standards are consistent with the hospice community's interest in assuring quality and encouraging a greater degree of uniformity. Attached you will find comments on those standards which, as a result of group review, we feel need further clarification or where the standards may seem to pose implementation difficulties. In addition, I have **highlighted our priority issues in bold type.**

Thank you for your attention to this matter.

Respectfully submitted,

Diane M Bergeron, RN, MSM
Executive Director

41 Montvale Avenue, Stoneham, MA 02180 • Phone: 781/279-4100 • Toll Free: 866/279-7103 • Fax: 781/279-4677
Hospice Care, Inc. is an affiliate of the Visiting Nurse Association of Boston Foundation

Proposed CoPs: file code **CMS-3844-P**

418.3 Definitions

Clinical note: **recommend** 'spiritual' be added to "any changes in physical, *spiritual* or emotional condition"

Drug restraint: **request clarification**, as some medications may be viewed as a chemical restraint in many instances, whereas in hospice the medications are likely being used for customary end-of-life treatment not as a restraint. **(Please see attachment I, our pharmacist addressed this in detail).**

Hospice Care: **consider** the inclusion of '*hospice is a comprehensive set of services* ***provided in the home, in the community and in facilities****, identified and coordinated by an interdisciplinary team…'.* It seems that there are an increasing number of Long Term Care facility based hospice programs that **only** provide hospice services to the residents of their facility and not in any other venue. I must say it is rather frustrating.

418.52 Patient's Rights

(a) Notice of Rights (1) *Translation*: **written/printed** requirement for translation of multiple languages would be a very expensive proposition, likely beyond the financial ability of most agencies. Oral **or** written notice would be more reasonable.

(a) Notice of Rights (3) *Tracking & disposing of controlled substances*: all the information that is currently given and discussed at admission is confusing and/or frightening enough no matter how we try to simplify the process. And the stigma attached to 'controlled substances' can be unsettling at best even in these circumstances. I would suggest that it is better to introduce the concept, if and when, a 'controlled substance' is added to the plan of care. That is not to say that the information should not be included in the patient/family admission packet.

(a) Notice of Rights (4) ***demonstrated:*** **please elaborate**; i.e. documentation of nod of head, verbal agreement or must the patient/family sign a document?

(b) Exercise of Rights (1) *Patient right*: would suggest adding (v) ***the right to refuse treatment***

(b) Exercise of Rights (4) *Hospice must:* recommend adding *'within 5 working days of the* ***discovery*** *of the incident'*

(e) Patient liability: Use of ABN in hospice is still rather confusing, request further clarification. Should 'patient' = primary caregiver/family, in certain circumstances, when the patient is not able? To what extent might we know the specific costs prior to the plan of care?

418.54 Comprehensive Assessment

(a) Initial Assessment: **the initial assessment within 24 hours is not a practical statement & the physician's admission order for care is somewhat ambiguous. I think I understand the intent, however I believe the wording needs some editing and further clarification, particularly for future referrence. A large number of hospice referrals are not physician driven. In fact, the primary physician may be reluctant to talk about hospice and the family makes the initial contact. We will then complete a consult and help the family/patient work with their physician. Therefore, an initial assessment has been completed prior to the order from the MD. Would that mean we would have to complete an additional 'initial' assessment? In addition, we may receive an admission 'order' from the physician on a Monday but the patient/family is in an approach-avoidance mode and insists that we can't visit until Friday the earliest. What would be the impact in this case?**

(b) Time frame: 4 days is a realistic time frame for most hospices. However, this time may have a negative impact for rural providers. Might this be interpreted in a broader sense, could phone contact be acceptable in some instances?

(e) Patient outcome measures: I believe 'outcome measures' are a necessary tool to quality and performance.

418.56 IDG care planning

(a) Approach to service delivery: (1) i **request remove** *'who is not the patient's attending physician'*

(c) Content of PoC: (6) There should be no requirement that the 'family' agree with the PoC, the patient drives the PoC as long as able. Further clarification is needed if the patient is not competent and there is disagreement among family members. Where does the Health Care Proxy fit in?

418.58 QA/PI

(b) Program data: **see attachment II** for detail

(e) Executive responsibilities: our QA/PI report is reviewed annually with our governing Board. And, if there are any issues that are identified at any other time, they are brought up at a scheduled Board meeting for review.

418.72 PT, OT and Speech

Would request **dieticians** added to the list of **non-core** services.

418.76 HHA & homemaker services

(h) Supervision of HHA: **this standard is confusing. The HHAs are currently supervised directly and indirectly twice a month, are you suggesting that the 28 day HHA assessment is in addition to what we currently do or instead of? Is the focus the patient, the aide or both? Is this intent to be a Human Resource function in addition to their annual evaluations? Our agencies HHAs are very experienced, we have little turnover, the last HHA hired was over 2 years ago. The clinical staff really knows the strengths and weaknesses of the individual HHAs. Imposing additional oversight would significantly increase the burden of the clinical staff who are already feeling a great deal of pressure. Essentially, we are doing this already, I would suggest that the current practice is more than adequate.**

418.100 Org & Admin services

Our management team & medical director had lengthy discussion regarding this standard. This standard is quite subjective and difficult, at best, to measure. How might this standard be audited? Family satisfaction survey? Families are often unrealistic with their expectations. We feel strongly that this standard needs modification and would like examples or language to be defined in the preamble and interpretive guidelines.

(a) Service the patient/family: (1) **would suggest adding '*to the extent possible within the context in which the patient is living*' following dignity; and.**

(a) Service the patient/family: (2) ***'desires'* could be a huge issue with many families. We suggest 'goals' within reason and/or according to the PoC.**

(b) Governing Body: request expanded definition of administrator

(e) Professional Mgm't: Hospice should have professional oversight for the **services** provided **not the contracted staff.**

418.102 Medical Director

(c) Coord of medical care: **'patient's medical care in its entirety'? What does this mean? What about dialysis and other specialty areas? Should this not be in conjunction with.... other physician as necessary?**

(c) Coord of medical care: **Our medical director strongly disagrees with 'directing' the QA/PI program... participating or playing an active role is more accurate. 'Directing' the QA/PI program is an administrative function under the auspices of the Executive Director with the involvement of the medical director. The medical director should be involved, but not have the primary responsibility. Our medical director recommends the use of the American Academy of Hospice & Palliative Care's definition of medical director.**

418.104 Clinical records

**** see **Attachment III** for a summary of the components of the electronic health record as requested

(b) Authentication: **this is not practical for home hospice care. We do not have the luxury of having the MDs on-site. We do check licensure on-line with the state registry. This would be a huge undertaking and may be setting us up for failure. I understand the intent, particularly coming from a hospital based background, however the full execution of this standard is doubtful.**

(d) Disch or transfer of care: **no facility or physician that I know of wants to receive a 'full' copy of the patient's medical record. This would be very costly, time consuming, cumbersome and generally annoying to the receiver. In addition, this standard would move us beyond the HIPAA Minimum Necessary Standard. And, to the best of my knowledge, it is not done in any other aspect of healthcare. What we really need is comprehensive discharge or transfer summary documentation.**

418.106 Drugs, controlled drugs

(b) Controlled drugs: request changing 'potential dangers' of controlled substances' to '**safety**' of controlled substances. 'Potential dangers' have a negative connotation.

(c) DME use & maint: the DME vendor is responsible for the repair and routine maintenance of the equipment, not hospice. The DME vendor is also responsible for the policies & procedures related to the repair and maintenance. Hospice is responsible for the professional management of the contract.

418.108 Short-term IP care:

General inpatient care should be appropriate and available to families who are experiencing a short-term crisis of a psychosocial nature. Criteria for the GIP and respite should be clear and separate as this is often a point of misunderstanding by professionals and the public.

(a) IP care for symptom mgm't & pain control: **The CoPs should retain the requirement that an RN be on-site at facilities providing the GIP benefit either as freestanding units or as contracted facilities. GIP, as the most acute level of hospice care, warrants the expertise and care of a RN to monitor pain and symptoms deemed unmanageable at the routine level of care.**

418.110 Hospice providing IP care:

(a) Staffing: **RN should be on-site 24/7 to provide direct care.**

(d) (6) (v) should be (iv)

(o) Seclusion & restraint: **At the end-of-life, certain medications can be a necessary treatment in the management of terminal agitation and/or to induce sedation for those experiencing intractable pain & suffering. Certain drugs are used to manage the treatment of symptoms and not intended as a restraint. There is a concern that some surveyors who are not expert in EoL care may view such treatments as chemical restraint rather than responsible and acceptable practice.**
(please see Attachment I)

(o) (3) (ii) (a) 'Orders for seclusion or restraints must never be written as a standing order or on an as needed basis'. Our medical director recommends **unless the 'as needed' is defined and has set parameters.**

418.112 hospice care in SNF... other facilities:

(e) Medical director: The medical director (suggest adding here) **and/or other MDs providing care** must provide overall coordination of the medical care of the hospice resident.

Our medical director recommends that the focus be on overall communication between facility staff, the attending MD & the hospice IDG team to optimize the care of the patient.

This standard as it is stated is operationally not feasible.

(i) Orientation & training of staff: Training of SNF staff by hospice is critical to the care of the nursing home resident in hospice care. However, depending upon the number of hospice contracts held by a facility, it may be impractical for all hospices to be required to provide training without overwhelming the facility staff. Wording should be 'must assure' orientation and training of facility staff.

418.114 Personnel qualifications:

(c) (7) Social Worker: There was consensus that the minimum education requirement for a direct care social worker should be a MSW. The level of clinical judgement and independence required in the culture and environment of an individual's home is gained through experience, education and training. However, a waiver exemption could be afforded where the hospice can demonstrate undue difficulty in recruiting a master's prepared social worker.

(d) background checks: CORI checks should be required for all hospice staff and volunteers.

LONG-TERM PHARMACY SOLUTIONS, INC.
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Lowell, MA 01851
Ph: (978) 458-4000
Fax: (978) 459-2485

July 13, 2005

Diane Bergeron, RN, MSN
Executive Director
Hospice Care Inc.

RE: Drugs used as a restraint with regard to the 2005 CMS proposed conditions of participation.

Dear Diane:

With regard to our conversation concerning drugs being used as a restraint, I have performed a literature search and given careful consideration using my clinical experience; and I submit the following synopsis.

Drugs that can be potentially used as a chemical restraint, or sometimes considered a chemical restraint, fall under several drug categories:

Antipsychotic/Neuorleptic agents:

Butyrophenones	**i.e., Haloperidol (Haldol[R])**
Phenothiazines	**i.e., Chlorpromazine (Thorazine[R])** **i.e., Perphenazine (Trilafon[R])** **i.e., Prochlorperazine (Compazine[R])**
Benzisoxazole	**i.e., Risperidone (Risperidal[R])**
Thienobenzodiazepine	**i.e., Olanzapine (Zyprexa[R])**
Dibenzothiazepine	**i.e., Quetiapine (Seroquel[R])**

Anti-anxiety Agents:

Benzodiazepines	**i.e., Lorazepam (Ativan[R])** **i.e., Diazepam (Valium[R])**

Although all of the above mentioned drugs could be considered chemical restraints, they are commonly used for symptom management in palliative and hospice care. In addition to pain, patients who are approaching the end of life commonly have other symptoms such as delirium (AKA: agitation, terminal restlessness, acute confusion), dyspnea, nausea, depression, among many other symptoms.

I will focus on ***delirium*** as this seems to be the area of greatest concern regarding drug restraint.

Delirium is a common psychiatric disorder in terminally ill patients. It is a disturbance of consciousness and cognition with a sudden onset that may be accompanied by increased psychomotor activity. Its prevalence in dying patients is believed to be up to 60%. Delirium often heralds the end of life and may require sedation in 25% to 50% of patients.[1] Delirium can deeply disturb the patient and family. "All episodes of delirium interfere with meaningful interpersonal contact with loved ones due to clouding of consciousness."[2] Because the period before death is a special time for patients and family members, it is imperative pharmacological and non-pharmacological measures be taken to control delirium. With the exception of treating delirium due to drug withdrawal or anticholinergic excess, neuroleptics are first line pharmacological agents for symptom management. Haloperidol is usually the agent of choice for most patients. It has a favorable side effect profile and can be administered orally, transdermally, or parenterally. Other neuroleptics may also control delirium as well as being good antiemetics. However, they may have higher incidence of extrapyramidal side effects and sedation. The newer atypical neuroleptics: olanzapine, quetiapine, and risperidone, can be useful particularly in patients with Parkinson's disease and other neuromuscular disorders or in patients with a history of extrapyramidal side effects from neuroleptics. As noted in the International Association for Hospice and Palliative Care manual of palliative care, second edition, section 4, symptom control "haloperidol is the agent of choice in treating delirium in terminally ill patients because it improves cognitive function and provides sedation."[3] Also noted in Symptom Management Algorithms, A Handbook for Palliative Care, second edition, haloperidol and lorazepam are first line agents for treatment of agitation and anxiety. It should be noted that lorazepam as well as benzodiazepines can sometimes cause paradoxic agitation and over sedation.[4]

"Haloperidol is the agent of choice for the management of delirium associated with hyperactivity at end of life period. A well designed double blind study[5] comparing haloperidol (a high potency neuroleptic) chlorpromazine (a low potency neuroleptic) and lorazepam (a benzodiazepine) in the treatment of delirium in hospitalized patients with AIDS, found haloperidol to be the preferred drug."[6]

These facts along with my clinical experience using haloperidol as well as other neuroleptics and benzodiazepines for symptom management lead one to the conclusion that these drugs, when used properly, are not chemical restraints, but a powerful tool in our armamentaria. To restrict the use of these medications would be a disservice to our patients and their families; and greatly impact our mission of providing quality end of life care to our terminally ill patients.

Table 1

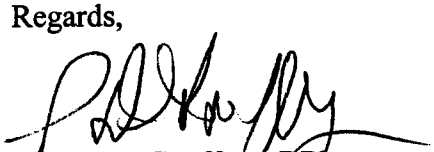
Medications commonly used to manage delirium in end of life care

Medication	Approximate Dosage Range	Route of Administration*
Neuroleptics		
Haloperidol	0.5-5mg every 2-12 hrs	PO IV SL SC IM TD
Chlorpromazine**	12.5 to 50mg every 4 to 12 hrs	PO IV IM TD
Perphenazine***	4-12mg every 4 to 12 hrs	PO TD
Olanzapine	5 to 20mg daily	PO
Quetiapine	50 to 300mg twice daily	PO
Risperidone	1 to 4mg daily	PO
Benzodiazepines		
Lorazepam	0.5 to 2mg every 1-4 hrs	PO IV SL SC IM TD
Diazepam	2 to 10mg every 4-6 hrs	PO IV SL SC IM TD

*PO = By Mouth
I V = Intravenous
SL = Sublingual
SC = Subcutaneous
IM = Intramuscular
TD = Transdermally
**Chlorpromazine also works well in the treatment of hiccough.
***Perphenazine is also used as an antiemetic drug or a combination with other antiemetics.

I hope you have found this information helpful. If you have any questions or desire additional information, please feel free to call.

Regards,



Steven D. Geoffroy, RPh
President

REFERENCES

[1]InTouch: Robert A. Milch, M.D., "Message from Robert A. Milch, M.D.", pg 2, Cheektowaga, NY: March 2003

[2]American Family Physician: Douglas D. Ross, M.D., PH.D., and Carla S. Alexander, M.D.: Management of Common Symptoms in Terminally Ill Patients: Part II.; Volume 64, No. 6., Pg. 1019, Sept. 15, 2001

[3]International Association for Hospice and Palliative Care: Manual of Palliative Care; http://www.hospicecare.com/manual/sysptoms-main.html, July 7, 2005

[4]Symptom Management Algorithms: Linda Wrede-Seaman, M.D.; A Handbook for Palliative Care, Second Edition, Intellicard, Yakima, WA; www.Intelli-card.com; 1999

[5]American Family Physician: Breitbart W, Marotta R, Platt MM, Wwisman H, Derevenco M, Grau C, etal. A double-blind trial of haloperidol, chlorpromazine, and lorazepam in the treatment of delirium in hospitalized AIDS patients. Am J Psychiatry 1996; 153:231-7

[6]American Family Physician: Douglas D. Ross, M.D., PH.D., and Carla S. Alexander, M.D.: Management of Common Symptoms in Terminally Ill Patients: Part II.; Volume 64, No. 6., Pg. 1021, Sept. 15, 2001

Hospice Care, Inc.

Attachment II

Outcome Measures Collected

1. Perforum Benchmarking which includes but not limited to the following:
    - NHPCO Dataset
    - NHPCO Family Evaluation of Hospice Care
    - NHPCO End Result Outcome Measures
    - Financial indicators
    - LOS indicators
    - Infection Control
    - Falls
    - Med errors

2. Concurrent Patient Satisfaction telephone surveys (LOS 7-21 days)

3. Long term Care Referrer Survey (annual mailed)

4. Physician Referrer Satisfaction Survey (annual mailed)

Attachment III

Electronic Health Record Contents

Demographic Information
Allergies
Precautions
Advanced Directives
Associated Physicians
Associated Hospice Personnel
Related Parties (PCG, Friends etc..)
Admission Information (Date, Referral Info)
Insurance Information
Diagnoses
Physician Orders
Medications
Care Plan
Level Of Care (Routine, Inpatient, etc..)
All Visit Documentation

POC Implementation Notes

Advantages to electronic documentation:

- Increased communication as all team members have access to the medical record in the field
- Increased accuracy
- Eliminates support staff from entering information that clinical staff have written out
- Documentation is available to others much sooner

Challenges in transitioning Clinical staff to electronic documentation:

- Lack of familiarity with basic computer skills
- Resistance to changing their practice
- Finding training time within their busy schedule
- Belief by many clinicians that the computer is impersonal in the home setting

Hospice Care, Inc Progress as of July 2005

- Off Hours team has full electronic access to patient information
- Admission team is using laptops, admissions done by staff nurses are still being done on paper
- 4 out of 10 staff nurses are completely electronic
- Clinical Managers document telephone calls electronically
- 85% of all field staff will be electronic by October 2005
- Early in 2006 the bulk of our medical records will be paperless

July 22, 2005

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

Dear Sir/Madam,

Enclosed you will find an orginal and two copies of proposed changes to the Hospice Conditions of Participation suggested by Hospice & Palliative Care, Inc., 4277 Middle Settlement Road, New Hartford, New York 13413.

We appreciate this opportunity to be heard on matters that will utimately guide the way we and our loved ones will experience at the end of life.

Thank you for your consideration of these proposed changes.

Sincerely,

Pi Gentile
Executive Director

4277 Middle Settlement Road, New Hartford, New York 13413 • (315)735-6484 • Fax: Administration - (315) 793-8852, Clinical - (315) 735-8545
Accredited by The Joint Commission on Accreditation of Healthcare Organizations
The recognized leader in end-of-life care since 1977.
www.hospicecareinc.org

July 22, 2005

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

Re: Hospice Conditions of Participation: Proposed Rule published on May 27, 2005 in the Federal Register. Hospice and Palliative Care, Inc. has carefully reviewed the Proposed Rule and wishes to submit the following recommendation for changes, which are in italics.

Section 418.3 Definitions

Section (a) Notice of Rights

(a) (3) Attending physician - add: *The hospice medical director, hospice physician or nurse practitioner may also act as the patient's attending physician.*

- **Drug restraint** – amend to read: Drug Restrint means a medication used to control behavior or to restrict the patient's freedom of movement, *which is not a standard hospice treatment or not requested by the patient or the patient's surrogate.*
- **Licensed Professional** – amend to include *dietary therapy* after occupational therapy.
- **Nursing Services** – include *care provided by a licensed nurse or under the supervision of a licensed nurse as allowed by law.*
- **Add a definition for patient's residence**: meaning *wherever the patient lives.*

Section 418.52 Condition of Participation: Patient's Rights

Section (a) Standard: Notice of Rights

- (a) (3) – Change to read: *"The hospice must inform the patient and family of the hospice's drug policies and procedures regarding management and disposal of controlled substances during the comprehensive assessment."*
- (a) (1) (v.) Add to this section: *The right of the patient to be involved in his or her plan of care.*
- (a) (1) (vi.)Add to this section: *The right of the patient to refuse treatment.*

Section (b) Exercise Rights and Respect for Property or Person

- (b) (3) at the end of the sentence add: , *"and practice".*
- (b) (4) revise the language to read: *"The hospice must investigate complaints made by a patient or the patient's family or guardian regarding treatment or care that is (or fails to be) furnished, or regarding the lack of respect for the patient's property by anyone furnishing services on behalf of the hospice, and must document both the existence of the complaint and the resolution of the complaint."*

Section (e) Patient Liability

- Amend this standard to read: *"Before care is initiated, the patient must be informed, verbally and in writing, and in a language that he or she can understand, if payment may be expected from the patient, as well as, hospice's intention to bill Medicare or Medicaid, third-party payers, or other resources of funding known to the hospice."*

Section 418.54 Condition of Participation: Comprehensive Assessment of the Patient

- In the last sentence of this standard, change the word "*care*" to the word "*assessment*". This would allow hospices to include items not related to the terminal illness that the hospice would want to assess.

Section (a) Standard: Initial Assessment

- As there is not a physician's "admission order" for care in Hospice, it is recommended that this be changed to *Physician's certification to consistent with the Hospice statute*. Also, to the bracketed phrase in the sentence ending with "...unless ordered by the physician", add *"or requested by the patient or family..."*.

Section (b) Standard: Timeframe for completion of the comprehensive assessment

- Recommend that the standard allow up to 7 days to complete the comprehensive assessment and that the following phrase be added after the phrase, "individual's attending physician", *"if he or she is willing to participate..."*. *The proposed 4 days is too intrusive upon the patient and family.*

Section (c) Content of the comprehensive assessment,
(3) (ii). Drug Therapy – add a notation that *Hospice cannot be held responsible for being aware of drugs that Hospice is not informed of by the patient, family, physician or other health care provider.*

Section (d) Standard: Update of comprehensive assessment

- It is strongly recommended that "*every 14 days*" be changed to *"every two weeks,"* or *"15 days."* This wording would accommodate the flexibility needed for holidays and emergencies and synchronize with Hospice's re-certification period of 90/90/60 days.

Section 418.56 Contition of Participation: Interdisciplinary group care planning and coordination of services

Section (a) Standard: Approach to Service Delivery

- (1) (i) This is changed to read: *"the hospice Medical Director or physician designee"*.

- (2) Change to read: *"If a hospice has more than one interdisciplinary group, there will be consistency across teams and an inclusive process for developing policies that represent all disciplines and teams, with final authority resting with the governing body and senior management."* In this manner, it is established that the Board determines the policy which is carried out consistently among teams of the organization.

Section (c) Standard: Content of the Plan of Care

- (c) (6) Remove the word *"agreement"* and therefore, the interdisciplinary group would document in the clinical record, the patient and family's understanding and involvement with the Plan of Care in accordance with the hospice's policies.

Section (d) Standard: Review of plan of care

- Modify the standard to change "every 14 days" to *"every two weeks", or "15 days."* This change would provide the flexibility needed to accommodate holidays and emergencies and synchronize with Hospice mandated certification periods.

- Modify the language to read: *The Medical Director or physician designee and the interdisciplinary team, "in collaboration with the individual's attending physician to the extent possible" must review..*

Section 418.58 Condition of Participation: Quality assessment and performance improvement

The hospice industry is in the developmental stage of identifying and measuring data for improvement. We urge CMS to recognize that full development of a hospice QAPI will occur over an extended period of time although the preliminary pieces are in place in many hospices.

The increased demands in quality assessment and performance will add significant cost burdens for hospice. This needs to be recognized and addressed in the hospice reimbursement system.

Section 418.64 Condition of Participation: Core Services

It is strongly recommended that hospices be allowed to contract for continuous care staffing on a "routine basis." Continuous care is a key component of hospice, allowing many patients to stay at home rather than go into a facility. Hospices need the flexibility of contracting routinely for this Core service due to the unpredictable demands and commensurate unavailability of qualified staff.

Section 418.76 Home health aide and homemaker services

Section (h) Standard: Supervision of home health aides

- (i) Remove the phrase *"qualified therapist"* as it does not apply to hospice regulations. We strongly recommend that *"every 14 days"* be changed to *"every two weeks"*, or *"15 days."*

- (j) Homemaker qualifications – Recommend that CMS uses the definition of homemaker in NYS statute. New York State has specific requirements for homemakers that are different from home health aides. To require a home health aide be used for homemaker services is inefficient use of very limited resources, which will only worsen with time.

- **Section 418.100 Condition of Participation: Organization and Administration of Services**

Section (e) Standard: Professional management responsibility

- Should be revised to: *Furnished in a safe and effective manner by qualified personnel.*

Section 418.102 Condition of Participation: Medical Director

- In the first paragraph, the third sentence should read: *"When the Medical Director is not available, a physician designated by the Medical Director or the Hospice, assumes the same responsibilities and obligations of the Medical Director."*

Section (c) Standard: Coordination of medical care

- Change the last sentence to read: *"The Medical Director or physician designee is also responsible for participating in the hospice's quality assessment and performance improvement program. The program may be directed by the Medical Director, physician designee or other qualified professional."*

Section 418.104 Condition of Participation: Clinical Records

Section (a) Standard: Content

- (2) Amend to state, *the election statement, which is required to include a consent to start hospice services as well as the patient rights.*

Section (b) Standard: Authentication

- This section is not applicable for a hospice services. It is recommended that this section be excluded. Hospices do not have a mechanism to authenticate a signature of a covering physician beyond the initial verbal order taken by a registered nurse.

Section (e) Standard: Discharge or transfer of care

- It is recommended that the requirement for a hospice "to provide a copy of the clinical record to the patient's attending physician in the case of revocation or discharge", be removed. The hospice does provide a discharge summary which is a succinct summary that provides all information that most physicians find acceptable.

  If this standard must continue as proposed, it is recommended that the hospice "offer" the attending physician or the accepting facility a copy of the complete medical record or any parts thereof which they feel are needed. It is our belief that this would satisfy the "minimum necessary requirements" of HIPAA standards.

Section 418.106 Condition of Participation: Drugs, Controlled Drugs and Biologicals

Section (a) Standard: Administration of drugs and biologicals

- Section (a)(2): After the present paragraph, add the following: *If the patient and/or family are determined to be unable to safely administer drugs and biologicals, the patient and family will be encouraged to relocate the patient to a setting where administration assistance can be routinely offered. However, it is recognized that the patient if competent and the patient's surrogate if the patient is not competent, can refuse to relocate. Given patient rights and the home setting, hospice will be expected to provide reasonable assistance. Hospice will not be expected to restrict the provision of medications unless there is a blatant safety issue for non-competent adults or children in the home.*

Section (b) Standard: Controlled drugs in the patient's home

- The first sentence should be revised to read: *"The hospice must have a written policy for disposing of controlled drugs that are in the Plan of Care and maintained in the patient's home."*

Section 418.108 Condition of Participation: Short-term inpatient care

We recommend a revision to the introduction as follows: *"Short-term General Inpatient Care and Respite Care are coordinated by the hospice in a participating Medicare or Medicaid facility."*

(a) Standard: Inpatient care for symptom management, pain control (add): <u>and psychosocial issues</u>

- Pain control and symptom management would be done on an inpatient basis either because of the specific need for the staff and equipment availability, or, because of the inability of the hospice and/or the patient's caregivers to assure that the services are properly provided in the home.

It is further recommended that short-term inpatient care is permitted for symptom management, pain control, and psychosocial issues. It is imperative that psychosocial issues/caregiver collapse be covered under general inpatient care. There are multiple situations where the patient's caregiver cannot assure that services will be properly provided in the home.

It is further recommended that there is a need for an RN presence on a 24-hour a day basis for the general inpatient level of care. It is felt that RN presence on a 24 hour basis for respite care is not seen as presenting the equivalent need.

(a) (1) Note that it should be a Medicare *"certified"* hospice, not a Medicare "approved" hospice.

(b) (2) Recommend changing the word "approved" to *"participating"* nursing facility. It would read: "A Medicare/Medicaid *participating* nursing facility…

Section 418.110 Condition of Participation: Hospices that provide inpatient care directly

Item (o) Standard: Restraint and seclusion

- It is recommended that this entire standard be eliminated as it is inappropriate to hospice regulations.

Section 418.12 Conditions of Participation: Hospices that provide hospice care to residents of a SNF/ICF, MR or other facilities

Clarify what is meant by "other facility," and define "nursing facility". Also clarify that this section should specifically apply only to Medicare and Medicaid participating faacilities. This condition cannot successfully be implemented until there is in the SNF/NF requirements, a parallel condition that confirms their requirements. We recommend that the effective date of this section by delayed until the companion section is enacted or that it be at least incorporated by reference in to the SNF/NF requirements. We understand that the nursing home COPS will add a section on nursing homes and hospice care. Does this condition match the requirements that will be proposed for nursing homes?

It is also requested that CMS work with surveyors on this issue and that hospices be allowed some leniency until the nursing faciliy regulations are complete.

Can this Condition be phased in?

(d) Standard: Medical Director

- It is recommended to eliminate the first sentence. Insert the statement: *"The Hospice IDG must communicate with appropriate members of the SNF clinical staff. Also, the Hospice Medical Director, or physician designee may communicate with the Medical Director of the SNF/NF, the patient's attending physician, and other physicians participating in the provision of care for the terminal illness and related conditions, in order to insure quality care for patients and families."*

(e) Standard: Written agreement

- (1) Modify the "written consent" to *"election statement"*.

(f) Standard: Hospice Plan of Care

- (f) (3) Recommend changing the 14-day requirement for care plan review to "*15 days*" which is in line with the current re-certification periods.

- (f) (4) Change the wording to read: "*Any changes in the Plan of Care must be discussed among representatives of both facilities and must be approved by the hospice before implementation.*

(g) Standard: Coordination of services

- (6) "Physician orders", by assumption they refer to "hospice" physician orders.

(h) Standard: Transfer, revocation or discharge from hospice care

- Change sentence to read: "*Discharge from or revocation of hospice care may not affect the eligibility to continue to reside in an SNF, NF, ICF/MR, or other facility.*"

  A concern is that while discharge from the hospice does not always mean discharge from the facility, it is believed that patients should not experience the trauma of an external move because they perhaps have stabilized and may not continue to be eligible for hospice.

418.114 Condition of participation: Personnel qualifications for licensed professionals

The use of State licensure as a standard for social workers is of concern to many hospices. Patient and family needs at the end-of-life present an extremely intense and demanding set of variables and require skills and training that are often more than a non-Masters Social Worker will possess. Every effort should be made by hospice to employ this level of professional worker and regulatory support for such a course is important.

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Vice President

* Terms expire in May.
** On both HCFI and HCI Boards

Resolution 10/31/01, authorizing amendment to the By-laws of HCFI, Article VI., P.2 Number of Directors, that the parameters for the number of directors has been modified to read "no less than three (3) and no more than seven (7)"; and, Article IX "to reflect that a majority of the Board will function as a quorum".

Revised 5/25/2005
See\barbara\foundation

Terms from 5/26/04 – 5/26/05

VNAA Visiting Nurse Associations of America®

the voice of home healthcare

July 19, 2005
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-3844-P
P.O. Box 8010
Baltimore, MD 21244-8010

Dear Dr. McClellan:

I am writing on behalf of the Visiting Nurse Association of America (VNAA) to comment on the proposed Medicare and Medicaid Hospice Conditions of Participation, CMS-3844-P. The VNAA represents over 400 non-profit; community based Visiting Nurse Associations across the United States. We appreciate the opportunity to provide input on this important regulation. We support this effort to strengthen the Medicare and Medicaid hospice programs and improve the quality of care furnished to patients.

PATIENT RIGHTS

Section 418.52(a)(3) -- We agree that the patient and family need to know about drug policies and procedures, but in our experience, providing this at the admission is too much for people to absorb. We suggest this requirement be moved into the comprehensive plan of care time frame.

Section 418.52 (b)(2)(3) -- We are support assuring that when a patient's rights are exercised by a representative that that person has clear authority to do. We are concerned, however, that in deferring exclusively to state law, those patients who become incompetent during the later phases of their illness may technically be without a "representative." We suggest that a representative also be defined as one who was designated in advance by the patient in writing as well as a representative recognized under the common law with in the State. The rule should make clear that these concepts be added to apply in situations where a representative determination under state law is unclear or has not yet taken place.

ASSESSMENT TIMEFRAMES

Section 418.54(a) -- We believe the 24-hour period for the initial assessment should be made slightly more flexible to comport the operational realities of hospice care. We suggest that the assessment be completed no later than the close of the day following the day the patient is referred. This will accommodate the situation, for example, in which a referral is not received at 10 AM but the scheduling needed to complete the initial assessment would be disruptive if it had to be completed by 10 AM the next day. We

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Boston, MA 02110
617-737-3200
1-888-866-8773
617-737-1144 (fax)
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8403 Colesville Road, Suite 1550
Silver Spring, MD 20910
240-485-1858
240-485-1818 (fax)
www.vnaa.org

strongly support completing the initial assessment no later than close of business on that following day, however.

Section 418.54(b) -- We believe the 4-day time frame to complete the comprehensive assessment is reasonable in most cases and is a worthwhile goal. But there are many situations in which the 4-day time frame is not feasible. The most frequent delay we encounter is getting information back from the patient's attending physician. Such delays are out of the hospice's control will create a compliance problem for the hospice with no realistic steps it can take to assure physician compliance. We also believe that the 4-day limit is unrealistic around holiday weekends when it is particularly challenging to gather all the information and expertise needed. Therefore, while 4-days is a good goal, we recommend that the time-frame for compliance regarding the comprehensive assessment be extended to 7-days after hospice election.

OUTCOME MEASURES

Section 418.54 (e) -- We strongly endorse the rule's emphasis on moving to patient outcome measures and the flexibility reflected in the rule as hospices experiment, test and adopt outcome measures. We urge that the final rule and subsequent interpretive guidelines make clear that hospice outcome measures are in a developmental stage and that compliance should not be evaluated based on the use of specific measures that are not mandated in regulations.

PLAN OF CARE

Section 418.56 (c)(6) – While we support the requirement that patients understand, be informed and be in agreement with the plan of care, the broader requirement that the "family" also agree with the plan of care is unrealistic. We often find that part of the family may agree and part may disagree, and more critically, often patients agree while the family may disagree. We believe that the plan of care is and must remain centered on the patient's needs and preferences, and while we seek family support and agreement, this is sometimes simply not realistic. We urge that his reality be reflected in the final rule.

QAPI

Section 418.58 (e) -- We support the requirement for governing body involvement but believe it is important that its role be one of assuring the implementation, maintaining and reviewing the outcomes of QAPI. The proposed requirement that the governing body "define" and "prioritize" QAPI activity over-reaches into the responsibility of the hospice managers and clinicians. We suggest the final rule reflect the responsibility of the governing body to implement an effective QAPI process but not suggest micromanagement of that process by the governing body.

ORGANIZATION AND ADMINISTRATION

Sections 418.100(A)(2) -- We are concerned that this provision will suggest that patients and families may expect that every "desire" they have must be met by the hospice. While infrequent, we do have patients and families that have very unrealistic expectations of the hospice program and this type of language could easily support such expectations. We suggest that language be substituted in the final rule that defines "desires" in term of reasonable expectations related to the goal of achieving the highest functional capacity of the patient.

MEDICAL DIRECTOR

Section 418.102(c) -- The requirement that the hospice medical director be responsible for "directing" the hospice's QAPI is not realistic or appropriate. It both undervalues the contributions of the other hospice team members and places expectations on the medical directors which are not consistent with their training or conditions of employment. It would be more appropriate to give the Medical Director responsibility to provide oversight to the QAPI program and review the reports of the QAPI activity.

CLINICAL RECORDS

Section 418.104(e)(1) – The requirement that the patient's entire medical record be forwarded on transfer or discharge is well intended but very wasteful. In our experience few entities either request or use more than the summary section of the medical record. Thus, even were we to take on the burden of shipping the entire record, the intended affect will not be achieved because it will not be used at the receiving end. We recommend that the requirement we limited to a complete summary and the entire record be furnished only upon request.

DRUGS, SUPPLIES AND DME

Section 418.106(b) -- We believe it is unrealistic for the hospice staff to take on the responsibility for collecting controlled drugs. We propose that the policy allow for the proper disposal of controlled drugs since we do not believe it is prudent or practical for hospice clinical staff to provide collection services of controlled drugs from patient homes.

Section 418.106(c) -- We do not believe that hospices are or can become prepared to maintain or repair DME furnished by other Medicare or Medicaid providers. The enrolled or certified DME supplier should continue to be responsible for the maintenance and repair of all the equipment provided.

SHORT TERM INPATIENT CARE

Section 418.108(a) -- While we agree that there need not be direct 24-hour nursing care furnished in these settings, we believe that there should be nursing available on-site, on a 24-hour basis.

SECLUSION AND RESTRAINT

Section 418.110(o)(3)(ii)(C) -- Allowing only one hour for the hospice medical director to see and evaluate the patient is not a viable option. A reasonable amount of response time must be provided since the physician is not on site or non-compliance will be assured.

Section 418.110(o)(3)(ii)(D) – We believe more practical timeframes for restraint orders would be: 8-hour intervals over a 24-hour period for adults while sleeping and 4-hour intervals while awake; 6-hour intervals while sleeping for 9 to 17 year olds, 2-hour intervals over 24-hours while awake; 2-hour intervals while sleeping for under 9 years old, 1-hour while awake. We also believe there should be a requirement for reordering restraint but not a required re-assessment every 24-hours because this places a unrealistic and unnecessary burden on the physician in many situations.

RESIDENTS RESIDING IN A FACILITY

Section 418.112(d) & (e) -- It is not reasonable to expect a hospice to secure the cooperation of nursing facilities with the hospice conditions of participation relating to patients residing in such facilities until the nursing facilities are placed under parallel requirements. We strongly urge that parallel provisions be put into SNF COPs simultaneously or the hospice provisions be made effective for hospice compliance purposes only when nursing facility rules go into effect.

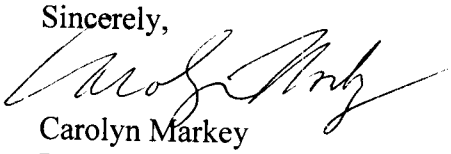
We also believe that section (d) should be extended beyond the hospice medical director to include the other staff and members of the hospice team who must coordinate care at the nursing facility.

PERSONNEL QUALIFICATIONS

Section 418.114(c)(3)(4) -- We believe it is important to maintain the principle that any physical therapy delivered by a person at the BA level be supervised by a Master's level PT.

Once again, the VNAA would like to thank you for the opportunity to comment on these rules. As our comments reflect, we are supportive of strengthening the hospice conditions of participation. Our comments are directed at providing feasible approaches to achieve our common purpose in that regard. You may direct any questions you have regarding these comments to Bob Wardwell at our Washington office at 240-485-1855.

Sincerely,



Carolyn Markey
President and CEO

Require that patient rights are ensured.

The Patient Rights CoP emphasizes a hospice's responsibility to respect and promote the rights of each hospice patient.

STATUTORY NURSING WAIVER

> *"Condition of Participation: Nursing Services Waiver of Requirement That Substantially All Nursing Services Be Routinely Provided Directly by a Hospice (Proposed Sec. 418.66)*
>
> *The requirements for obtaining a nursing services waiver as provided by section 1861(dd)(5) of the Act is currently set forth in Sec. 418.83, and remains virtually unchanged in this proposal. This condition provides hospices the opportunity to obtain a waiver from the requirement that substantially all nursing services be routinely provided directly by the hospice., ..."*

In our experience, the Statutory Nursing Waiver has been nothing but confusing and ineffective. Even though the waiver clearly states it is intended for *nonurbanized* areas:

> *"CMS may waive the requirement in Sec. 418.64(b) that a hospice provide nursing services directly, if the hospice is located in a nonurbanized area."*
>
> *"The Act specifies that to obtain a waiver a hospice must be located in an area that is not an urbanized area"*

We have still seen many hospices and even many surveyors attempt to apply it to hospices in urban areas

An additional problem is the following statement:

> *" The location of a hospice that operates in several areas is considered to be the location of its central office.....*
> *(1) The location of the hospice's central office is in a nonurbanized area as determined by the Bureau of the Census."*

It would not matter if the central office is located in an urban area in regards to the service area of the branch office. That is why hospices set up branch offices, to effectively service patients who are located great distances from the central office. To judge a small rural branch office by the large staff available to the urban central office does not make sense. If the central office could effectively service the rural patients in the first place, there would be no need for a branch office.

This is just an example of the confusion this waiver brings to the entire outside staffing concept. The real issue is that we have seen to many conflicting interpretations surrounding all the regulations that attempt to regulate or quantify the hospice's ability to contract

qualified outside agency to care for its patients when there is a shortage of staff within the hospice coupled with unpredictable and expanding patient care level requirements.

> *...This waiver, set in statute, may be obsolete. We do not know how many hospices meet the criteria for the waiver, nor do we know if any hospices actually use the waiver. We request comments on the use of this waiver.*

I agree the waiver is obsolete. Once again, it states above that it is intended for use by hospices in non-urban areas. We have personally witnessed over and over again the surveyors attempt to apply the waiver to hospices in urban areas. Secondly, it is a bad concept when applied to continuous care staffing. Even if a hospice has been responsible and hired enough staff for their patient load, there will be occasions when a patient or two needs care above their normal census. There is no time for a hospice to file a waiver when someone is lying in a bed at home having pain crises, or any other critical care need.

We do not understand why the CoPs seem to single out continuous care:

> *"We believe that the new MMA provision authorizes us to propose that hospices may not routinely contract for a specific level of care (e.g., continuous care) or for specific hours of care (e.g., evenings and week-ends), as these are regularly occurring situations that hospices are able to plan staffing for."*

This would be the perfect example of the type of care that hospices *cannot* plan staffing for. e. g., If a hospice has hired a continuous care staff to handle it's average continuous care load of 3 patients, what happens when one weekend the hospice has all their CC staff working, and three additional patients go into a pain crises that requires constant monitoring? Should we assume that the hospice should hire and retain staff sufficient for its highest potential needs? That is obviously impractical. Under that scenario, the hospices would go out of business as they would be paying staff that isn't working a great deal of the time. We must remember, the Medicare reimbursement rates are calculated based on the actual estimated cost of patient care, which includes the average pay rates in a given area. While a percentage is built in for operating overhead, there is certainly not a built in "buffer" to account for overstaffing for potential peak patient loads. In other words, the reimbursement rates do not have an extra percentage built in to pay for two or three nurses getting paid for 40 hours that they are not working, just in case the hospice needs them. Also, because the reimbursement rates are calculated so carefully, there is an automatic obstacle to prevent hospices from over using agency, which is of course more expensive than their own staff. Finally on this point, Medicare does not reimburse a nickel more for agency, so there is no additional expense to the taxpayer.

> *[[Page 30886]]*

> *"The hospice may contract for physician services as stated in Sec. 418.64(a). A hospice may use contracted staff provided by another Medicare certified hospice to furnish core services, if necessary, to supplement hospice employees in*

order to meet the needs of patients under extraordinary or other non-routine circumstances, as described in Sec. 418.64."

Why can a hospice contract for physicians or other specialized care, but it seems that the regulations deliberately skirt the issue of LVNs and continuous care, or outright oppose the use of agency in continuous care?

All this still does not address the main point of patient care. In the Introduction it states:

> *"As a result, we are revising the Medicare hospice requirements, which are also used by Medicaid, to focus on a patient-centered, outcome-oriented process that promotes patient care foremost, rather than penalizing unproductive providers."*

All of the above seems to contradict your own goals set forth in these CoPs. If even one patient goes without care and suffers needlessly, when there may be a qualified, licensed professional a phone call away, there will have been a failure in the system.

Why is there an obvious bias against Agency?

The following is an excerpt from Page 30842:

> *"Below is a list of the most cited deficiencies found by surveyors (year ending September 3, 2002):*
> *1. Plan of care was not complete.*
> *2. No written plan was established.*
> *3. Plan was not reviewed at specific intervals.*
> *4. Plan did not include an assessment of needs.*
> *5. Plan was not established before providing care.*
> *6. RN supervisory visits were not made for home health aide services.*
> *7. No plan of care was included for bereavement services.*
> *8. Hospice did not conduct a self-assessment of quality and care provided.*
> *9. Clinical record was not maintained for every patient.*
> *10. Interdisciplinary group did not review and update the plan of care for each patient.*
> *We note that 8 of the 10 top deficiencies are related to plan of care, assessment, and quality assurance."*

Note that there is nothing in your own list that has anything to do with problems arising from the use of qualified agency, so why the obvious slant against agency that is in the proposed CoPs?

Doctor's offices and clinics are allowed to utilize temporary staffing. If you go to the emergency room you often receive care from nurses or doctors who are not employees of the hospital, but are provided by agency. Even in surgery you may be put under general anesthesia by a temporary staff member, some even brought in from outside the country.

Yet the stance taken throughout the CoPs is that hospice should not utilize outside agency. This is contrary to accepted practice throughout the medical community. The issues of orientation to policy and specialized training needs have been effectively dealt with in all the above examples. Actually, the regulations had effectively addressed that to some degree in:

42 CFR § 418.80 Condition of participation—Furnishing of core services.

"....A hospice may use contracted staff if necessary to supplement hospice employees in order to meet the needs of patients during periods of peak patient loads or under extraordinary circumstances.

If contracting is used, the hospice must maintain professional, financial, and administrative responsibility for the services and must assure that the qualifications of staff and services provided meet the requirements specified in this sub-part.

Unfortunately, any "permission" granted by this regulation is effectively contradicted or negated by other language throughout the old as well as proposed CoPs. The government obviously recognized a need for supplemental care at some point. Why allow for it in one section, then disallow it every other time it is addressed?

[[Page 30850]]

Condition of Participation: Licensed Professional Services (Proposed Sec. 418.62)

Sections of current regulations at Sec. 418.82, Nursing services; Sec. 418.84, Medical social services; and Sec. 418.92, Physical therapy, occupational therapy and speech-language pathology, identify detailed tasks that must be performed by agency staff.

We are proposing to delete Sec. 418.82, Sec. 418.84, and Sec. 418.92, and replace them with a more simplified condition, licensed professional services.

This section has been revised to reflect changes to the Act made by section 946 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (``MMA"). In accordance with that provision, we are proposing to allow a hospice (the primary hospice) to enter into arrangements with another Medicare certified hospice to obtain core hospice services. This could be done under extraordinary or other non-routine circumstances. Pursuant to Section 1861(dd)(5)(D) of the Act, as added by section 946(a) of the MMA, those circumstances are: Unanticipated periods of high patient loads; staffing shortages due to illness or other short-term temporary situations that interrupt patient care such as natural disasters; and temporary travel of a patient outside the hospice's service area.

You have proposed that the solution to staffing shortages is that hospices would contract with each other. I fear this will result in patients going without care. Hospices are very competitive, and there will be too many instances of hospices electing to deny needed care

rather than turn over all information about a patient to a competitor. This plan might work for highly specialized services that are used on a sporadic basis, such as a speech therapist, but I do not believe that hospices will be comfortable with swapping nurses back and forth.

Still, the above section completely avoids the question of hospices using qualified agency LVNs to assist during peak patient loads for continuous care.

[Page 30851]]

> *" In this standard we have also proposed to allow hospices to provide certain types of nursing services under a legally binding written contract. .....These nursing services must be highly specialized and provided non routinely and so infrequently that their provision by hospice employees would be impracticable and prohibitively expensive. .....Highly specialized services, as described, would not include continuous care because, while time intensive, such care does not require highly specialized nursing skills."*

This has all the appearances of a ban on contracting for LVN staffing for continuous care under any circumstances. While it may be intended to delineate between highly specialized nursing services and those services that are not, it is our experience that surveyors will take the most restrictive interpretation of any regulation, and therefore will tell hospices that they may not contract for LVNs for continuous care under any circumstances.

The Bottom Line

All the above probably appears to be convoluted and confusing. But that is my point exactly. Because of the contradictory nature of much of the regulations, I fear that there will be many patients that have a desperate need for around the clock care who will be denied that care and suffer needlessly' if for no other reason that the hospices and surveyors will be confused as to the exact intention of some of the regulations.

I believe that the correct spirit exists in the following:

"Require that patient rights are ensured.

The Patient Rights CoP emphasizes a hospice's responsibility to respect and promote the rights of each hospice patient."

Note that it says "each patient", not most patients, substantially all patients, or all the patients that a hospice can cover with their own staff. I am not and would never suggest that hospices should be able to utilize unqualified staff on their patients or avoid the responsibility of hiring their own staff. I simply request that there be some sort of language in the regs that clearly states:

> *A hospice may utilize contracted staff for continuous care during peak patient loads provided:*
>
> 1. *The hospice retains responsibility and supervision for the patient and care plan.*
> 2. *The contracted staff is appropriately licensed or certified per their discipline.*

3. *The staff has been trained to the nature of hospice and palliative care, as well as the hospices policies and procedures.*

I want nothing more than the knowledge that we are working together to get all hospice patients all the care they need. As long as the staff is appropriately trained and supervised, I see no reason that a patient should be denied care because the nurse is contracted rather than directly employed by the hospice. The source of the care is invisible to the patient; only the quality is of concern. Page 30849 states:

> *"We expect that a hospice would take immediate action to correct any identified problems that directly or potentially threatened the care and safety of patients."*

We all share in this responsibility together. Please help us help those that need it most. Thank you for your time.

Sincerely,

Bob Allen
Continuous Care Solutions

24

HOME HEALTH
CARE ASSOCIATION
OF MASSACHUSETTS, INC.

July 5, 2005

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

Dear Sir/Madam:

On behalf of the nearly 40 hospices affiliated with our member home health agencies, the Home & Health Care Association of Massachusetts appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) 2005 Proposed Medicare Conditions of Participation for Hospice Programs.

The Home & Health Care Association of Massachusetts (HHCAM) is the trade association that represents the home health industry in Massachusetts. The following comments represent the suggestions of our 100 member agencies and their clinical staff members who care for patients in the community.

We concur with the hospice industry that the proposed COPs are more logical in the way they are organized and therefore more user friendly and helpful. This in turn will encourage a greater degree of uniformity among hospice providers and ensure that a high standard of quality hospice care is available for patients and their families – wherever they are receiving that care.

§ 418. 54 Condition of Participation: Comprehensive assessment of the patient

(a) Standard: Initial Assessment

The requirement for the assessment within 24 hours is not practical. About half of hospice referrals come from a non-physician and is not subject to an attending physician order. Even with a physician referral, the first physician order may be for a consult not for an admission. Whatever the source of the referral, the patient/family not the hospice is ultimately in control as to when the admission takes place as the patient must elect the

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benefit. The language should be changed to make available to the patient/family a *visit or contact within 24 hours* or as otherwise requested by the patient/family.

(b) Standard: The time frame for completion of the comprehensive assessment within 4 calendar days is realistic and necessary given that 1/3 of hospice patients die within 7 days. Once the patient is "ready" the process needs to move quickly.

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

We agree that it is appropriate that the new COPs require a "qualified health care professional" rather than the RN to coordinate the care. This takes into account the uniqueness of each patient and their particular needs which may determine which member of the IDT is most appropriate.

At © Standard: Content of the Plan of Care

(6) IDT's documentation of patient and family understanding, involvement, and *agreement* with the plan of care...

We recognize that the unit of care is both patient and family. This regulatory language may be problematic in situations where the family is not in agreement with the plan of care but the patient is. We would suggest that there needs to be some clarification in situations where there is a difference of opinion, and the patient is competent to make his/her own decisions. In these situations a hospice would be in compliance if the patient is in agreement with the plan of care.

At (d) Review of the Plan of Care. The requirement for the hospice medical director to collaborate with the attending MD may be desirable but is not always possible. The attending MD may not wish to participate with this level of patient care and/or time constraints may make this difficult. This issue should be considered by the IDT and decided on an individual patient basis.

§418: 58 Condition of Participation: Quality Assessment and Performance Improvement

Quality Assessment and Performance Improvement is a complex area as the home health OBQI process has demonstrated. We recommend that CMS work with the hospice industry in their efforts to develop standardized outcome measures that truly measure the care being provided. "Adverse Events" also needs clarification. It is essential that language in the interpretive guidelines is included that differentiates hospice care from other community-based care when reviewing adverse events.

§418: 76 Condition of Participation: Home Health Aide and Homemaker Services
(h) Supervision of home health aides

We support the concept of a supervisory visit being done with the aide present to supervise the care plan no less frequently than every 28 days. This insures that what the aide is doing continues to meet the patient and family needs and those tasks being delegated by the nurse or therapist are being done appropriately. In fact, this has become a community standard in Massachusetts and is part of the policies in many home health agencies. It is a clinical function and not a "human resource" one.

With this proposed standard, a clarification is needed. As written, the regulation is not clear. In-person supervision of every aide who works for the hospice every 28 days would be very burdensome especially where there may be several aides with one patient and aides work with more than one patient during the course of a 24 hour period.

There are many ways to assess the competency of an aide including the competency assessment done when the aide is hired. Short length of stay should not be the determining factor for a "human resource" issue. To meet the CMS goal of closer supervision of aides, HHCAM strongly recommends that the Conditions of Participation require documentation in the personnel file of aide assessment done every six months for newer aides and yearly for those with more experience.

§418:100 Condition of Participation: Organization and Administration of Services

(a) Standard: Serving the hospice patient and family

(2) That each patient experience hospice care.....*consistent with patient and family needs and desires.*

As in §418.56 © (6), although the patient and family are the unit of care, the language of the standard should reflect the primacy of the patient's wishes, needs, etc. that take precedence if there is a conflict.

Further, words such as "dignity, needs, and desires" are subjective in nature and can create problems for providers during a survey. A "difference of opinion" with a surveyor is not an uncommon occurrence and a survey process that has no appeal rights for providers can result in a hospice program receiving deficiencies when it is the "Standard" that is unclear!

(f) Standard: Hospice satellite locations

Based on the experiences of home health providers, this language is a welcome addition to the COPs. CMS must provide further clarification so the standard is clear and interpreted in the same manner by all state survey agencies. Interpretive Guideline safeguards such as clarifying level of administration, staffing and the distance of the service area from the main office are necessary and needed to maintain high quality care.

§418.102 Condition of Participation: Medical Director

© Standard: Coordination of Medical Care

".....the medical director.....is also responsible for directing the hospice's quality assessment and performance improvement program."

Most physicians have a passive understanding of and little interest in QAPI! And, in many hospices, the medical director is a volunteer or part time. HHCAM recommends strongly that Quality Assurance & Performance Improvement, as with many of the other hospice program requirements, should be under the general direction of the hospice program executive director. He/She may then delegate this responsibility to the most appropriate member of the hospice staff. This individual may vary from hospice to hospice depending on the interests and credentials of the hospice staff. §418: 58 (Quality Assessment and Performance Improvement) provides the necessary framework to further support this effort.

As a general comment, the proposed COPs hint at a heightened level of responsibility and importance of the hospice medical director. The custom of hospice is that the medical director is a member of an interdisciplinary team and carries equal weight with the other members.

§ 418.112 Condition of Participation: Hospice in the SNF
At (d) Medical Director: The requirement for communication between the hospice medical director, attending physician, SNF medical director and other physicians will restrict access to hospice care for nursing home patients. The communication should be *encouraged* when the involved parties express a desire to be involved and/or the IDT feels this would be helpful.

§418.104 Condition of Participation: Clinical Records
© Standard: Discharge or Transfer of care

If a patient transfers to another facility or hospice, that provider would do their own comprehensive assessment. Sending a patient's clinical record is burdensome and unnecessary. The COPs should require following the minimum necessary standard, so that a discharge summary would be adequate. If specific issues come up after that, they can be addressed on an individual basis.

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

(b) Standard: Controlled Drugs in the Patient's Home

The language in this standard must be redrafted to address safety rather than its current focus on a host of potential dangers. It is difficult enough to provide pain management without mandated language that further scares the family. Concerns about addiction are prevalent with families given the media's focus on the dangers. Hospice COPs should focus on providing symptom relief in a safe manner.

Also at §418.52 Patient Rights (a) (1) Information about tracking and disposal of controlled substances is too overwhelming and frightening for families on admission.

The written information in the patient/family handbook is sufficient. The discussion can be held at a more appropriate time.

© Standard: Use and Maintenance of Equipment
"where there is no manufacturer recommendation for a piece of equipment, the hospice must develop its own repair and maintenance policies..."

Repair and maintenance is not an area of expertise for a hospice! The language of the standard needs to reflect that this is the responsibility of the DME provider/vendor. The regulations should require that the responsibility for the hospice is to be sure these policies exist and that schedules are in place and being followed.

§418.108 Condition of Participation: Short-term in-patient care

HHCAM recommends that "crises of a psychosocial/family nature" should be added to the "purposes" list for respite care. Fragile and/or dysfunctional families may need this added support to enable them to deal with their own issues and continue providing care and support to a hospice patient.

(a) Standard: Inpatient Care for pain control and symptom management need the *assessment skills of a nurse* and to meet the need, the COPs should require a registered nurse be on site on a 24 hour basis. This would be our comment for §418.110 Condition of Participation: Hospices that provide inpatient care directly

(o) Standard: Seclusion and restraint
The concepts of seclusion and restraint in a hospice are different than in a nursing home. With a survey process that has no appeal rights, there must be language in the Interpretive Guidelines that clarify and reflect acceptable home-based hospice practice.

For example, surveyors who survey nursing homes need to be aware that seclusion is the restricted confinement of a person alone in a room where they are physically prevented from leaving. They also need to know that medications that in other settings are used to restrain may be the appropriate intervention for terminal agitation which is a common occurrence during the last few hours of life

§ 418.114 Condition of Participation: Personnel Qualifications for licensed professionals
© Standard: Social Worker

Patients and/or families in a hospice program have many complex end of life issues with which to deal. These issues frequently exacerbate long-standing problems. It is important that an MSW be required as the base-line qualification for a hospice social worker. HHCAM recommends that CMS reinstate the current requirement so that the standard of care for hospice patients is that care is provided by an MSW or by a social work assistant with a bachelor's degree under the supervision of an MSW.

(c) Standard: Criminal background Checks

HHCAM supports CMS'position requiring criminal background checks on each hospice employee before employment.

It is the position of the HHCAM that working with patients and families in the isolation of the home setting at a vulnerable time in their lives demands the added protection of background checks – for all staff of the hospice who work directly with the patients and their families in the home. It is not something that can be ignored for expediency. Absent a state mechanism for doing this, contracting with national companies would allow hospices to comply with this standard.

We appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) 2005 Proposed Medicare Conditions of Participation for Hospice Programs. HHCAM supports your efforts in revising these regulations and in recognizing that the world of community-based care is far different than it was in 1983 when these regulations were finalized.

Very truly yours,

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

File Code CMS-3844-P

COMMENTS SUBMITTED FROM *THE CAROLINAS CENTER FOR HOSPICE AND END OF LIFE CARE*-- HOSPICE FACILITY-BASED WORKGROUP

P.O. BOX 4449
CARY, NORTH CAROLINA 27519

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.	

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2005 CMS PROPOSED COPS	*REQUEST FOR COMMENTS*
Drug restraint means a medication used to control behavior or to restrict the patient's freedom of movement, which is not a standard treatment for a patient's medical or psychiatric condition.	
Employee means a person who works for the hospice and for whom the hospice is required to issue a W–2 form on his or her behalf, or if the hospice is a subdivision of an agency or organization, an employee of the agency or organization who is appropriately trained and assigned to the hospice or is a volunteer under the jurisdiction of the hospice.	
Hospice means a public agency or private organization or subdivision of either of these that is primarily engaged in providing hospice care as defined in this section.	
Hospice care means a comprehensive set of services described in 1861(dd)(1) of the Act, identified and coordinated by an interdisciplinary team to provide for the physical, psychosocial, spiritual, and emotional needs of a terminally ill patient and/or family members, as delineated in a specific patient plan of care.	
Licensed professional means a licensed person sanctioned by the State in which services are delivered, furnishing services such as skilled nursing care, physical therapy, speech-language pathology, occupational therapy, and medical social services.	
Palliative care means patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice.	
Physical restraint means any manual method or physical or mechanical device, material, or equipment attached to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body.	"equip. attached or adjacent to the pt's body" would be approp. addition. Clinical judgement to use "restraint" needs to be allowed for sx management & safety as addressed in 418.110/o
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	

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

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

2005 CMS PROPOSED COPS *Subpart C*	*REQUEST FOR COMMENTS*
§ 418.52 Condition of participation: Patient's rights.	
(a) Standard: Notice of rights.	
(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.*	
(b) *Standard: Time frame for completion of the comprehensive assessment.*	
(c) *Standard: Content of the comprehensive assessment.*	
(d) *Standard: Update of the comprehensive assessment.*	
(e) *Standard: Patient outcome measures.*	
§ 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 PROPOSED MEDICARE CONDITIONS OF PARTICIPATION FOR HOSPICE PROGRAMS WITH REQUEST FOR COMMENTS

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.	
(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.	
(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.*	
§ 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.*	
(h) *Standard: Supervision of home health aides.*	
(i) *Standard: Individuals furnishing Medicaid personal*	

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

2005 CMS PROPOSED COPS Subpart C	*REQUEST FOR COMMENTS*
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.*	
§ 418.104 Condition of participation: Clinical records.	
(a) *Standard: Content.* Each patient's record must include the following:	
(b) *Standard: Authentication.*	
(c) *Standard: Protection of information.*	
(d) *Standard: Retention of records.*	
(e) *Standard: Discharge or transfer of care.*	
(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.*	
(c) *Standard: Use and maintenance of equipment and supplies*	
§ 418.108 Condition of participation: Short-term inpatient care.	**The provision of short-term inpatient must include provision of that care for crises of a psychosocial/family/caregiver nature**
(a) *Standard: Inpatient care for symptom management and pain control.*	**Due to the nature of the care, general inpatient level of care must require 24 hour nursing onsite at the RN level due to the need for critical thinking skills**

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

2005 CMS PROPOSED COPS ***Subpart C***	*REQUEST FOR COMMENTS*
(b) *Standard: Inpatient care for respite purposes.*	**Respite care should be redefined as a routine level of care and therefore not requiring 24 hour nursing onsite at the RN level**
(c) *Standard: Inpatient care provided under arrangements.*	
(d) *Standard: Inpatient care limitation.*	**We request that respite days be removed from the count of GIP days (if changed from respite inpatient to routine respite care)**
(e) *Standard: Exemption from limitation.*	
§ 418.110 Condition of participation: Hospices that provide inpatient care directly.	**Clarify that subsequent standards in 418.110 applies to hospice owned facilities, not contracted nursing facilities**
(a) *Standard: Staffing..*	
(b) *Standard: Twenty-four hour nursing services.*	**24hr RN on site at GIP, RN on call for respite/routine**
(c) *Standard: Physical environment.*	**Equip. failure reporting only if sentinel event? required by whom & to whom? (ii) may be from Safe Medical Device Act**
(d) *Standard: Fire protection.*	
(e) *Standard: Patient areas*	
(f) *Standard: Patient rooms.*	**This proposed requirement is not seen as a burden**
(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.*	
(m) *Standard: Pharmaceutical services.*	**Agree to cross ref. 418.106 as whole agency.**
(n) Pharmacist.	**(n)(2)(iii) include pt identified caregiver**
(o) *Standard: Seclusion and restraint.*	**This new standard needs to allow for the management of the safety of the resident and the staff. There must be language that speaks to common symptom management in a terminally ill patient that might be construed as chemical restraints in other healthcare settings. The language in this standard appears to apply to hospital settings—the hospice inpatient facility is not a hospital or a long-term nursing facility.** **"control behavior" must be delineated from methods needed to ensure comfort/freedom from distress for the hospice patient & safety of the hospice patient & caregivers.** **Allow for hospice documentation to support treatment options for the patient & family.** **Examples needing appropriate hospicereatment that may be misconstrued as restraint: terminal restlessness, existential distress, intractable pain, dementia, anxiety, brain disease** **Examples of meds used: lorazepam, haloperidol, midazolam, chlorpromazine** **(O)(3)(ii)(c):MD eval w/in 1 hr: could be burdensome & unnecessary in hospice owned facility.**
§ 418.112 Condition of participation: Hospices that provide hospice care to residents of a SNF/NF, ICF/MR, or other facilities.	
(a) *Standard: Resident eligibility, election, and duration*	

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

2005 CMS PROPOSED COPS *Subpart C*	*REQUEST FOR COMMENTS*
of benefits.	
(b) *Standard: Professional management.*	
(c) *Standard: Core services.*	
(d) *Standard: Medical director.*	
(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.*	**If the issue is BSW vs MSW it is felt that this is not an issue, experience is the key and a BSW might be sufficient.**
(b) Personnel qualification for physicians, speech-language pathologist, and home health aides.	
(c) *Personnel qualifications when no State licensing, certification or registration requirements exist.*	
(d) *Standard: Criminal background checks.*	**This requirement is not seen as a burden but a must – leave it in**
§ 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.

Caring Community Hospice
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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 or Madam:

July 22, 2005

Thank you for the opportunity to comment on the Medicare and Medicaid programs: Hospice Conditions of Participation: Proposed Rule published on May 27, 2005 in the Federal Register, and for taking our comments under consideration. As a smaller rural program, our concerns are just as important as larger programs, since we all have to live under the same Conditions. We believe that a lot of work went into these proposed revisions, and most are very workable, indeed are many of the same things we are already doing to a large extent. Here are the few that cause us some concern:

Section 418.3 Definitions

We request the following changes in this section:

1. The definition for *Drug restraint*: consider amending as follows: means a medication used to control behavior or to restrict the patient's freedom of movement, "which is not a standard hospice treatment or not requested by the patient or the patient's surrogate." Hospice commonly uses medications such as Haldol or Ativan to control symptoms, which are considered a drug restraint in other settings. The issue here is patient's rights. Our concern is that in trying to protect patient's rights, this will actually restrict a hospice patient's right to control end-of-life symptoms. Hospice provides most care in the patient's home where there would be no benefit to hospice staff to have the patient restrained. Dying patients also have the right to have troubling symptoms managed effectively. Whether a patient/family choose to actually use an ordered medication (after full education re: dose, use, side effects) is entirely up to them. **That is NOT a restraint.**

Section 418.52 Condition of Participation: Patient's Rights

1. Section (a) (3) "tracking" of drugs - Prescriptions are dispensed to the patient and are their property, unlike in an institution, where they are owned and fully under the control of the facility. It will be virtually impossible for hospice to "track" drugs when they are not under our complete control. We already do limited prescription fills, know when refills are due, and count narcotics remaining at death. That's as far as we can "track". Plus, we can't be held responsible for narcotics dispensed

that are NOT supplied by the hospice, since they are not related to the terminal diagnosis. We have no control over their dispensing, refilling, etc.

Section 418.54 Condition of Participation: Comprehensive Assessment

Section (a):

- **We have a problem with the 24 hour rule (we believe you mean "physician certification" rather than "physician order"?). This requirement is problematic for many reasons:**

1) If you leave this as "order", ANY physician might call in a referral, but not be willing to act as attending physician and therefore would not be the certifying physician. (Surgeons are notorious for this- they wash their hands after they make a referral call.) So, with this wording, we'd have to go and assess whether or not we have a certifying physician, without being able to admit. . . .a waste of time and very unkind to a patient!
2) The 24 hour rule leaves absolutely no leeway for patient/ family need or preference- something hospice is all about in the first place. It is very common to try to set up a home visit time, only to have the patient want to wait for her daughter to be available at a later time, well beyond the 24 hours. This is NOT the same as a home care admission where you can walk in and admit. Here we are required to give FULL explanation of the waiver of their standard Medicare, election of palliative comfort care, etc. There are MANY ramifications when a family member (who wasn't at the initial assessment and program explanation) hauls Mom off to the specialist again after hospice admission (and (s)he's not the attending physician and doesn't know patient is in hospice), who does an MRI or CT scan. . . . . guess who gets the bill? Admission consents clearly state the patient agrees all tests related to the hospice diagnosis must be preapproved by the hospice to be paid. In this scenario, hospice doesn't pay, Medicare refuses to pay, and the 87 yr old patient who forgot that requirement gets a bill for thousands of dollars, all because we didn't have that family member on board with the program. How the program is explained up front is CRUCIAL. . .that's why we try to get as many family members as possible (that the patient wants involved) at that initial visit.
3) We do weekend admissions when we know about them on a Friday, have enough medical information to review, have a certifying physician, and can explain the program and consents to the patient/family (done by a primary hospice RN). Our on-call nurse then goes out to do the assessment and start care. We have exactly two primary RNs in our program. Otherwise, we have on-call nurses to respond to patients' needs after hours. There is too much explanation of the program and consents in an admission assessment to teach an on-call nurse to do. . . . . .to say nothing of the fact that the full program explanation process is lengthy, followed by the "assessment of needs". We can't tie up an on-call nurse who must respond to other patients in a timely manner. **We have no idea how we could meet this requirement without paying another nurse to be on standby for admissions only. That would devastate our nursing salary budget.**

Doctor's offices are not routinely open in our area on the weekends. We have had exactly one referral in the past year that came in on a Saturday- it came at 10 pm on Saturday night from a surgeon in an ER. So, with your requirement, we would have had no medical information (other than the little the ER had) to review, we would have no promise of a certifying physician (surgeon would not act as attending), but we would still be forced to have gone out to the patient by 10 pm on Sunday evening to do the initial "assessment of needs". And if the patient had not been Medicare or Medicaid, it is likely we would have no idea what to tell them about their insurance because their insurance offices would be closed (another requirement of yours . . patients have the right to know their financial liability prior to service delivery). So what good is the "initial assessment of needs" when we precious little information we can tell them AND we could not have admitted without a certifying physician and more information?

We believe your intent was to make sure that hospices are responding in a timely manner to referrals. Let me assure you that our small rural hospice (whose doctor's offices are closed on weekends) is just as timely as large urban hospices (whose doctor's offices are open on weekends making referrals, and whose hospices have separate admission teams working full time on the weekends.) How do we know this? Our median length of stay in 2003 was 18 days, in 2004 was 17.5 days. The median length of stay for all of New York State hospices for 2003 (latest data available) was 18 days. We are admitting just as timely as large hospices with offices open on weekends.

The 24 hour requirement makes no sense and places an undue unnecessary burden on small rural hospices, which we don't believe was your intent. Large urban hospices and state hospice associations probably will not even comment on this because it does not affect them, but for us, this is very problematic and very costly to implement for the one time a year it might come up.

Section (c) Content of the comprehensive assessment- It needs to be recognized that hospice is dependent upon the patient/family/physican regarding the use of drugs other than for the terminal illness. Hospice cannot be held responsible for being aware of drugs that hospice is not informed of by the patient, family, physician or other health care provider.

Section (d) Standard: Update of the comprehensive assessment.

- **Please consider "every 14 days" be changed to "every two weeks," or "15 days" to provide the leeway needed for holidays and emergencies.** This is yet another burden that home care agencies do NOT have. We need some leeway here. Otherwise, a future surveyor will take out a calendar, count off 14 calendar days, and fault a hospice for being one day early once and not sticking with that revised schedule from then on.

(d) Review of plan of care – recommend 14 days be changed to two weeks or 15 days. **(Same rationale as already discussed previously**.)

(h) i. change every 14 days to every two weeks, **(same rationale as discussed previously**) and change 28 days to 60 days to be consistent with NYS statute.

Section 418.102 Condition of Participation: Medical Director

1. **Section (c)** Medical Directors are not the best choice to direct the hospice's quality assessment and performance improvement program. Seeing how it works in other institutions (hospitals, NFs), the Medical Director delegates all the actual planning, analysis and work to others, then signs off on the results. We sincerely do not believe that is your intent. Please rethink this issue. Medical Directors know medical issues. They are not as informed overall when it comes to other programatic quality issues (and there are many). They are definitely NOT the best to oversee this important piece of hospice.

Section 418. 104 Condition of Participation: Clinical Records

1. Section (e) – please drop the requirement for hospice to provide a "copy of the clinical record" to the patient's attending physician in the case of a revocation or discharge. The discharge summary is more than adequate. Under HIPAA, we really only can supply the "minimum necessary". What is the "entire medical record" needed for? If it is, they can request the parts they need. **The purpose of a discharge summary is to ensure coordinated continuing care by the next provider**. That is the intent of this reg. Doctors will be steaming mad if they start to receive volumes of papers they don't need and did not request. This requirement makes no sense.

Section 418.106 Condition of Participation: Drugs, Controlled Drugs and Biologicals

1. **Section (b)** Hospice is not legally able to collect controlled drugs in a patient's home – it is illegal to transport a controlled substance without a prescription and this would typically be done when the patient has died so the prescription is no longer valid. The word "collecting" MUST BE REMOVED. The term tracking is also of concern. **We have previously discussed this**.

Item (o) *Standard: Restraint and seclusion.*
As noted in the previous section "Definitions" We have great concern over the potential impact on end-of-life care when use of a medication to control some symptoms such as terminal agitation or restlessness, is perceived as imposition of a chemical restraint. It is not. That is standard acceptable hospice symptom management. **Suggested change** for inclusion in (o)(1) is the addition

after"...normal access to ones' body" is "**Bed rails are not included in this definition of restraint if used for the safety of the patient or to assist the patient in independent functioning."**

418.110 Conditions of Participation: Hospices that provide hospice care to residents of a SNF/ICF, MR or other facilities.

Does this condition match the requirements that will be proposed for nursing homes? They need to be match and be very clearly in nursing home regs.

(c) *Standard: Medical Director*

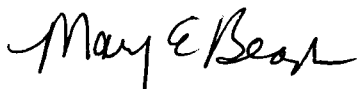
Good communication between hospice medical director through the hospice team (generally the hospice nurse) works well for most NF patients most of the time. It is not realistic nor necessary for medical director to speak directly with a NF medical director UNLESS there is a problem. That's the current practice. Physicians are incredibly busy. Why are you mandating direct communication on each and every patient? Why is this any different than a patient we serve at home with an attending doctor? To be consistent, you would have to mandate that the hospice medical director directly call each and every attending physician for a home care case, too. This requirement makes no sense for any case- NF or home care.

(d) *Standard: Hospice Plan of care*

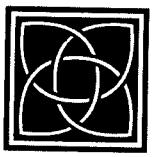
Item (3) regarding the 14-day requirement for care plan review. Suggestion that this be changed to 15 days to better synch with the existing certification schedule.

Thank you again for your consideration of all our comments. We appreciate the time and effort involved in making these revisions. We all want the same thing. Quality care for hospice patients and families.

Sincerely,



Mary E. Beach
Hospice Director



Texas Non-Profit Hospice Alliance

July 22, 2005

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

Re: File code CMS-3844-P

To Whom It May Concern:

The Texas Non-Profit Hospice Alliance (TNPHA) represents twenty (20) non-profit hospices serving the majority of the population of Texas. We would like to submit the attached comments on the proposed revision of the Conditions of Participation for hospice providers and would appreciate your review and consideration of them.

We appreciate the time and work that has gone into the proposed revisions and look forward to reviewing any proposed changes in a second comment period.

Thank you for your consideration of these comments.

In the Spirit of Hospice-
Respectfully,

Edd Hess, President
Texas Non-Profit Hospice Alliance
c/o Cypress Basin Hospice
207 W. Morgan Street
Mount Pleasant, Texas 75455
(903) 577-1510

Attachments:
One original and two copies

Submitted on Behalf of the Following Members of the Texas Non-Profit Hospice Alliance:

VNA and Hospice of South Texas
San Antonio, Texas

Hospice of Midland
Midland, Texas

Houston Hospice
Houston, Texas

Christus Spohn Hospice
Corpus Christi, Texas

Texas Non-Profit Hospice Alliance

Hospice of Wichita Falls
Wichita Falls, Texas

Home Hospice of Grayson County
Sherman, Texas

Hospice of South Texas
Victoria, Texas

Community Hospice of Texas
Fort Worth, Texas

Hospice of Texarkana
Texarkana, Texas

Hospice of San Angelo
San Angelo, Texas

Greater Hill Country Hospice
Fredericksburg, Texas

Hospice Team Care
Texas City, Texas

Lakes Area Hospice
Jasper, Texas

Hospice of East Texas
Tyler, Texas

Hospice of Brazos Valley
Bryan, Texas

Hospice Austin
Austin, Texas

Cypress Basin Hospice
Mount Pleasant, Texas

Hospice of El Paso
El Paso, Texas

Hendrick Hospice Care
Abilene, Texas

Hospice of Deep East Texas
Nacogdoches, Texas

2005 Proposed COPs	Comments by Texas Non-Profit Hospice Alliance (Alliance)
418.52 Condition of Participation: Patient's Rights	
(a) Standard: Notice of rights: (1) The hospice must provide the patient or representative with verbal and written notice of the patient's rights and responsibilities in a language and manner that the patient understands during the initial evaluation visit in advance of furnishing care.	**The hospice must provide the patient or representative with <u>verbal</u> notice of the patient's rights and responsibilities in a language and manner that the patient understands during the initial evaluation visit in advance of furnishing care. The hospice must provide the patient or representative with <u>written</u> notice of the patient's rights and responsibilities in the predominant language(s) of the hospice's service area during the initial evaluation visit in advance of furnishing care.** *Rationale: In some communities, there are hundreds of dialects and it will be extremely costly and expensive to translate these documents into all languages & dialects. This requirement will become a significant barrier to accessing hospice for these patients. Verbal translation occurs now and works well and does not deny patients access to hospice care.*
(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.	**<u>Delete requirement related to informing patient and family of hospice's drug policies and procedures upon admission.</u>** *Rationale: We believe that patients and families are already overwhelmed at the time of admission and this information should be presented to the patient and family by the appropriate member of the IDT after, not during, admission.*
(b) Standard: Exercise of rights and respect for property and person.	**The Alliance recommends that CMS consider using the patient rights requirements as defined in the Home Health**

	COPs at 484.10 for the hospice COPs, which we believe are more appropriate to the hospice/home environment.
(4) The hospice must- (i.) Ensure that all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property are reported to State and local bodies having jurisdiction (including to the State survey and certification agency) within at least 5 working days of the incident, and immediately to the hospice administrator.	**(4) The hospice must-** **(i.) Ensure that all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property are reported to State and local bodies having jurisdiction (including to the State survey and certification agency) within 5 working days of the incident, and immediately to the hospice administrator.** *Rationale: We believe that "within 5 working days" is less confusing.*
(e) Standard: Patient liability. Before care is initiated, the patient must be informed, verbally and in writing, and in a language that he or she can understand, of the extent to which payment may be expected from the patient, Medicare or Medicaid, third-party payers, or other resources of funding known to the hospice.	**Before care is initiated, the patient must be informed, ~~verbally and in writing, and in a language that he or she can understand,~~ of the extent to which payment may be expected from the patient, Medicare or Medicaid, third-party payers, or other resources of funding known to the hospice.** *Rationale: In some communities, there are hundreds of dialects and it will be extremely costly and expensive to translate these documents into all languages & dialects. This requirement will become a significant barrier to accessing hospice for these patients. Verbal translation occurs now and works well and does not deny patients access to hospice care.*
418.54 Condition of Participation: Comprehensive assessment of the patient.	
(a) Initial assessment: The hospice registered nurse must make an initial assessment visit within 24 hours after the hospice receives a physician's admission order for care	**The hospice registered nurse must make an initial assessment visit within <u>48 hours</u> after the hospice receives a physician's admission order for care (unless ordered otherwise by the**

(unless ordered otherwise by the physician), to determine the patient's immediate care and support needs.	**physician <u>or requested otherwise by the patient and/or family</u>), to determine the patient's immediate care and support needs.** *Rationale: We believe that while most hospices make the initial assessment visit within 24 hours, this standard is too restrictive and will result in deficiencies when the hospice occasionally is unable to make the initial assessment visit within 24 hours.*
(b) 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.	**The hospice interdisciplinary group in consultation with the individual's attending physician must complete the comprehensive assessment no later than <u>7 calendar days</u> after the patient elects the hospice benefit.** *Rationale: We believe that many patients and families will object to having 4 different people contact them within 4 days of initiating hospice care to complete the comprehensive assessment. We have a 7 day standard in Texas now and we often receive comments from families that it is, "raining hospice people".* **<u>The Alliance recommends that CMS not prescribe WHO must complete the comprehensive assessment, but instead prescribe WHAT must be assessed, namely the patient/family's physical, emotional, social and spiritual needs.</u>** *Rationale: Many patients and families refuse hospice services from a social worker and chaplain/counselor, and emotional, social and spiritual needs are assessed by the member(s) of the hospice IDT who are providing services to that patient/family. By prescribing WHAT is to be assessed, rather than WHO is to do*

	the assessing, the COPs will be much more in keeping with hospice care as it is actually provided. If CMS prescribes WHO must assess the patient/family, hospices will continually be out of compliance, because this requirement is impossible to meet and attempted compliance will alienate hospice patients/families and contribute to unnecessary revocation of hospice services.
(c) Standard: Content of the comprehensive assessment.	
(3) Factors that must be considered in developing individual care plan interventions, including- (i.) Bereavement: An initial bereavement assessment of the needs of the patient's family and other individuals focusing on the social, spiritual, and cultural factors that may impact their ability to cope with the patient's death. Information gathered from the initial bereavement assessment must be incorporated into the bereavement plan of care.	**(3) Factors that must be considered in developing individual care plan interventions, including-** **(i.) Bereavement: An initial bereavement assessment of the needs of the patient's family and other individuals focusing on the social, spiritual, and cultural factors that may impact their ability to cope with the patient's death. Information gathered from the initial bereavement assessment must be incorporated into the ~~bereavement~~ plan of care.** *Rationale: A bereavement assessment must be started at the time of admission and becomes part of the overall hospice plan of care.*
(d) Update of the comprehensive assessment. (1) As frequently as the condition of the patient requires, but no less frequently than every 14 days.	**The Alliance recommends that updates to the comprehensive assessment be called "Ongoing Assessment(s)" to help differentiate between the comprehensive assessment and updates to the comprehensive assessment.** **(1) As frequently as the condition of the patient requires, ~~but no less frequently than every 14 days~~.** *Rationale: If CMS requires that all 4 core disciplines (physician, RN, social worker and counselor) assess that patient every 14 days, patients and families will feel overwhelmed by the number of hospice staff who are contacting them. The Alliance believes*

	that this will cause many patients and families to refuse further contact from social work or counseling services.
(e) Standard: Patient outcome measures.	**The Alliance believes that outcome measures such as the NHPCO Dataset, the NHPCO Family Evaluation of Hospice Care and the NHPCO End Result Outcome Measures are important to the hospice's QAPI program.**
418.76 Condition of participation: Home health aide and homemaker services.	
(h) Standard: Supervision of home health aides.	
i. ....A registered nurse or a 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.	**i. ....A registered nurse or a 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~~ <u>at least annually.</u>** The Alliance strongly opposes the 28 day timeframe for supervisory home health aide visits. This standard is extremely burdensome to hospices, both financially and as far as ensuring compliance. The standard does not ensure that care will improve and in fact, care might decline since the standard requires that scarce nursing resources must be deployed for a task that can be handled through the agency's QAPI program. Even the Alliance's smallest member hospices projected the need for an additional full time equivalent (FTE) to ensure compliance with this standard. Either RN caseloads would have to be adjusted downward, or an extra nurse would have to be hired to conduct supervisory visits. The cost to each hospice is estimated to be approximately $50,000 per RN, including salary and benefits.

	Hospice nurses are not able to schedule their visits with the certainty that home health nurses can schedule their visits. Patient deaths, pain crises, family crises, etc., can and should disrupt hospice nurses routine scheduled visits each day. The Community Health Accreditation Program (CHAP) requires that hospices evaluate home health aides annually, including on-site evaluation of competency testing. The Alliance strongly urges CMS to consider utilizing this CHAP standard for the COP standard.
418.100 Condition of participation: Organization and administration of services.	
(a) Standard: Serving the hospice patient and family. The hospice must ensure that-	
(2) That each patient experience hospice care that is consistent with patient and family needs and desires.	**(2) That each patient experience hospice care that is consistent with patient and family assessed needs ~~and desires~~.** *Rationale: Patient and family needs and desires are vast and if interpreted literally, this standard could require that a hospice meet every family request, such as flying in family members from out of town, etc. The hospice IDT must assess patient and family needs and create a plan of care that meets those needs but the hospice cannot ensure that every patient and family desire is met.*
418.102 Condition of participation: 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.	**……. The medical director and physician designee communicate ~~coordinate~~ with other physicians and health care professionals to ensure that each patient experiences medical care that reflects hospice philosophy. ~~policy~~.** *Rationale: A Medical Director is responsible for overseeing the*

	medical care provided to hospice patients. The IDG is responsible for coordinating care. *Care should be consistent with the hospice philosophy, e.g., palliative, inclusive of the patient and family. Hospice "policy" is too prescriptive, and may not allow for each patient and family's unique needs.*
(c) Standard: Coordination of medical care. The medical director or physician designee, and other members of the interdisciplinary group are jointly responsible for the coordination of the patient's medical care in its entirety. The medical director or physician designee is also responsible for directing the hospice's quality assessment and performance improvement program.	**(c) Standard: Coordination of medical care.** **The medical director or physician designee, and other members of the interdisciplinary group are jointly responsible for the coordination of the patient's <u>hospice care.</u> ~~medical care in its entirety.~~ The medical director or physician designee is also responsible for <u>participating</u> in ~~directing~~ the hospice's quality assessment and performance improvement program.** *Rationale: Most hospice QAPI programs are directed by an RN experienced in QAPI and knowledgeable about the agency's operations. The hospice Medical Director is an essential member of the QAPI team, but he or she may or may not have expertise in QAPI. Each hospice should be allowed to appoint the most appropriate individual to direct its QAPI program, regardless of that individual's discipline.* *Also, "medical care" usually refers to physician services and "hospice care" is a broader term that better fits in this context.*
418.104 Condition of participation: Clinical records. (b) Standard: Authentication. All entries must be legible, clear, complete, and appropriately authenticated and dated. All entries must be signed, and the hospice must the able to authenticate each handwritten and electronic signature of a primary author who has	**(b) Standard: Authentication. All entries must be legible, clear, complete, and appropriately authenticated and dated. All entries must be signed, and the hospice must the able to authenticate each ~~handwritten and~~ electronic signature of a primary author who has reviewed and approved the entry.**

reviewed and approved the entry.	*Rationale: This standard seems more appropriate for a hospital. While hospitals are able to have lengthy credentialing processes for physicians, hospices must be able to respond quickly to referring physicians. Hospices have implemented expedited credentialing processes, such as verifying each physician's state license. Hospices are not able to easily authenticate each referring physician's handwritten signature, and requiring hospices to do so will delay hospice admissions and cause many last minute referrals to hospice to be denied hospice care entirely.* *Also, the manpower to collect the signatures from attending physicians and continuously monitor their authenticity would be significant and would be a tremendous financial burden for the hospice.*
(e) Standard: Discharge or transfer of care. (1) If the care of a patient is transferred to another Medicare/Medicaid-approved facility, the hospice must forward a copy of the patient's clinical record and the hospice discharge summary to the facility. (2) If a patient revokes the election of hospice care, or is discharged from hospice because eligibility criteria are no longer met, the hospice must provide a copy of the clinical record and the hospice discharge summary of this section to the patients' attending physician.	**(e) Standard: Discharge or transfer of care.** **(1) If the care of a patient is transferred to another Medicare/Medicaid-approved facility, the hospice must forward a copy of the patient's ~~clinical record and the~~ hospice discharge summary to the facility.** *Rationale: A discharge summary would be sufficient to ensure coordination of care. The entire record could be made available to the facility receiving the patient if requested as is stated in current hospital regulations.* **(2) If a patient revokes the election of hospice care, or is discharged from hospice because eligibility criteria are no longer met, the hospice must provide a copy of ~~the clinical record and~~ the hospice discharge summary of this section to the patients' attending physician upon request.**

	Rationale: Many physicians already complain about the amount of paperwork they receive from hospices. Physicians who want to review the patient's hospice record can easily request a copy from the hospice.
418.106 Condition of participation: Drugs, controlled drugs and biologicals, medical supplies, and durable medical equipment. 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.	**418.106 Condition of participation: Drugs, controlled drugs and biologicals, medical supplies, and durable medical equipment.** **(c) 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.** *Rationale: Hospices do not control the home environment and cannot be responsible for tracking and collecting controlled drugs.* *The word "tracking" implies that hospice nurses will be responsible for conducting a physical inventory of each patient's controlled drugs at each visit, and calculating if the correct number of pills remain, according to their prescribed use. While hospice nurses do strive to monitor patient's usage of controlled drugs to ensure that the patient has good symptom control and that refills are ordered on a timely basis, hospice nurses do not have the time to conduct an physical inventory of the patient's pills at each visit and calculate if the correct number of pills are remaining.* *Similarly, hospice nurses are not permitted to "collect" controlled drugs because the only person who is authorized to possess a controlled drug is the patient for whom the medication*

	was prescribed.
418.108 Condition of participation: Short-term inpatient care. Inpatient care must be available for pain control, symptom management, and respite purposes, and must be provided in a participating Medicare or Medicaid facility.	**418.108 Condition of participation: Short-term inpatient care. Inpatient care must be available for pain control, symptom management, ~~and~~ respite purposes and for crises of a psycho-social nature that make it infeasible for care to be provided in the patient's home, and must be provided in a participating Medicare or Medicaid facility.** *Rationale: Inpatient care is defined as short term and a short admission for a psychosocial crises is very appropriate in end-of-life care and can prevent patients from unnecessarily revoking hospice benefits and returning to (more costly) acute care.*
(a) Inpatient care for symptom management and pain control. (2) ---regarding 24 hour nursing services"	The Alliance strongly recommends keeping the requirement for 24 hour RN staffing for inpatient care, but removing it for respite care. *Rationale: Respite care is a more routine level of care and easily carried out by a licensed nurse. Inpatient care requires constant assessment that is most appropriately carried out by an RN.*
(c) Standard: Inpatient care provided under arrangements. If the hospice has an arrangement with a facility to provide for short-term inpatient care, the arrangement is described in a legally binding written agreement that at a minimum specifies- (3) That the hospice patient's inpatient clinical record includes a record of all inpatient services furnished, events regarding care that occurred at the facility, and that a copy of the inpatient clinical record and discharge summary is	**(c) Standard: Inpatient care provided under arrangements. If the hospice has an arrangement with a facility to provide for short-term inpatient care, the arrangement is described in a legally binding written agreement that at a minimum specifies-** **(3) That the hospice patient's inpatient clinical record includes a record of all inpatient services furnished, events regarding care that occurred at the facility, and that a copy of the ~~inpatient clinical record and~~**

available to the hospice at the time of discharge. (4) That the inpatient facility has identified an individual within the facility who is responsible of the implementation of the provisions of the agreement;	**discharge summary is available to the hospice at the time of discharge.** **(4) That the inpatient facility has identified a ~~individual~~ position within the facility who is responsible of the implementation of the provisions of the agreement;** *Rationale: The hospital discharge summary is sufficient for the hospice to ensure continuity of care. The hospice-facility contract should specify what position is responsible for implementing the provisions of the contract.*
(o) Seclusion and restraint (1) …*A drug used as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard treatment for a patient's medical or psychiatric condition.	**(o) Seclusion and restraint** …*A drug used as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard hospice treatment for a patient's medical or psychiatric condition. *Rationale: Although the intent of these guidelines is to prevent the use of medication or devices to unnecessarily restrain patients who should be managed through redirection or other non-restrictive methods, they can be construed to deter the use of medications when these interventions are necessary for the control of symptoms that cannot be managed through other methods or when patients are at risk of harming themselves or others. More desirable language would acknowledge the appropriate use of such medication in hospice patients to manage symptoms of life-limiting illnesses. Examples of appropriate use would be for pain management and terminal agitation.*
(3) (ii) (d) Each order for a physical restraint or seclusion must be in writing and limited to 4 hours for adults; 2 hours	(3) (ii) (d) Each order for a physical restraint or seclusion must be in writing and limited to 8 hours for adults while sleeping and 4

for children and adolescents ages 9 through 17; or 1 hour for patients under the age of 9.	hours while awake; 6 hours for children and adolescents ages 9 through 17 while sleeping and 2 hours while awake; or 2 hours for patients under the age of 9 while sleeping and 1 hour while awake.
(7) The hospice must report to the CMS regional office any death that occurs while the patient is restrained or in seclusion, within 24 hours after a patient has been removed from restraint or seclusion.	7) The hospice must report to the CMS regional office any unexpected death that occurs while the patient is restrained or in seclusion, or within 24 hours after a patient has been removed from restraint or seclusion. *Rationale: This would be a reasonable expectation, while defining and reporting every death while a patient is secluded or restrained might place more of a burden on the CMS office.*
418.112 Condition of participation: Hospices that provide care to residents of a SNF/NF, ICF/MR, or other facilities.	**The Alliance recommends that the effective date of this section be delayed until the SNF/NF requirements contain a parallel condition.**
(b) Professional management. The hospice must assume full responsibility for professional management of the resident's hospice care, in accordance with the hospice conditions of participation and make any arrangements necessary for inpatient care in a participating Medicare/Medicaid facility according to 418.100.	**(b) Professional management. The hospice must assume full responsibility for professional management of the resident's hospice care, in accordance with the hospice conditions of participation and make any arrangements necessary for inpatient care in a participating Medicare/Medicaid facility according to 418.100. The SNF/NF continues to provide services at the same level it would have provided if that resident had not elected the hospice benefit.**
(d) Medical Director. The medical director and physician designee of the hospice must provide overall coordination of the medical care of the hospice resident that resides in an SNF, NF or other facility. The medical director and physician designee must communicate with the medical director of the SNF/NF, the patient's attending physician, and other physicians participating in the provision of care for the	**(d) Medical Director.** ~~The medical director and physician designee of the hospice must provide overall coordination of the medical care of the hospice resident that resides in an SNF, NF or other facility.~~ The medical director and physician designee must communicate with ~~the medical director of the SNF/NF, the patient's attending physician, and~~ other physicians and healthcare professionals within a SNF/NF to ensure that each patient

terminal and related conditions to ensure quality care for the patient and family.	experiences medical care that reflects the hospice philosophy. ~~participating in the provision of care for the terminal and related conditions to ensure quality care for the patient and family.~~
418.114 Personnel qualification for licensed personnel (a) General qualification requirements. Except as specified in paragraph (c) of this section, all professionals who furnish services directly, under an individual contract, or under arrangements with a hospice, must be legally authorized (licensed, certified or registered) to practice by the State in which he or she performs such functions or actions, and must act only within the scope of his or her State license, or State certification, or registration. All personnel qualifications must be kept current at all times.	The Alliance agrees with this section and specifically with the qualification of state licensure for hospice social workers.
(7) Social worker. A person who has a baccalaureate degree from a school of social work accredited by the Council on Social Work Education	The Alliance agrees with CMS that this qualification should only apply in states that do not license social workers.

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Hospice

Texas & New Mexico Hospice Organization

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♦ tnmho@sbcglobal.net ♦ www.TxNMHospice.Org

July 21, 2005

Centers for Medicare and Medicaid Svcs.
Dept. of Health& Human Svcs.
ATTN: CRS 3844-P
PO Box 8010
Baltimore, MD 21244-8010

Attached are the original and two copies of the comments on the proposed Hospice Conditions of Participation submitted by the Texas & New Mexico Hospice Organization. The Texas & New Mexico Hospice Organization is the professional organization representing 154 hospices providing services in Texas and New Mexico.

Very truly yours,

Larry A. Farrow
Executive Director

Attach. (3)

COMMENTS ON
42 CFR Part 418
Medicare and Medicaid Programs:
Hospice Conditions of Participation;
Proposed Rule, dated May 27, 2005

NOTE: When recommendations are made to reword a portion of the proposed rule, items to be deleted will be lined through and new language will be underlined.

§ 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.

> ***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.
> (3) <u>A hospice medical director or a hospice nurse practitioner may fill this function if so designated by the individual.</u>

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

> ***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<u>, spiritual</u> or emotional condition.

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.

> <u>***Counseling Services*** means services that assist the patient/family to minimize the</u>

Board payment to nursing facilities. Normally, hospices cannot access patient liability information in this area until after the patient has been brought into hospice.

ASSESSMENT TIME FRAMES

§ 418.54

The comprehensive assessment section, as written, will be particularly difficult for our member hospices, especially in regards to the time frames which are unrealistic in regards to the comprehensive assessment.

> **§ 418.54 Condition of participation: Comprehensive assessment of the patient.**
> The hospice must conduct and document in writing a patient-specific comprehensive assessment that identifies the patient's need for hospice care and services, and the patient's need for medical, nursing, psychosocial, emotional, and spiritual care. This ~~care~~ assessment 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~~ complete an initial assessment visit within 24 hours after the hospice receives a physician's ~~admission order~~ certification for care (unless ordered otherwise by the physician or requested by the patient or family), to determine the patient's immediate care and support needs.
>
> (b) *Standard: Time frame for completion of the comprehensive assessment.* The hospice interdisciplinary group in consultation with the individual's attending physician must complete the comprehensive assessment of the physical, psychosocial, and spiritual needs of the patient/family within 7 calendar days ~~no later than 4 calendar days~~ after the patient elects the hospice benefit.

§ 418.54(c)(3)(i)

Bereavement counseling is a portion of the plan of care, but should not be a part of the initial or comprehensive assessment. The bereavement plan of care should be developed as needed. As such, we recommend the deletion of this entire section.

> ~~*(i.) Bereavement.* An initial bereavement assessment of the needs of the patient's family and other individuals focusing on the social, spiritual, and cultural factors that may impact their ability to cope with the patient's death. Information gathered from the initial bereavement assessment must be incorporated into the bereavement plan of care.~~

§ 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. As such we are recommending some minor changes.

> (d) *Standard: Update of the comprehensive assessment.* The update of the comprehensive assessment must be accomplished by the hospice interdisciplinary group and must consider changes that have taken place since the initial assessment. It must include information on the patient's progress toward desired outcomes, as well as a reassessment of the patient's response to care. The assessment update must be accomplished—
>
> (1) As frequently as the condition of the patient requires, but no less frequently than every 14 days, unless it is documented that the 14th day falls on a national holiday ; and
>
> (2) At the time of each recertification. If the recertification falls within 5 days of a regular meeting of the hospice interdisciplinary group, then that assessment can be used for the recertification assessment.

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". It also doesn't recognize the standard practice of utilizing an interdisciplinary administrative team to establish policies and oversee day-to-day provision of hospice care and services rather than designating one of the IDG teams.

> (a) *Standard: Approach to service delivery.*
>
> (1) The hospice must designate an interdisciplinary group or groups composed of individuals who work together to meet the physical, medical, social, emotional, and spiritual needs of the hospice patients and families facing terminal illness and bereavement. Interdisciplinary group members must provide the care and services offered by the hospice, and the group in its entirety must supervise the care and services. The hospice must designate a qualified health care professional that is a member of the interdisciplinary group to provide coordination of care and to ensure continuous assessment of each patient's and family's needs and implementation of the interdisciplinary plan of care. The interdisciplinary group must include, but is not limited to, individuals who are qualified and competent to practice in the following professional roles:
>
> (i) A doctor of medicine or osteopathy (who is not the patient's

attending physician, unless the hospice physician/medical director is also serving in that capacity).

(ii) A registered nurse.

(iii) A social worker.

(iv) A pastoral, clergy, or other ~~spiritual~~ counselor.

(2) If the hospice has more than one interdisciplinary group, it must designate in advance ~~only~~ one of those groups or an interdisciplinary administrative team to establish policies governing the day-to-day provision of hospice care and services.

§ 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.

c) *Standard: Content of the plan of care*. The hospice must develop a written plan of care for each patient that reflects prescribed interventions based on the problems identified in the initial comprehensive and updated comprehensive assessments, and other assessments. The plan of care must include services for the palliation and management of the terminal condition but not be limited to—

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

§ 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. The inclusion of collaboration with the attending physician is a positive move.

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

every 14 calendar days. A revised plan of care must include information from the patient's ~~updated comprehensive~~ assessments and the patient's progress toward outcomes specified in the plan of care.

§ 418.62(b)

It is recommended that "hospice" be inserted to insure that this section is not misinterpreted.

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

§ 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)

There is a concern that the use of "infrequently" is so unspecific that its interpretation may lead to confusion. As such it is recommended that it be changed to:

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

§ 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)

The requirement that home health aide services be ordered by a physician or nurse practitioner needs to be changed so the IDG can order these services.

(2)A home health aide provides services that are:
(i) Ordered by the ~~physician or nurse practitioner~~ interdisciplinary team;

§ 418.76(h)

The standard that a nurse or qualified therapist make an onsite visit every 14 days to observe to assess a home health aide's services and every 28 days to observe the home health aide is one of the few proposed changes that hospice providers are unanimous in their opposition. We agree that contact with the family either by telephone or in person every 14 days and an annual observation and assessment of an home health aide are both needed. The requirements for every 14 day onsite visits and every 28 day observation are not needed, impractical and a waste of the resource of valuable nursing hours.

(h) *Standard: Supervision of home health aides.*
i. A registered nurse or qualified therapist must make an onsite visit or telephone call 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~~ contact. 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~~ once annually.

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.

(a) *Standard: Serving the hospice patient and family.* The hospice must strive to ensure—
(1) That each patient receives and experiences hospice care that optimizes comfort and dignity; and
(2) That each patient experience hospice care that is consistent with

patient and family needs and desires that are consistent with hospice practices.

§ 418.100(e)

When a hospice contracts for services, it should be responsible to supervise the services rather than the staff providing those services.

> (e) *Standard: Professional management responsibility.* A hospice that has a written agreement with another agency, individual, or organization to furnish any services under arrangement must retain administrative and financial management, and ~~supervision~~ oversight of ~~staff and services for~~ all arranged services, to ensure the provision of quality care. Arranged services must be supported by written agreements that require that all services be—
>
> (1) Authorized by the hospice;
> (2) Furnished in a safe and effective manner by qualified personnel ~~having at least the same qualifications as hospice employees~~; and
> (3) Delivered in accordance with the patient's plan of care.

§ 418.100(f)

We support this provision so long as these standards are uniformly and consistently implemented across CMS regions.

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.

> **§ 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 a volunteer with, employed by, or under contract with, the hospice. When the medical director is not available, a physician designated by the ~~medical director~~ hospice assumes the same responsibilities and obligations as the medical director. The medical director and physician designee along with other members of interdisciplinary group coordinate with other physicians and health care professionals to ensure that each patient experiences medical care that reflects hospice 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.

> (b) *Standard: Recertification of the terminal illness.* Before the recertification period for each patient, as described in § 418.21(a), the medical director or physician designee must review:
>
> (1) The patient's clinical information~~; and~~
>
> ~~(2) The patient's and family's expectations and wishes for the continuation of hospice care.~~

§ 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.

> (b) *Standard: Coordination of medical care.* The medical director or physician designee, and the other members of the interdisciplinary group are jointly responsible for the coordination of the patient's medical care in its entirety. The medical director or physician designee shall participate and be aware of the hospice's quality assessment and performance improvement program and the hospice shall designate a medical professional who is ~~also~~ responsible for directing the hospice's quality assessment and performance improvement 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. One hospice in a small city reported that they would have to verify signatures on more than 350 physicians.

> (b) *Standard: Authentication.* All entries must be legible, clear, complete, and appropriately authenticated and dated. All entries must be signed, and the hospice must be able to authenticate each handwritten and electronic signature of a primary author who has reviewed and approved the entry. The author of each entry must be identified and must authenticate his or her entry. Authentication may include signatures, 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.

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

(1) If the care of a patient is transferred to another Medicare/ Medicaid-approved facility, the hospice must forward a copy of ~~the patient's clinical record and~~ the hospice discharge summary to that facility.

(2) If a patient revokes the election of hospice care, or is discharged from hospice because eligibility criteria are no longer met, the hospice must provide a copy ~~of the clinical record and~~ the hospice discharge summary of this section to the patient's attending physician.

(3) The hospice discharge summary must include—

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

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

(iii)The patient's latest physician orders; and

(iv)Any other documentation that will assist in post-discharge continuity of care.

§ 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.

(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 appropriate use of controlled substances. ~~regarding the uses and potential dangers of controlled substances.~~ The hospice nurse must document that the policy was discussed with the patient and family.

§ 418.106(c)

The maintenance and training in the use of durable medical equipment can be handled in

most case through contractual agreements.

(c) *Standard: Use and maintenance of equipment and supplies.*

(1) The hospice must follow directly or through contractual agreements manufacturer recommendations for performing routine and preventive maintenance on durable medical equipment. The equipment must be safe and work as intended for use in the patient's environment. Where there is no manufacturer recommendation for a piece of equipment, the hospice must develop in writing its own repair and routine maintenance policy. The hospice may use persons under contract to ensure the maintenance and repair of durable medical equipment.

(2) The hospice must ensure directly or through contractual agreements that the patient, where appropriate, as well as the family and/or other caregiver(s), receive instruction in the safe use of durable medical equipment and supplies. The patient, family, and/or caregiver must be able to demonstrate the appropriate use of durable medical equipment to the satisfaction of the hospice or contractual staff.

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 Condition of participation: Short-term inpatient care.
Inpatient care must be available for pain control, symptom management, short-term family psychosocial crises and respite purposes, and must be provided in a participating Medicare or Medicaid facility.

§ 418.108(b)

(b) *Standard: Inpatient care for respite purposes.* Inpatient care for respite purposes and/or short-term family psychosocial crises must be provided by one of the following:

(1) A provider specified in paragraph (a) of this section.

(2) A Medicare/Medicaid approved nursing facility ~~that also meets the standards specified in § 418.110(b) and (f)~~.

§ 418.108(c)(3)

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

(3) That the hospice patient's ~~inpatient clinical record includes a record of all~~

~~inpatient services furnished, events regarding care that occurred at the facility, and that a copy of the inpatient clinical record and~~ discharge summary is available to the hospice at the time of discharge;

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, Phernagen, 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 the following changes.

> (b) *Standard: Professional management.* The hospice ~~must assume full responsibility for~~ assumes professional management of the resident's hospice care, in accordance with the hospice conditions of participation and make any arrangements necessary for inpatient care in a participating Medicare/Medicaid facility according to §418.100. The nursing facility continues to provide services at the same level (same level of services that 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

> (c) *Standard: Core services.* ~~A hospice must routinely provide all core services. These services include nursing services, medical social services, and counseling services. The hospice may contract for physician services as stated in § 418.64(a). A hospice may use contracted staff provided by another Medicare certified hospice to furnish core services, if necessary, to supplement hospice employees in order to meet the needs of patients under extraordinary or other non-routine circumstances, as described in § 418.64.~~
> 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.

> (d) *Standard: Medical director*. The medical director ~~and or~~ physician designee as well as other professional members of the hospice interdisciplinary team ~~of the hospice must provide overall coordination of the medical care of the hospice resident that resides in an SNF, NF, or other facility. The medical director and physician designee must communicate with the medical director of the SNF/NF, the patient's attending physician, and other physicians participating in the provision of care for the terminal and related conditions to ensure quality care for the patient and family.~~ designee coordinates with other physicians and healthcare professionals within a SNF/NF to insure that each patient experiences medical care that reflects hospice philosophy.

§ 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. This is a requirement for the hospice during intake.

> (e) *Standard: Written agreement*. The hospice and the facility must have a written agreement that specifies the provision of hospice services in the facility. The agreement must be signed by authorized representatives of the hospice and the facility before the provision of hospice services. The written agreement must include at least the following:
>
> ~~(1) The written consent of the patient or the patient's representative that hospice services are desired.~~
>
> ~~(2)~~ (1)The services ~~that~~ to be provided by the hospice ~~will furnish and that the facility will furnish~~.
>
> (2) The services to be provided by the facility.
>
> (3) The manner in which the facility and the hospice are to communicate with each other to ensure that the needs of the patient are addressed and met 24 hours a day.
>
> (4) A provision that the facility immediately notifies the hospice if—
>
> (i) A significant change in the patient's physical, mental, social, or emotional status occurs;
>
> (ii) Clinical ~~complications~~ symptoms appear that suggest a need to alter the plan of care;
>
> ~~(iii) A life threatening condition appears;~~
>
> ~~(iv)~~ (iii)A need to transfer the patient from the facility and the hospice makes arrangements for, and remains responsible for, any necessary continuous care or inpatient care necessary related to the terminal illness; or

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

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

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

~~(7)~~ (6)A delineation of the hospice's responsibilities, which include, but are not limited to, providing medical direction and management of the patient, nursing, counseling (including spiritual and dietary counseling), social work, bereavement counseling for immediate family members, provision of medical supplies and durable medical equipment, and drugs necessary for the palliation of pain and symptoms associated with the terminal illness, as well as all other hospice services that are necessary for the care of the resident's terminal illness.

~~(8)~~ (7)A provision that the hospice may use the facility's nursing personnel where permitted by law ~~and as specified by the facility~~ to assist in the administration of prescribed therapies included in the plan of care ~~only to the extent that the hospice would routinely utilize the services of a hospice resident's family in implementing the plan of care~~.

§ 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. However, we will not comment on those aspects and merely suggest one change to (f)(4), since these COP's only govern hospices. It is assumed that nursing facility COP's will eventually address this area .

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

§ 418.112(g)

We are recommending the inclusion of the Physician Certification of Terminal Illness and Recertification's.

(g) *Standard: Coordination of services.* The hospice must designate a member of its interdisciplinary group to coordinate the implementation of the plan of care with the representatives of the facility. The hospice must provide the facility with the following information:

(1) Hospice ~~Plan~~ of care.

(2) Patient or patient's representative hospice consent form and advance directives.

(3) Names and contact information for hospice personnel involved in hospice care of the patient.
(4) Instructions on how to access the hospice's 24-hour on-call system.
(5) Medication information specific to the patient
(6) Hospice ~~Physician~~ orders and the Physician Certification of Terminal Illness and all subsequent recertification's.

§ 418.112(i)

Many nursing facilities have contract with more than one hospice and could possibly have a number of hospices wanting to provide orientation in-services. As such, we recommend the following change.

> (i) *Standard: Orientation and training of staff.* Hospice staff must ~~orient~~ assure the orientation of facility staff furnishing care to hospice patients in the hospice philosophy, including hospice policies and procedures regarding methods of comfort, pain control, symptom management, as well as principles about death and dying, individual responses to death, patient rights, appropriate forms, and record keeping requirements.

PERSONNEL QUALIFICATIONS

§ 418.114(c)(7)

We support this standard as written. Some hospices or other states may require social workers with MSW's, but both Texas and New Mexico allow BSW's to fill this capacity. If the standard was changed to require MSW's, it would create major problems for the 200+ hospices operating in these states both as to the retention of those individuals currently employed and the recruitment of qualified MSW's (especially in the predominately rural areas) in both states.

29

July 22, 2005

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

Re: File Code CMS-3844-P

To Whom It May Concern:

Hospice of East Texas provides care to over 1500 patients and families annually, throughout thirteen (13) east Texas counties. I am submitting the attached comments on the proposed revisions of the conditions of participation for hospice providers.

Hospice of East Texas appreciates the time and effort that has been devoted to the proposed revisions and looks forward to the opportunity to review subsequent changes in a second comment period.

Thank you for your consideration of our thoughts and comments.

Sincerely,

Marjorie A. Ream
President/CEO

Attachments:
(3) copies of Hospice of East Texas comments

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www.hospice-etex.com

NON-PROFIT ■ COMMUNITY SERVICE SINCE 1982

CMS-3844-P

2005 Proposed COPs	Comments by Hospice of East Texas (HOET)
418.52 Condition of Participation: Patient's Rights	
(a) Standard: Notice of rights: (1) The hospice must provide the patient or representative with verbal and written notice of the patient's rights and responsibilities in a language and manner that the patient understands during the initial evaluation visit in advance of furnishing care.	**The hospice must provide the patient or representative with <u>verbal</u> notice of the patient's rights and responsibilities in a language and manner that the patient understands during the initial evaluation visit in advance of furnishing care. The hospice must provide the patient or representative with <u>written</u> notice of the patient's rights and responsibilities in the predominant language(s) of the hospice's service area during the initial evaluation visit in advance of furnishing care.** *Rationale: In some communities, there are hundreds of dialects and it will be extremely costly and expensive to translate these documents into all languages & dialects. This requirement will become a significant barrier to accessing hospice for these patients. Verbal translation occurs now and works well and does not deny patients access to hospice care.*
(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.	**<u>Delete requirement related to informing patient and family of hospice's drug policies and procedures upon admission.</u>** *Rationale: We believe that patients and families may be overwhelmed at the time of admission and this information should be presented to the patient and family by the appropriate member of the IDT after, not during, admission.*
(b) Standard: Exercise of rights and respect for property and person.	**HOET recommends that CMS consider using the patient rights requirements as defined in the Home Health COPs at**

	484.10 for the hospice COPs, which we believe are more appropriate to the hospice/home environment.
(4) The hospice must- (i.) Ensure that all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property are reported to State and local bodies having jurisdiction (including to the State survey and certification agency) within at least 5 working days of the incident, and immediately to the hospice administrator.	**(4) The hospice must-** **(i.) Ensure that all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property are reported to State and local bodies having jurisdiction (including to the State survey and certification agency) within at <u>most</u> 5 working days of the incident, and immediately to the hospice administrator.** *Rationale: We believe that "at most 5 working days" is less confusing.*
(e) Standard: Patient liability. Before care is initiated, the patient must be informed, verbally and in writing, and in a language that he or she can understand, of the extent to which payment may be expected from the patient, Medicare or Medicaid, third-party payers, or other resources of funding known to the hospice.	**Before care is initiated, the patient must be informed, ~~verbally and in writing, and in a language that he or she can understand,~~ of the extent to which payment may be expected from the patient, Medicare or Medicaid, third-party payers, or other resources of funding known to the hospice.** *Rationale: In some communities, there are hundreds of dialects and it will be extremely costly and expensive to translate these documents into all languages & dialects. This requirement will become a significant barrier to accessing hospice for these patients. Verbal translation occurs now and works well and does not deny patients access to hospice care.*
418.54 Condition of Participation: Comprehensive assessment of the patient.	
(a) Initial assessment: The hospice registered nurse must make an initial assessment visit within 24 hours after the	**The hospice registered nurse must make an initial assessment visit within <u>48 hours</u> after the hospice receives a physician's**

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.	**admission order for care (unless ordered otherwise by the physician <u>or requested otherwise by the patient and/or family</u>), to determine the patient's immediate care and support needs.** *Rationale: We believe that while most hospices make the initial assessment visit within 24 hours, this standard is too prescriptive and will result in deficiencies when the hospice occasionally is unable to make the initial assessment visit within 24 hours.*
(b) 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.	**The hospice interdisciplinary group in consultation with the individual's attending physician must complete the comprehensive assessment no later than <u>7 calendar days</u> after the patient elects the hospice benefit.** *Rationale: We believe that many patients and families will object to having 4 different people contact them within 4 days of initiating hospice care to complete the comprehensive assessment. We have a 7 day standard in Texas now and we often receive comments from families that it is, "raining hospice people".* **<u>HOET recommends that CMS not prescribe WHO must complete the comprehensive assessment, but instead prescribe WHAT must be assessed, namely the patient/family's physical, emotional, social and spiritual needs.</u>** *Rationale: Many patients and families refuse hospice services from a social worker and chaplain/counselor, and emotional, social and spiritual needs are assessed by the member(s) of the hospice IDT who are providing services to that patient/family. By prescribing WHAT is to be assessed, rather than WHO is to do*

	the assessing, the COPs will be much more in keeping with hospice care as it is actually provided. If CMS prescribes WHO must assess the patient/family, hospices will continually be out of compliance, because this requirement is impossible to meet and attempted compliance will alienate hospice patients/families and contribute to unnecessary revocation of hospice services.
(c) Standard: Content of the comprehensive assessment.	
(3) Factors that must be considered in developing individual care plan interventions, including- (i.) Bereavement: An initial bereavement assessment of the needs of the patient's family and other individuals focusing on the social, spiritual, and cultural factors that may impact their ability to cope with the patient's death. Information gathered from the initial bereavement assessment must be incorporated into the bereavement plan of care.	**(3) Factors that must be considered in developing individual care plan interventions, including-** **(i.) Bereavement: An initial bereavement assessment of the needs of the patient's family and other individuals focusing on the social, spiritual, and cultural factors that may impact their ability to cope with the patient's death. Information gathered from the initial bereavement assessment must be incorporated into the ~~bereavement~~ plan of care.** *Rationale: A bereavement assessment must be started at the time of admission and becomes part of the overall hospice plan of care.*
(d) Update of the comprehensive assessment. (1) As frequently as the condition of the patient requires, but no less frequently than every 14 days.	**HOET recommends that updates to the comprehensive assessment be called "Ongoing Assessment(s)" to help differentiate between the comprehensive assessment and updates to the comprehensive assessment.** **(1) As frequently as the condition of the patient requires, ~~but no less frequently than every 14 days~~.** *Rationale: If CMS requires that all 4 core disciplines (physician, RN, social worker and counselor) assess that patient every 14 days, patients and families will feel overwhelmed by the number of hospice staff who are contacting them. The Alliance believes*

	that this will cause many patients and families to refuse further contact from social work or counseling services.
(e) Standard: Patient outcome measures.	**HOET believes that outcome measures such as the NHPCO Dataset, the NHPCO Family Evaluation of Hospice Care and the NHPCO End Result Outcome Measures are important to the hospice's QAPI program.**
418.76 Condition of participation: Home health aide and homemaker services.	
(h) Standard: Supervision of home health aides.	
i. ....A registered nurse or a 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.	**i. ....A registered nurse or a 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~~ <u>at least annually.</u>** HOET strongly opposes the 28 day timeframe for supervisory home health aide visits. This standard is extremely burdensome to hospices, both financially and as far as ensuring compliance. The standard does not ensure that care will improve and in fact, care might decline since the standard requires that scarce nursing resources must be deployed for a task that can be handled through the agency's QAPI program. Hospice of East Texas projects that at least two(2) additional full time equivalent (FTE) RNs would be required to ensure compliance with this standard. Extra nurses would have to be hired to conduct supervisory visits. The cost is estimated to be approximately $50,000 per RN, including salary and benefits. Hospice nurses are not able to schedule their visits with the

	certainty that home health nurses can schedule their visits. Patient deaths, pain crises, family crises, etc., can and should disrupt hospice nurses routine scheduled visits each day. The Community Health Accreditation Program (CHAP) requires that hospices evaluate home health aides annually, including on-site evaluation of competency testing. HOET strongly urges CMS to consider utilizing this CHAP standard for the COP standard.
418.100 Condition of participation: Organization and administration of services.	
(a) Standard: Serving the hospice patient and family. The hospice must ensure that-	
(2) That each patient experience hospice care that is consistent with patient and family needs and desires.	**(2) That each patient experience hospice care that is consistent with patient and family assessed needs ~~and desires~~.** *Rationale: Patient and family needs and desires are vast and if interpreted literally, this standard could require that a hospice meet every family request, such as flying in family members from out of town, etc. The hospice IDT must assess patient and family needs and create a plan of care that meets those needs but the hospice cannot ensure that every patient and family desire is met.*
418.102 Condition of participation: 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.	**……. The medical director and physician designee communicate ~~coordinate~~ with other physicians and health care professionals to ensure that each patient experiences medical care that reflects hospice philosophy. ~~policy~~.** *Rationale: A Medical Director is responsible for overseeing the medical care provided to hospice patients. The IDG is responsible for coordinating care.*

	Care should be consistent with the hospice philosophy, e.g., palliative, inclusive of the patient and family. Hospice "policy" is too prescriptive, and may not allow for each patient and family's unique needs.
(c) Standard: Coordination of medical care. The medical director or physician designee, and other members of the interdisciplinary group are jointly responsible for the coordination of the patient's medical care in its entirety. The medical director or physician designee is also responsible for directing the hospice's quality assessment and performance improvement program.	**(c) Standard: Coordination of medical care.** **The medical director or physician designee, and other members of the interdisciplinary group are jointly responsible for the coordination of the patient's <u>hospice care.</u> ~~medical care in its entirety.~~ The medical director or physician designee is also responsible for <u>participating</u> in ~~directing~~ the hospice's quality assessment and performance improvement program.** *Rationale: Most hospice QAPI programs are directed by an RN experienced in QAPI and knowledgeable about the agency's operations. The HOET Medical Director is an essential member of the QAPI team, but he or she may or may not have expertise in QAPI. Each hospice should be allowed to appoint the most appropriate individual to direct its QAPI program, regardless of that individual's discipline.* *Also, "medical care" usually refers to physician services and "hospice care" is a broader term that better fits in this context.*
418.104 Condition of participation: Clinical records. (b) Standard: Authentication. All entries must be legible, clear, complete, and appropriately authenticated and dated. All entries must be signed, and the hospice must the able to authenticate each handwritten and electronic signature of a primary author who has reviewed and approved the entry.	**(b) Standard: Authentication. All entries must be legible, clear, complete, and appropriately authenticated and dated. All entries must be signed, and the hospice must the able to authenticate each ~~handwritten and~~ electronic signature of a primary author who has reviewed and approved the entry.** *Rationale: This standard seems more appropriate for a hospital.*

	While hospitals are able to have lengthy credentialing processes for physicians, hospices must be able to respond quickly to referring physicians. Hospices have implemented expedited credentialing processes, such as verifying each physician's state license. Hospices are not able to easily authenticate each referring physician's handwritten signature, and requiring hospices to do so will delay hospice admissions and cause many last minute referrals to hospice to be denied hospice care entirely. *Also, the manpower to collect the signatures from attending physicians and continuously monitor their authenticity would be significant and would be a tremendous financial burden for the hospice.*
(e) Standard: Discharge or transfer of care. (1) If the care of a patient is transferred to another Medicare/Medicaid-approved facility, the hospice must forward a copy of the patient's clinical record and the hospice discharge summary to the facility. (2) If a patient revokes the election of hospice care, or is discharged from hospice because eligibility criteria are no longer met, the hospice must provide a copy of the clinical record and the hospice discharge summary of this section to the patients' attending physician.	**(e) Standard: Discharge or transfer of care.** **(1) If the care of a patient is transferred to another Medicare/Medicaid-approved facility, the hospice must forward a copy of the patient's ~~clinical record and the~~ hospice discharge summary to the facility.** *Rationale: A discharge summary would be sufficient to ensure coordination of care. The entire record could be made available to the facility receiving the patient if requested as is stated in current hospital regulations.* **(2) If a patient revokes the election of hospice care, or is discharged from hospice because eligibility criteria are no longer met, the hospice must provide a copy of ~~the clinical record and~~ the hospice discharge summary of this section to the patients' attending physician <u>upon request</u>.** *Rationale: Many physicians already complain about the volume*

	of paper they receive from hospices. Physicians who want to review the patient's hospice record can easily request a copy from the hospice.
418.106 Condition of participation: Drugs, controlled drugs and biologicals, medical supplies, and durable medical equipment. 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.	**418.106 Condition of participation: Drugs, controlled drugs and biologicals, medical supplies, and durable medical equipment.** **(c) 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.** *Rationale: Hospices do not control the home environment and cannot be responsible for tracking and collecting controlled drugs.* *The word "tracking" implies that hospice nurses will be responsible for conducting a physical inventory of each patient's controlled drugs at each visit, and calculating if the correct number of pills remain, according to their prescribed use. While HOET nurses do strive to monitor patient's usage of controlled drugs to ensure that the patient has good symptom control and that refills are ordered on a timely basis, hospice nurses do not have the time to conduct an physical inventory of the patient's pills at each visit and calculate if the correct number of pills are remaining.* *Similarly, hospice nurses are not permitted to "collect" controlled drugs because the only person who is authorized to possess a controlled drug is the patient for whom the medication was prescribed.*

418.108 Condition of participation: Short-term inpatient care. Inpatient care must be available for pain control, symptom management, and respite purposes, and must be provided in a participating Medicare or Medicaid facility.	**418.108 Condition of participation: Short-term inpatient care. Inpatient care must be available for pain control, symptom management, ~~and~~ respite purposes <u>and for crises of a psycho-social nature that make it infeasible for care to be provided in the patient's home</u>, and must be provided in a participating Medicare or Medicaid facility.** *Rationale: Inpatient care is defined as short term and a short admission for a psychosocial crises is very appropriate in end-of-life care and can prevent patients from unnecessarily revoking hospice benefits and returning to (more costly) acute care.*
(a) Inpatient care for symptom management and pain control. (2) ---regarding 24 hour nursing services"	HOET strongly recommends keeping the requirement for 24 hour RN staffing for inpatient care, but removing it for respite care. *Rationale: Respite care is a more routine level of care and easily carried out by a licensed nurse. Inpatient care requires constant assessment that is most appropriately carried out by an RN.*
(c) Standard: Inpatient care provided under arrangements. If the hospice has an arrangement with a facility to provide for short-term inpatient care, the arrangement is described in a legally binding written agreement that at a minimum specifies- (3) That the hospice patient's inpatient clinical record includes a record of all inpatient services furnished, events regarding care that occurred at the facility, and that a copy of the inpatient clinical record and discharge summary is available to the hospice at the time of discharge. (4) That the inpatient facility has identified an individual within the facility who is responsible of the	**(c) Standard: Inpatient care provided under arrangements. If the hospice has an arrangement with a facility to provide for short-term inpatient care, the arrangement is described in a legally binding written agreement that at a minimum specifies-** **(3) That the hospice patient's inpatient clinical record includes a record of all inpatient services furnished, events regarding care that occurred at the facility, and that a copy of the ~~inpatient clinical record and~~ discharge summary is available to the hospice at the time of discharge.** **(4) That the inpatient facility has identified a**

implementation of the provisions of the agreement;	**~~individual~~ position within the facility who is responsible of the implementation of the provisions of the agreement;** *Rationale: The hospital discharge summary is sufficient for the hospice to ensure continuity of care. The hospice-facility contract should specify what position is responsible for implementing the provisions of the contract.*
(o) Seclusion and restraint (1) …*A drug used as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard treatment for a patient's medical or psychiatric condition.	**(o) Seclusion and restraint** …*A drug used as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard hospice treatment for a patient's medical or psychiatric condition. *Rationale: Although the intent of these guidelines is to prevent the use of medication or devices to unnecessarily restrain patients who should be managed through redirection or other non-restrictive methods, they can be construed to deter the use of medications when these interventions are necessary for the control of symptoms that cannot be managed through other methods or when patients are at risk of harming themselves or others. More desirable language would acknowledge the appropriate use of such medication in hospice patients to manage symptoms of life-limiting illnesses. Examples of appropriate use would be for pain management and terminal agitation.*
(3) (ii) (d) Each order for a physical restraint or seclusion must be in writing and limited to 4 hours for adults; 2 hours for children and adolescents ages 9 through 17; or 1 hour for patients under the age of 9.	(3) (ii) (d) Each order for a physical restraint or seclusion must be in writing and limited to 8 hours for adults while sleeping and 4 hours while awake; 6 hours for children and adolescents ages 9 through 17 while sleeping and 2 hours while awake; or 2 hours for patients under the age of 9 while sleeping and 1 hour while

	awake.
(7) The hospice must report to the CMS regional office any death that occurs while the patient is restrained or in seclusion, within 24 hours after a patient has been removed from restraint or seclusion.	7) The hospice must report to the CMS regional office any unexpected death that occurs while the patient is restrained or in seclusion, or within 24 hours after a patient has been removed from restraint or seclusion. *Rationale: This would be a reasonable expectation, while defining and reporting every death during which a patient is secluded or restrained might place more of a burden on the CMS office.*
418.112 Condition of participation: Hospices that provide care to residents of a SNF/NF, ICF/MR, or other facilities.	**The HOET recommends that the effective date of this section be delayed until the SNF/NF requirements contain a parallel condition.**
(b) Professional management. The hospice must assume full responsibility for professional management of the resident's hospice care, in accordance with the hospice conditions of participation and make any arrangements necessary for inpatient care in a participating Medicare/Medicaid facility according to 418.100.	**(b) Professional management. The hospice must assume full responsibility for professional management of the resident's hospice care, in accordance with the hospice conditions of participation and make any arrangements necessary for inpatient care in a participating Medicare/Medicaid facility according to 418.100. The SNF/NF continues to provide services at the same level it would have provided if that resident had not elected the hospice benefit.**
(d) Medical Director. The medical director and physician designee of the hospice must provide overall coordination of the medical care of the hospice resident that resides in an SNF, NF or other facility. The medical director and physician designee must communicate with the medical director of the SNF/NF, the patient's attending physician, and other physicians participating in the provision of care for the terminal and related conditions to ensure quality care for the patient and family.	**(d) Medical Director.** ~~The medical director and physician designee of the hospice must provide overall coordination of the medical care of the hospice resident that resides in an SNF, NF or other facility.~~ The medical director and physician designee must communicate with ~~the medical director of the SNF/NF, the patient's attending physician, and~~ other physicians and healthcare professionals within a SNF/NF to ensure that each patient experiences medical care that reflects the hospice philosophy. ~~participating in the provision of care for the terminal and related~~

	~~conditions to ensure quality care for the patient and family.~~
418.114 Personnel qualification for licensed personnel (a) General qualification requirements. Except as specified in paragraph (c) of this section, all professionals who furnish services directly, under an individual contract, or under arrangements with a hospice, must be legally authorized (licensed, certified or registered) to practice by the State in which he or she performs such functions or actions, and must act only within the scope of his or her State license, or State certification, or registration. All personnel qualifications must be kept current at all times.	HOET agrees with this section and specifically with the qualification of state licensure for hospice social workers.
(7) Social worker. A person who has a baccalaureate degree from a school of social work accredited by the Council on Social Work Education	HOET agrees with CMS that this qualification should only apply in states that do not license social workers.

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Rec'd 7/25/05 L.N.W.

Indiana Hospice & Palliative Care ORGANIZATION, INC.

July 22, 2005

CMS
Room 445-G Hubert H. Humphrey Bldg.
200 Independence Avenue SW
Washington, DC 20201

Dear CMS:

Re: CCMS-2844-P-Medicaid and Medicaid Programs: Hospice Conditions of Participation Comments

The Board and members of the Indiana Hospice & Palliative Care Organization appreciate the efforts of CMS in revising the purposed conditions of participation that hospice must meet in order to participate in the Medicare and Medicaid programs. We would like to offer the following comments for your consideration as you finalize the conditions and prepare the interpretative guidelines.

418.3 Definitions

1. Attending physician
    a. Include in this definition that the hospice medical director or nurse practitioner may also act as the patient's attending physician. The definition should read as follows: "*the hospice medical director or nurse practitioner may also act as the patient's attending physician*" based upon 1812(d)(2)(A) Except as provided in subparagraphs (B) and (C) and except in the exceptional and unusual circumstances as the Secretary may provide, if an individual makes such an election from a period with respect to a particular hospice program, the individual shall be deemed to have waived all rights to have payment made under this title except…physicians' services furnished by the individual's attending physician (if not an employee of the hospice program) "The regulations should somewhere note that this is a permissive section relating to the patient so that the attending physician's input is required if (1) the patient has one, and (2) the MD is willing to participate. See also section 418.54(b) below.
2. Bereavement Counseling
    a. Who can perform counseling? Should that be defined? Or should it be left to the state?
3. Clinical note
    a. We request that the word "*spiritual*" is added to "any changes in physical or emotional condition" at the end of this definition.
4. Counseling Services
    a. We request that a definition of Counseling services be: *Counseling services means services that assist the patient/family to minimize the stress and problems that arise from the terminal illness or from the dying process.*
5. Comprehensive Assessment
    a. Include a definition of comprehensive assessment in this section.

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6. Covering Physician
    a. Add the following definition for "covering physician": *Covering physician means a physician acting on behalf of the attending physician.*
7. Dietitian
    a. Define dietitian as: *a person who is registered by the Commission of Dietetics Registration or the American Dietetic Association.*
8. Drug Restraint
    a. Clarification is needed. Some medications that may be viewed as a chemical restraint in some instances may be normal patient care protocol in hospice.
9. Employee
    a. Use the word "*staff*" in place of "employee" consistently throughout the document.
10. Facility
    a. The following definition should be included for the term "facility": *Facility means a place where the patient resides where care is provided for the patient.*
11. Family
    a. Please use the following definition: *Family means the person(s) identified as having a significant role in the patient's life.*
12. Hospice Patient
13. Licensed professional
    a. Include dietary therapy in this definition.
14. Nursing services
    a. Please add that *nursing service are provided by a licensed nurse* and further clarification in the preamble to clarify that nursing services are at times delegated to a home health aide.
15. Homemaker
    a. Please include clarification of the role and qualifications of the homemaker.
16. Patient's residence
    a. Please use the following definition: *Patient's residence means a house, apartment, SNF/NF, ICF/MR, assisted living facility, shelter, foster home or any other location where the patient lives.*
17. Physical Restraint
    a. Please add the phrase "or adjacent" as follows: "*or equipment attached or adjacent to the patient's body*".
18. Representative
    a. Please add after "...courts of the state" the words "*or common law within the State*" in order to take care of situations that are permitted but not statutory. See this from NF Rules: (4) in the case of a resident who has not been adjudged incompetent by the State court, any legal surrogate designated in accordance with State law may exercise the resident's rights to the extent provided by state law.

<u>418.52 Condition of Participation: Patient's Rights</u>

1. (a) Standard: Notice of rights
    a. Please remove "during the initial evaluation visit" and make reflective of the home health regulation
    b. In some parts of the state there are many dialects and it would be impossible to provide written rights in the patient's language. Please change to relate that the patient understands their rights via an interpreter, a family member or other who understand the rights.
    c. We request that the right for the patient to be involved in their plan of care be added.
    d. We believe that informing the patient of drug policies and procedures at the time of admission will be confusing to the patient & primary caregivers, especially disposal policies. 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 intricacies of hospice. We request that the discussion on drug disposal policies with patients and families be a part of the admission packet. Please clarify who tracks, how they track, what exactly needs to be tracked and what would the surveyor be looking for? We suggest

that tracking and disposal of drug policies are demonstrated during the 4 calendars day period.

2. (b) Standard: Exercise of rights and respect for property and person
    a. Please include wording that a patient has the right to refuse treatment: *The patient has the right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive.*
    b. Add " *and practice*" at the end of the sentence (3).
    c. We request that the right to keep the patient's attending physician be added.
    d. We request that the patient maintains the right to be involved in their plan of care.
    e. We suggest that the CMS language from the Home Health Conditions of Participation may be more appropriate. HHA COP Requirement 484.10 may be more appropriate to the hospice/home environment:
        i. *The Hospice must investigate complaints made by a patient or the patient's family or guardian regarding treatment or care that is (or fails to be) furnished, or regarding the lack of respect for the behalf of the hospice, and must document both the existence of the complaint and the resolution of the complaint.*
        ii. *We request that a change be made to the complain policy, which includes the following: an overall review of the complain policy and its applicability to hospice; and a change to (1) five days from the discover of the incident.*
3. (c) Standard: Pain Management and symptom control
    a. We disagree with the way it is written in respect to SNF patients. Hospice has no knowledge of what amount of liability each dually might have.
4. (e) Standard: Patient Liability
    a. Instead of "before care is initiated" use "*at the time of initial assessment*"; do not want to have to use dollar amount; needs to be more general (spend down, co-pay, etc.)
    b. How does this relate to the Advance Beneficiary Notice requirements? The ABN requirement applies whenever the patient wants something the hospice doesn't think is covered but is willing to pay for it (e.g. Deluxe DME, or HH Aide beyond the POC). The ABN is given to the patient so that (1) CMS know the beneficiary is protected, and (2) it can determine if the service should have been covered.
    c. We request that the responsibility for collecting the patient's liability in the Medicaid Room and Board payments remain with the nursing home and that the standard be specific about this requirement.

<u>418.54 Condition of Participation: Comprehensive Assessment of Patient</u>

a. The words "includes, but is not limited to," may be too broad and needs to be modified.
b. Change "care" to "*assessment*" in the last sentence so we can include items not related to the terminal illness that we would still want to assess.

1. (a) Standard: Initial Assessment
    a. Certification of the terminal illness itself is not particularly time-consuming, requiring only a signature on a pre-formatted document. Defense of unclear cases, however, requires generation of individual summary documents, themselves a product of chart review.
    b. Replace the word "make" with the word "*complete*".
    c. Clarify the appropriate language for the "physician's admission order for care".
    d. Instead of "physician's order for care", it should read "*physician's certification for care*".
    e. Add language "24 hours upon request by patient or representative". Strong feeling that an RN needs to perform the initial or admission assessment. If a social worker goes to sign up the patient and all the paperwork is signed and the patient dies prior to the nurse arriving to do the initial assessment, will the hospice be reimbursed? Concern that the RN and the initial assessment might be used to indicate total admission and therefore reimbursement.

f. Our guidelines for initial contact or pre-assessment are within 24 hours, however, our guidelines for complete initial assessments are 72 hours.
g. There is a difference between a hospice referral or evaluation- and an order to "admit to hospice." Any care team member can explain hospice and do an initial evaluation. The information is then taken back to the team for consensus. Some patient's/caregivers don't want the initial visit within 24 hours. Also some patients want to think about hospice or talk with family before they decide to be admitted. The initial assessment is completed at a mutually agreed upon date.
h. Replace "registered nurse" with a *licensed professional.*
i. We propose language for a (c) comprehensive assessment that includes, at a minimum, an in person assessment by the nurse and social worker within the first 7 days of care. These documents, as well as any other generated by other IDT members would form the Comprehensive Assessment. We would not be expected to complete the full assessment and data element collection of patients that did not live this long.
j. Please add "*as otherwise order by physician or requested by family*" after order for care.

2. (b) Standard: Time frame for completion of the comprehensive assessment
   a. Comprehensive assessment should be 7 days
3. (c) Standard: Content of the comprehensive assessment
   a. The content of the comprehensive assessment is focused on needs- this would be the prelude to the plan of care.
   b. Bereavement
      1. The statute (SEC, 1862, (42 U.A.C. 1395y ((a)) says: "Notwithstanding any to other provision of this title, no payment may be made under Part A or Part B for any expenses incurred or items or services____
         (1)
         (A)
         (B)
         (C) in the case of the hospice care, which are not reasonable and necessary for the palliation or management of terminal illness"
         This statute limits coverage. This language is OK for the assessment but not for a terminal plan. NHPCO should comment that this should be clear in the regulation- comprehensive assessment but duty for care plans limited to management and palliation.
   c. Please make exclusion for chaplain assessments.
   d. Remove ineffective drug therapy; beyond an RN's scope of practice.
   e. We request that the comprehensive assessment and care planning be limited to the care needed for the management and palliation of the terminal illness.
4. (d) Standard: Update of the comprehensive assessment
   a. Please specify; is this to mean your IDT meetings?
   b. We disagree that an IDT every 14 days on each patient should be required.
   c. The benefit periods (90/90/endless 60s) are divisible by 15 and the regulation should allow an assessment update with, say 5 days, to count for recertification by the hospice so that the disjunction between the 14 day periods wouldn't have a negative impact for a hospice. For example, if the rules were followed to the letter, the hospice would be doing a reassessment on day 99 (to meet the 14 requirement) and again on day 90 (to meet the 14 day requirement.)
   d. We request that the update closest to the recertification timeframe be acceptable as an update at the time of recertification.
5. (e) Standard: Patient Outcome
   a. It can be time consuming and costly but is important regarding safety issues and overall process improvement.
   b. This doesn't belong in the assessment portion. It could affect care planning at times depending on the data collected. Looking at data outcomes and evidence based

practice items are important in doing PI. It can be difficult to find hospice appropriate indicators.

c. Would you have to track quality improvement differently when the patient is in-home versus in-patient?

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

1. (a) Standard: Approach to Service Delivery
   a. The change in (iv) has to do with moving spiritual care out of the volunteer section of the COPs.
   b. One IDT does not establish governing policies of the day-to-day care. An administrative team that is generally interdisciplinary establishes policies and oversees day-to-day provision of hospice care and services.
   c. This needs to be an RN.
   d. What is meant by this section of the standard?
   e. Why was this IDG team role narrowed from the original COPs? Should say "(iv) a counselor, including pastoral, clergy, spiritual, or other counselor." The language in the law is:
      1. "B) has an interdisciplinary group of personnel which-
         (i.) includes at least-
            (I) one physician (as defined in subsection (r)(I), (II) one registered professional nurse, and (III) one social worker,
            Employed by or, in the case of a physician described in sub clause (I), under contract with the agency or organization, and also includes at least one pastoral or other counselor,"
2. (c) Standard: Content of the plan of care
   a. After "include," the regulation should read "*services for the palliation or management of the terminal condition, including...*" so that it is clear that the hospice doesn't need to treat all the patient's problems.
   b. Remove "detailed statement".
   c. Remove the word "agreement" out of this sentence. The family may not be in agreement with the plan of care, but the patient may be in agreement.
3. (d) Standard: Review of the plan of care
   a. 14 days is acceptable; define what they expect as collaboration by attending physician; and what proof would a surveyor want to see demonstrating this.
   b. The interdisciplinary team (in collaboration with the individual's attending physician to the extent possible)...
   c. Review of patient status and plans of care every 14 days requires assembly of chart materials on all the patients and takes about 2 hours a week per patient for that function alone every 2 weeks.
4. (e) Standard: Coordination of services
   a. (4) Should allude to sharing of information with non-hospice providers who are sharing the care (e.g., an ERSD dialysis facility for a cancer patient who gets dialysis for kidney failure).
   b. (4) Provide for and ensure the ongoing sharing of information between all disciplines providing care and services in the home, in outpatient settings, and in inpatient settings, irrespective of whether the care and services are provided directly or indirectly under arrangement.
   c. We request adding some wording such as: "*Sharing of information may be accomplished through paper documents or electronic media, or telephonic or in person meetings, or some combination of these methods.*"
   d. The model proposed describes regularly occurring conversations among the Hospice Medical Director and referring physicians as well as Medical Directors of ECF's. A full-time director has enough control of his/her schedule to accommodate this task, but the part-timers have a great deal more difficulty. Favor stipulating the

coordination of care as an IDG-level function with contribution from the Medical Director when circumstances require.

418.58 Condition of Participation: Quality assessment and performance improvement

a. Management of the QA/PI program requires development and maintenance of procedures, regular attention to quality indicators for the purposes of identifying initiatives, conduct of meetings and the like.
b. Where QA/PI and coordination of care are concerned, the language could be changed to reflect what probably happens most of the time, which is that the Medical Director *oversees* these functions at regular intervals (usually quarterly) but intervenes directly only when more customary interactions are not productive.
c. Nurses traditionally perform this QA/PI function in hospitals with fairly remote physician oversight.

1. (a) Standard: Program scope
    a. The hospice industry is in the development stage of identifying and measuring data for improvement. It would be our hope that CMS would recognize and ensure leniency in this industry.
    b. There is some confusion throughout the document as to the language regarding data elements. We would like language used throughout the document that is consistent with Quality Assessment and Performance Improvement Programs.
    c. Examples of adverse patient events: Adverse programmed incorrectly; medication errors and fall in inpatient facility.
2. (c) Standard: Program activities
    a. What is meant by adverse events?

418.62 Condition of Participation: Licensed professional services

a. (b) Add the word "*hospice*" after "patient's".

418.64 Condition of Participation: Core services

1. (b) Standard: Nursing Services
    a. There is not a clear definition of what is included in nursing services- RN, LPN, and LVN? Please provide a clear definition in the definition section of nursing services?
2. (d) Standard: Counseling services
    a. (ii) Bereavement counseling also extends to employees of SNF. It is not feasible to expect a hospice agency to have individual bereavement plans on each employees of SNF who cared for deceased person. Please delete this sentence.
    b. (ii) The proposed plan to extend bereavement services to residents and employees of SNF/NF/ICF/and MRs "when appropriate and identified in the bereavement plan of care. Hospice care and bereavement support of individuals and families directly affected by personnel loss will be significantly diminished or diluted. Allow individual hospices the flexibility to offer support to any SNF/NH/ICF/ and MR on an as needed basis when contracted by that institution.
    c. Leave spiritual counselor.
    d. Suggest that language be deleted and replaced with "*consistent with the patient's and families' wishes and the willingness of the designated counselors to respond.*"

418.66 Condition of Participation: Nursing requirements- waiver of requirement that substantially all nursing services be routinely provided directly by a hospice

a. There is a problem of accessing the waiver for nursing throughout the country. CMS regions do not understand the process and limit access to hospices because of this. We would like the process to be more user friendly. We also would like clarification as to who is eligible for the waiver, rural/urban. With the nursing shortage there is a need for the waiver in urban areas as well as rural.
b. No one utilizes the nursing waiver.
c. Everyone is in agreement that they should remove the "non-urbanized area".

418.72 Condition of Participation: Physical therapy, occupational therapy, and speech language pathology

a. We request dietitians added to the list of non-core services.

418.76 Condition of Participation: Home health aide and homemaker services

a. While it seems that there is a significant expansion of the requirements and qualifications for home health aides and homemakers, the regulations written in the home health conditions of participation are written out here and cited by number in the current COPs.
b. Need assurance that this does not indicate 24-hour care.

1. (a) Standard: Home health aide qualifications
    a. Please provide a definition of homemaker services.
2. (c) Standard: Competency evaluation
    a. This standard should add the word "aide" after home health.
3. (e) Standard: Qualifications for instructors conducting classroom supervised practical training, competency evaluations and in-service training
    a. We propose to add the words "...Of which must be in *hospice* or home health care..." to this standard.
4. (f) Standard: Eligible training organizations
    a. We propose to substitute "hospice" for the words "home health agency" in the beginning of this standard.
5. (g) Standard: Home health aide assignments and duties
    a. Hospices would like to defer this to state law. Home health aides are not allowed to assist with medications according to state law.
    b. (2) We would like this to be more fluid, if the care is outcome driven there should not be a need for a physician's order. The IDT should have the authority to decide when the patient needs the services of a home health aide. We would like clarification on this standard. We request that the IDG should have the authority to determine when the patient needs the services of a home health aide, and that no physician order is required.
    c. (iv) We would like clarification regarding home health aides assisting with administering medications.
6. (h) Standard: Supervision of home health aides
    a. What is meant by therapist? Please define.
    b. Home health agencies have 60 days to observe and assess each aide.
    c. (i) HHA supervision should not be 28 days but should be done annually. This is more stringent than Home Care Regulations (60-day HHA supervisory visit while HHA is present is only in "non-skilled cases." Hospice is Skilled Care, therefore the 60-day supervisory visit should not even apply to hospice because home care does not have to do it if it is a skilled patient.).
    d. The length of stay should not be a factor if the assessment is of the aide and not the patient. This is a human resource issue and the assessment would go in the personnel file rather than the clinical record. Ongoing competency assessments should take care of this issue.
7. (j) Standard: Homemaker qualifications
    a. Remove "a qualified homemaker is a home health aide." Many hospices use HHA and Volunteers for homemaker duties; do not want to lose ability to have a volunteer to perform this function.

418.78 Condition of Participation: Volunteers

1. (b) Standard: Role
    a. (b and e) Remove "day to day" so special events that might only occur 1 time a year can be included in the calculation of Administrative Time. (b) Takes away flexibility of dates for volunteers and may effect recruitment and selection of volunteers. Leave as it was...and/or.
2. (e) Standard: Level of Activity
    a. Refer to comments on (b).

418.100 Condition of Participation: Organization and Administration of services

1. (a) Standard: Serving the hospice patient and family
    a. Instead of "must ensure" use "*must work*".

b. Replace "desires" with "*goals*" or just stop after "*needs*". Suggested wording would be "(2) *That each patient experience hospice care that is consistent with patient and family needs and goals. (3) Where the patient and family are not in agreement as to the election and plan of treatment, the hospice will identify and list the group of individuals to whom (1) shall apply.*"

2. (e) Standard: Professional management responsibility
   a. Please change to "*requiring supervision of services*".
   b. We suggest that the language of the preamble, particularly "*supervisory responsibility of services*" [not staff] *and "by qualified personnel"* rather than personnel having "at least the same qualifications as hospice employees."
      1. From the preamble: "This standard would require written agreements for services furnished under arrangement, and would require that the hospice retain professional management and supervisory and financial responsibility for all services that are provided to the patient and family. The hospice would be required to ensure that all services provided are authorized by the hospice, are furnished in a safe and effective manner by qualified personnel, and that items and/or services specified in that plan of care are provided."
   c. The term "arrangements" is limited to arrangements under which receipt of payment by the hospital. Critical access hospital, skilled nursing facility, home health agency, or hospice program (whether in its own right or as agent), with respect to services for which an individual is entitled to have payment made under this title, discharges liability of such individual or any other person to pay for the services.
   d. Replace "supervision" with "*oversight*" under the notion that the actual supervision of the employees would be by the employer with whom the arrangement is made and the oversight would include the employer and employees.
   e. We request a wording change in the first sentence to read "*must retain administrative and financial management, and supervision oversight of staff and services for all arranged services ...because the actual supervision of the staff would be done by the contracting agency.*"
3. (f) Standard: Hospice Satellite locations
   b. We would like a consistent policy across CMS Regions in defining and approving satellite locations.
   c. Clarify Medicare appeals process §498.3.

<u>418.102 Condition of Participation: Medical Director</u>

a. The condition states, "who is either employed by, or under contract with, the hospice." Is it an oversight that medical directors who are volunteers were not included? Would a volunteer medical director also need to be under contract?
b. We propose that when the medical director is not available that a physician is designated by the hospice.
c. The last sentence is an example of how the role of the medical director/physician seems to supercede the IDT of which the medical director is a member.
d. Take out "and"; replace with "or". No need to contract for volunteer MD. Add "the medical director or physician designee and/or the hospice team will coordinate with other physicians..." OR- The MD or physician designee with IDT coordinates with other physicians and health care professionals.
e. We request that there needs to be ability for hospice to contract with an entity for a physician to serve as medical director, rather than with an individual physician.

1. (a) Standard: Initial certification of terminal illness
   a. We ask for clarification/discussion of criteria for determining appropriateness and eligibility.
2. (b) Standard: Recertification of the terminal illness
   a. We ask for clarification on what documentation the medical director would look at to review "the patient's and family's expectations and wishes for the continuation of hospice care."

3. (c) Standard: Coordination of medical care
    a. Removal of "Medical Director or physician designee is also responsible for directing the hospice's quality assessment and performance improvement program.
    b. Please clarify the difference between a patient's "medical care" and "hospice care".
    c. In light of the scope of the QAPI requirements and the fact that many medical directors are part time or volunteers, what is expected in terms of the medical director "directing" the hospice's QAPI program? Why not expand this to "or other qualified professional" so that a full time employee could be hired to do most of the work.
    d. Of these tasks, the review of records and certification of terminal illness and provision of care in the absence or unavailability of the attending physician can only be done by the Medical Director. The others require some oversight by the Medical Director, but can be done by other staff, with general direction and review coming from the Medical Director. Indeed, in most hospitals, the QA/PI functions are usually coordinated by nursing staff with oversight from the Medical Staff when issues arise and at intervals approximating quarterly. Coordination of care is more nebulous, since some of it clearly requires conversation among providers, but some of it can be done at the office staff level.

<u>418.104 Condition of Participation: Clinical records</u>

a. Electronic medical records are costs prohibitive to small hospices- not only the hardware (laptops) but also the software costs or rental.
b. We would like a clarification for "accurate".

1. (a) Standard: Content
    a. Since patient's rights condition of participation is intended to replace the current condition, could you clarify what is required here?
    b. What do they mean by authorization? Authorization to release health information? Authorization to disclose information? The only authorization currently required from patients may fall under HIPAA privacy regulations but this is not something that would be required of every patient and therefore not included in every clinical record.
2. (b) Standard: Authentication
    a. This standard comes from the hospital conditions of participation. Home care is much broader than hospital care. More information is needed as to how this standard can be realistically applied to hospice.
    b. The preamble states that a similar requirement is in the conditions of participations for hospitals. Our concern is that home care is so broad that it may not be feasible to completely comply with this standard. For example, does this standard apply to all consulting or covering physicians?
    c. Note in the comments that NF and HHA do not have such a standard, only hospitals, whose rule says:
    482.24(c) Standard: Content of record. The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services.
        (1) All entries must be legible and complete, and must be authenticated and dated promptly by the person (identified by name and discipline) who is responsible for ordering, providing, or evaluating the service furnished.
            (i) The author of each entry must be identified and must authenticate his or her entry.
            (ii) Authentication may include signatures, written initials or computer entry.
3. (d) Standard: Retention of records
    a. We would like this to follow the HIPPA requirements for records retention.
    b. Recommend 6 years to be in compliance with HIPPA.
4. (e) Standard: Discharge or transfer of care
    a. This is in conflict with "minimal necessary" disclosure; remove the clinical record to

be sent.

b. Sending a copy of the patient's clinical record if the patient transfers, revokes or is discharged is particularly onerous, not necessary since the discharge summary requirements are comprehensive and receipt of the entire printed clinical record (sometimes hundreds of pages) is not likely to be welcomed by facilities or attending physicians. The release of information should follow the Minimum Necessary Standard in HIPAA.

c. Patients care plan appropriate for transfer but not for discharge.

d. In this Standard the description of the discharge summary is thorough—perhaps providing a copy of the discharge summary to the new facility and the attending physician will be adequate.

e. We are concerned with sharing non-medical information, i.e. family information

f. Please add: *When electronic medical records are available, sharing of the discharge summary and/or medical record through an electronic format will be preferable. The electronic sharing of records may include access to the record through secure internet access or other electronic access available through transferable data storage media. The record should be in an industry standard file format. If the recipient is unable to utilize the electronic files, a paper copy will be provided.*

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

a. We request the language from 418.110(m) be inserted in here—so that the more comprehensive language would apply the behavior of the hospice as a whole (and so the hospice could import the service into an inpatient setting instead of having to establish it there).

1. (b) Standard: Controlled drugs in the patient's home
   a. Please remove the word "collecting" out of this sentence. We also question using the term "potential dangers" with controlled substances. Hospice has worked for years to dispel myths associated with narcotic use with terminally ill patients. Please remove potential dangers of controlled substances;
   b. Please add a definition for "tracking meds"
2. (c) Standard: Use and maintenance of equipment and supplies
   a. When a hospice contracts for DME isn't it the vendor's responsibility to have repair and routine maintenance policies? And where it is a dealer with a CMS supplier number, can't the hospice assume it meets this requirement since it is a general CMS requirement, too?
   b. Please use the following language:

      The hospice, either directly or through contractual agreement, ensures that there is a process for providing routine and preventive maintenance of equipment and that the equipment is safe and works as intended for use in the patient's environment. This may occur directly or through contractual arrangement. (Addition: "either directly or through contractual agreement" clarifies the responsibilities of contractors if they are used to supply medical equipment.)

418.108 Conditions of Participation: Short-term inpatient care

a. Add *"psychosocial/family crisis/issues"*.

b. This introduction should define the care as "care provided by the hospice on an inpatient basis in a facility that meets the requirements of...and then lists the provider standards in (a) and (b). Then it should say that inpatient care for symptom management and pain control and respite may be provided in any of these facilities. Paragraph (a) should note that pain control and symptom management would be done on an inpatient basis either because of the specific need for the staff and equipment available there or because of the inability of the hospice and/or the patient's caregivers to assure that the services are properly provided in the home. Paragraph (b) would discuss respite and the five-day limit.

1. (a) Standard: Inpatient care for symptom management and pain control
   a. Include same language as 418.108. Respite- NO RN. GI—YES RN.

b. The word "approved" should be replaced with "*certified.*"

2. (b) Standard: Inpatient care for respite purposes
   a. Define Medicare/Medicaid approved nursing facility? Does this mean "certified?"
3. (c) Standard: Inpatient care provided under arrangements
   a. Clarify whether or not the hospice is required to have a copy of the patient's entire inpatient clinical record in its possession or whether it can arrange with the inpatient provider to retain the records on its behalf until required. Why require duplication of records if not needed? If a surveyor needed them, they could be requested.
   b. The hospital discharge summary should be sufficient for the hospice to ensure continuity of care.

418.110 Condition of Participation: Hospices that provide inpatient care directly

1. (a) Standard: Staffing
   a. Is it permissible for hospices to ensure the 24-hour coverage in a nursing facility by providing nurses for shifts not covered by the nursing facility?
2. (b) Standard: Twenty-four hour nursing services
   a. If skill is a concern than offer a certification for inpatient hospice nursing and put as a criteria to work in hospice house or facility.
   b. Clarify what "nursing services" means. We suppose that it means services of both RN and LPN/LVN as it does in the NF requirements.
   c. Is there a minimum requirement of services or qualifications?
3. (c) Standard: Physical environment
   a. Define and provide examples of "equipment failures" that would be required to be reported? We would also like to know where the section (ii) originated.
4. (f) Standard: Patient rooms
   a. Add this to the end of (iv): except during community disasters and/or evacuations.
5. (m) Standard: Pharmaceutical services
   a. Section (m) should also be included in 418.106 as an indication that these are requirements laid on the hospice as a whole, not just on an inpatient basis. (m) Should cross-refer to the earlier standard.
   b. Clarify whether or not patients are allowed to bring prescription drugs from home into a facility.
6. (n) Standard: Pharmacist
   a. (iii) We may suggest adding *"if required by law"* to the end of this paragraph.
7. (o) Standard: Seclusion and restraint
   a. Please remove drug/chemical restraint language- opening the door to surveyor interpretation.
   b. Suggested changes underlined: Bed rails are not included in this definition of restraint if used for the safety of the patient or to assist the patient in independent functioning. A drug used, as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard treatment for a hospice patient's hospice medical or psychiatric condition. Seclusion is the restricted confinement of a person alone in a room or an area where a person is physically prevented from leaving.
   c. Add the word *"unpredicted"* before death.
   d. We would like clarification on (7) as to why this has to be reported to CMS and to what office at CMS?

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

a. Please define the term "facility". This section should specifically apply only to Medicare and Medicaid participating facilities. Also, this condition cannot successfully be implemented until there is in the SNF/NF requirements a parallel condition that conforms their requirements. We recommend that the effective date of this section be delayed until the companion section is enacted or that it be at least incorporated by reference into the SNF/NF requirements. We understand that the nursing home COPs will add a section on nursing homes and hospice care. Does this condition match the requirements that will be proposed for nursing homes?

b. We ask that CMS work with surveyors on this issue and that hospices be allowed some leniency until the nursing facility regulations are complete.

1. (b) Standard: Professional management
   a. Add "*hospice*" after "inpatient".
   b. Please provide some information regarding how this standard is or is not related to nursing home regulations. We assume that this means that the hospice must avoid making assumptions about care provisions and specify the services to be provided by the facility and the ones to be provided by the hospice and the processes for management and routine communication.
2. (c) Standard: Core Services
   a. Add "*work*" behind "medical social".
3. (d) Standard: Medical director
   a. We are concerned that the requirements of this standard may cause unnecessary strain in the relationship between the hospice and the facility. Intent good, but not realistic- Please delete.
   b. Explain why in this instance (as well as elsewhere in the proposed regulations) the Medical Director appears to be separated out from the rest of the IDT? We believe that the best language would be to require that the IDT assume this duty through a designee of its choice, either an MD or a nurse.
   c. Is it permissible for the NF Medical Director to also be the Hospice Medical Director?
   d. We are concerned that the requirements in this standard may cause unnecessary strain between the hospice and the facility. Rather, care coordination between members of the hospice IDG and the nursing home team who are likely to have more daily contact with the patients should be encouraged.
4. (e) Standard: Written agreement
   a. Is the written consent of the patient to be part of the facility/hospice contract?
   b. We would like clarification of a life threatening condition other than the patient's hospice terminal diagnosis.
   c. States vary in what they consider included in the room and board rate and what their responsibility is in the provision of room and board. How does this impact this Standard? Will the room and board definition in the State Operation Manual be changing in relation to the hospice regulations?
   d. Add "*hospice*" before " inpatient care". The phrase would read: *"arrangements necessary for hospice inpatient care..."*
5. (f) Standard: Hospice plan of care
   a. Needs clarification of "all".
   b. Please clarify who is expected to review the plan of care, hospice, nursing facility, or both?
   c. We would like a definition or clarification on what is meant by "all caregivers".
   d. We are concerned that this standard gives the hospice authority over the nursing staff decision making and may be contrary to the current nursing home requirement that nursing home staff be responsible for everything that happens.
6. (g) Standard: Coordination of services
   a. Are we correct in assuming that physician orders refers to the hospice physician orders?
7. (h) Standard: Transfer, revocation, or discharge from hospice care
   a. For some facilities, discharge from the hospice could mean the person may no longer reside in the facility. Please provide some clarification of this standard including how compliance would be audited. Why not change "does not directly impact" to "may not affect"?
8. (i) Standard: Orientation and training of staff
   a. We are concerned that facilities may be inundated with hospice in-services if they have contracts with multiple hospice providers. Reword this standard to state, "*must assure orientation of facility staff*".

418.114 Conditions of Participation: Personnel qualifications for licensed professionals

a. Is the implication here that non-degreed social workers can be hired and work as social workers because they are licensed by the State? If so, the effect of going to State licensure here is to lower the requirement for social workers that has been in this rule up to now. We question whether this is appropriate, given the importance of social workers in this context and we believe CMS should consider reinstating the current requirement.

1. (c) Standard: Personnel qualifications when no state licensing certification or registration requirements exist.
   a. We request that the current social work requirement should be retained.: *A social worker is a person who has a baccalaureate degree from a school of social work accredited by the Council on Social Work Education with one phrase changed" "A social worker is a person who has at least a baccalaureate degree..."* This will clarify and include all MSW-prepared social workers whose undergraduate degree is in another field.
2. (d) Standard: Criminal background checks
   a. Would compliance with State laws regarding criminal background checks suffice for compliance with this standard? We agree with this provision only if there is an established mechanism available to hospices by which the checks may be made. If there is not, this requirement creates open-ended jeopardy for hospices with no prospect that they can actually meet the requirement effectively.
   b. We are concerned by the phrase "before employment at the hospice". There should be some flexibility in hospice policy about what the hospice can do with the employee until the results of background check are returned, if the process in the state is lengthy.
   c. Another area of concern is whether contracted employees would be the responsibility of the hospice. A criminal background check should be the responsibility of the contracting agency as part of the written agreement.

We appreciate this opportunity to provide comments to CMS regarding the proposed changes in the Conditions of Participation for Hospice. The comments provided are from our members—hospice providers, hospice professionals and individuals supporting our missions of education Hoosiers about end of life care. The comments are made to assure open access for all to quality of end of life care.

Thank you for your consideration of our comments.

Sincerely,

Harriet O'Connor
President/CEO
Indiana Hospice & Palliative Care Organization

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Rec'd 7/25/05 d.n.w.

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July 22, 2005

CMS
Room 445-G Hubert H. Humphrey Bldg.
200 Independence Avenue SW
Washington, DC 20201

Dear CMS:

Re: CCMS-2844-P-Medicaid and Medicaid Programs: Hospice Conditions of Participation Comments

The Board and members of the Illinois Hospice & Palliative Care Organization appreciate the efforts of CMS in revising the purposed conditions of participation that hospice must meet in order to participate in the Medicare and Medicaid programs. We would like to offer the following comments for your consideration as you finalize the conditions and prepare the interpretative guidelines.

418.3 Condition of Participation: Definitions

1. Please add definitions for the following:
   a. Initial Assessment
   b. Comprehensive Assessment
      Please clarify requirement by giving a definition.
   c. Counseling Services
      We request the definition of Counseling Services include bereavement counseling
   d. Dietitian
      We propose the following definition: *Dietitian means a person who is registered by the Commission of Dietetics' Registration or the American Dietetic Association.*
   e. Facility
      We propose the following definition: *Facility means a place where the patient resides where care is provided for the patient*
   f. Hospice patient
   g. Social Worker
      Please use language from the current COP's.
   h. Nursing Services
      Please add that nursing service are provided by a licensed nurse, and provide further clarification in the preamble to clarify that nursing services are at times delegated to a home health aide.
   i. Homemaker
      Please include clarification of the role and qualifications of the homemaker
   j. Patient's residence
      We propose the following definition: Patient's residence means a house, apartment, SNF, NF, ICF/MR, assisted living facility, shelter, foster home or any other location where the patient lives.

k. Family members
We propose the following definition: *Family members means the person(s) identified as having a significant role in the patient's life.*

2. Please clarify the difference between Plan and Care and Care Plan.
3. Attending physician
    a. Please add the following to the definition of attending physician: "*the hospice medical director or nurse practitioner may also act as the patient's attending physician*" based upon 1812(d)(2)(A) Except as provided in subparagraphs (B) and (C) and except in the exceptional and unusual circumstances as the Secretary may provide, if an individual makes such an election for a period with respect to a particular hospice program, the individual shall be deemed to have waived all rights to have payment made under this title except...physicians' services furnished by the individual's attending physician (if not an employee of the hospice program)" The regulations should somewhere note that is a permissive section relating to the patient so that the attending physician's input is required if (1) the patient has one, and (2) the physician is willing to participate See also section 418.54 (b)
    b. Please clarify the difference between "covering physician" versus "Physician designee". *A covering physician is a physician acting on behalf of the attending physicians. A physician designee is a physician acting on behalf of the hospice medical director.*
    c. (1, (i), (ii)): Please delete "and surgery".
    d. Please add "Nurse Practitioner may also act as the patient's attending physician."

4. Bereavement Counseling.
    a. Please note that bereavement is not limited to after death but includes anticipatory grief and family members who have had bad death experiences in the past may need attention from bereavement counselors pre-death.
5. Clinical Note
    a. Please add the word *spiritual* to "any changes in the physical or emotional condition" at the end of this definition. Please clarify the difference between progress note or clinical note. Please define the requirements for each.
6. Drug Restraint
    a. This definition needs to be clarified because some medications that may be viewed, as a chemical restraint in some instances may be normal patient care protocol in hospice.
7. Employee
    a. Please adhere to the HIPAA language and use of workforce.
8. Licensed professional
    a. Please add dietary therapy to this definition.
9. Physical restraint
    a. Please add the phrase "or adjacent" as follows: "*...or equipment attached or adjacent to the patient's body....*"
10. Representative
    a. Please add after "...courts of the state" the words "*or by common law within the State*" in order to take care of situations that are permitted but not statutory. See this from NF Rules: (4) in the case of a resident who has not been adjudged incompetent by the State court, any legal-surrogate designated in accordance with State law may exercise the resident's rights to the extent provided by state law.

<u>418.52 Condition of Participation: Patient's rights</u>

a. Hospice providers and professionals have a real concern about information overload of patient/families. The admission process will take even longer (thus wearing out the patient more) if we have to demonstrate not only disclosure, but understanding of the bill of rights pertaining to advance directives and P/P for medication tracking and disposing. What about the consents we mail- how is that affected? Will we be able to do this by phone?

b. Burden estimates are underestimated by far. Estimated by nurses to be triple the estimates in the proposed COPs. Ex. 15 minutes to document and resolve a complaint? That can take days. Ex. 5 minutes to explain payer and extent to coverage??? Ex. Comprehensive assessment.

1. (a) Standard: Notice of rights
    a. Please remove "during the initial evaluation visit" and make reflective of the home health care regulation
    b. In some parts of the state there are many dialects and it would be impossible to provide written rights in the patient's language. Please change to relate, so that the patient understands their rights via an interpreter, a family member or other who understand the rights.
    c. We request that the right for the patient to be involved in their plan of care be added.
    d. We believe that informing the patient of drug policies and procedures at the time of admission will be confusing to the patient and primary caregivers, especially disposal policies. Patient and their caregivers are given a tremendous amount of information at the time of admission and it is impossible to retain all of the intricacies of hospice. We suggest that notice of drug policy/tracking should be addressed during the admission process-this information can be provided in the section where explanation of equipment and meds are in admission packet.
    e. We believe that there needs to be clarification of who tracks, how they track, what exactly needs to be tracked and what would the surveyor be looking for? We suggest that tracking and disposal of drug policies are demonstrated during the 4-calendar day assessment period.
2. (b) Standard: Exercise of rights and respect for property and person
    a. Please include wording that a patient has the right to refuse treatment. Proposed wording could be: *The patient has the right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive.*
    b. Add "*and practice.*"
    c. We suggest that the CMS language from the Home Health Conditions of Participation may be more appropriate. HHA COP Requirement 484.10 may be more appropriate to the hospice/home environment: *The Hospice must investigate complaints made by a patient or the patient's family or guardian regarding treatment or care that is (or fails to be) furnished, or regarding the lack of respect for the patient's property by anyone furnishing services on behalf of the hospice, and must document both the existence of the complain and the resolution of the complain.*
    d. We recommend that the right to keep the patient's attending physician be added.
    e. We recommend that the patient maintains the right to be involved in their plan of care.
    f. We recommend that a change be made to the complaint policy, which includes the following: an overall review of the complaint policy and its applicability to hospice; and a change to (5) five days from the discovery of the incident.
3. (e) Standard: Patient liability
    a. How does this relate to the Advance Beneficiary Notice requirement? The ABN requirement applies whenever the patient wants something the hospice doesn't think is covered but is willing to pay for it (e.g. Deluxe DME, or HH Aide beyond the POC) The ABN is given to the patient so that (1) CMS know the beneficiary is protected, and (2) it can determine if the service should have been covered.
    b. LIABILITY/ASIGNMENT OF PAYMENT. Before care is initiated the patient is informed verbally and in writing, and in a language that he or she understands that services provided by hospice will be billed to: Medicare, Medicaid, Insurance, another third party payer. Patient is informed that, if applicable, patient may be asked to pay deductibles, co-payments and any other amounts due after payments on patient's behalf have been made by any and all third party payers. Hospice related services not approved by the hospice interdisciplinary care team, would be billed to patient.

418.54 Condition of Participation: Comprehensive assessment of the patient

a. The words "includes but is not limited to" may be too broad and we may need to modify.
b. Change "care" to "assessment" in the last sentence so we can include items not related to the terminal illness that we would still want to assess.

1. (a) Standard: Initial assessment
    a. Please clarify the term "initial assessment" Is this an initial assessment of immediate needs and if so the RN may not be the most appropriate person to complete this because the immediate needs may not be physical in nature? The word "RN" should be replaced by *"a member of the hospice interdisciplinary team"*.
    b. The RN should be there within 24 hours following a referral (with the family's permission) but a Social Worker or Chaplain can go before the RN to discuss hospice service.
    c. Add language *"24 hours upon request by patient or representative"*. We recommend that "physician's order for care" be changed to *"physician's certification of care."*.
    d. We request that the words "ordered by the physician" be changed to *"ordered by the physician or requested by the family."*
    e. We propose language for a Comprehensive Assessment that would include, at a minimum, an in person assessment by the nurse and social worker within the first 7 days of care. These documents, as well as any other generated by other IDT members would form the Comprehensive Assessment. We would not be expected to complete the full assessment and data element collection of patients that did not live this long.
2. (b) Standard: Time frame for completion of the comprehensive assessment
    a. Comprehensive assessment should be included in the definitions; 4 calendar days should be replaced with "7 calendar days or upon a time frame agreed to by the patient or authorized representative."
    b. "Comprehensive assessment" is not clear. Does this mean each team member completes an assessment or can the RN complete the comprehensive assessment? If only the RN completes the comprehensive assessment then is it really comprehensive because the perspective of other core services are not represented? Is the comprehensive assessment a process or a document?
3. (c) Standard: Content of comprehensive assessment
    a. The content of the comprehensive assessment is focused on needs- this would be the prelude to the plan of care.
    b. The comprehensive assessment identifies physical, psychosocial, emotion, and spiritual needs including a bereavement risk assessment and a review of the patient's prescription & OTC medications. Look at comprehensive assessment as a process which starts on the initial nursing visit including the plan of care…all disciplines review the plan of care on each visit, assessing and evaluating outcomes and revising as needed. On going process which involves all disciplines.
    c. We request that this comprehensive assessment and care planning be limited to the care needed for the management and palliation of the terminal illness.
    d. The statute (SEC, 1862, (42 U.A.C. 1395y((a) says: "Notwithstanding any to other provision of this tile, no payment may be made under Part A or Part B for any expenses incurred or items or services___
    (1)
    (A)
    (B)
    (C) in the case of the hospice care, which are not reasonable and necessary for the palliation or management of terminal illness.)"
    The statute limits coverage. This language is OK for the assessment but not for a terminal plan. This should be clarified in the regulation—comprehensive assessment but duty for care plans limited to management and palliation.

4. (d) Standard: Update of the comprehensive assessment
    a. We request that the update closest to the recertification timeframe be acceptable as an update at the time of recertification.
5. (e) Standard: Patient outcome measures
    a. We recommend the development of meaningful outcome measures at first IDG after admission. Order and develop meaningful measures.
    b. Outcome measures should be part of the ongoing process of the care plan not the comprehensive assessment. Eliminate comprehensive assessment- go to comprehensive care plan.

<u>418.56 Condition of participation: Interdisciplinary group care planning and coordination for services</u>

a. Apply the concepts of "initial" and "comprehensive" to care planning rather than assessment. Base an initial plan of care on the admission assessment completed by a nurse and develop a comprehensive plan of care based on assessments by all disciplines. Updates to the plan of care are then based on ongoing assessment visits made by all disciplines.

1. (a) Standard: Approach to service delivery
    a. One IDT does not establish governing policies of the day-to-day care. An administrative team that is generally interdisciplinary establishes policies and oversees day-to-day provision of hospice care and services.
    b. Why was this IDG team role narrowed from the original COPs? Should say "(iv) a counselor, including pastoral, clergy, spiritual, or other counselor." The language in the law is:
    "B) has an interdisciplinary group of personnel which—
    includes at least--
    (I)one physician (as defined in subsection
    (r)(1),
    (II) one registered professional nurse, and
    (III)one social worker,
    Employed by or, in the case of a physician described in sub clause (I), under contract with the agency or organization, and also includes at least one pastoral or other counselor, " should you cite the law.
    c. (1.i): Hospice medical director and attending physician can be one in the same.
    d. A social worker, chaplain, MD can coordinate and facilitate the team meetings and care. The RN can still be the "care manager".
    e. What does this section of the standard mean?
    f. We request that the language in (iv) be consistent wit the statutory provision for the IDG—"a pastoral, clergy, or other counselor"
2. (b) Standard: Plan of care
    a. How should acceptance of the care plan by the family be noted? Can it be done by omission; that is, they are not disagreeing?
    b. A patient has a right to self-determined life closure—families do not need to agree.
3. (c) Standard: Content of the plan of care
    a. We request that after "*includes*," the regulation should read "*services for the palliation and management of the terminal condition, including...*"
    b. (c.2) Omit the word detailed so patients can have flexibility in their number of visits.
    c. Family should understand and be involved but agreement should come from the patient or legal representative. Delete the word agreement out of this sentence. The family may not be in agreement with the plan of care, but the patient may be in agreement.
4. (d) Standard: Review of the plan of care
    a. Reword to read, "The interdisciplinary team (in collaboration with the individuals, attending physician to the extent possible..."
5. (e) Standard: Coordination of services
    a. The language should allude to sharing of information with non-hospice providers, who are sharing the care (e.g., an ERSD dialysis facility for a cancer patient who gets dialysis for kidney failure).

b. (4): Provide for and ensure the ongoing sharing of information between all disciplines providing care and services in the home, in outpatient settings, and in inpatient settings, irrespective whether the care and services are provided directly or indirectly under arrangement.
c. We recommend expanding the role of IDT leader to include the social worker.
d. We suggest adding some wording such as: "Sharing of information may be accomplished through paper documents or electronic media, or telephonic or in person meetings, or some combination of these methods."

418.58 Condition of Participation: Quality assessment and performance improvement

a. 5 hours a year implementing performance improvement activities??? Hardly enough. (p30872) Where did they get hourly employee rates? Too high for some and too low for other hospices. 5 minutes to document HHA requirements???

1. (a) Standard: Program scope
   a. Include language that the hospice defines adverse events by organizational policy based on accepted such as JCAHO NPSG, etc. Death is not an adverse event for hospice. What is meant by adverse events? Please define adverse event. Adverse event should be defined as unexpected death or an incident that leads to a serious consequence .It's important to identify hospice adverse events. An examples of adverse event would be s a physician who refuses to follow advance directive.
   b. There is some confusion throughout the document as to the language regarding data elements. We would like language used throughout the document that is consistent with Quality Assessment and Performance Improvement Programs.
2. (b) Standard: Program data
   a. We request that the governing body staff provide oversight of the agency's performance improvement program, and delegates responsibility to qualified hospice employees who report improvement activities and findings back to the governing body.
3. (e) Standard: Executive responsibilities
   a. Change to: *The governing body is responsible for monitoring the following…*

418.60 Condition of Participation: Infection Control

a. Do we have documentation that infection control is a significant enough problem? To focus on it to the extent listed, which does not seem practical. Can we do this based on need- that is an infection of the patient or any family member; standard precautions for biological wastes and other basic precautions is reasonable to expect for all patients.

1. (a) Standard: Prevention
   a. The standard of practice in hospice care is that some infections such as pneumonia are expected and may not be treated. There is concern regarding how this will be interpreted at the survey level. We suggest giving the agency the latitude to use and treat the patient according to direction of IDT and patient/family's needs. (b.2.ii) This is counterproductive to the hospice mission; please delete this item.

418.62 Condition of Participation: Licensed professional services

a. (b) Please add the word "*hospice*" after "patient's".

418.64: Condition of Participation: Core services

a. Include continuous care as a circumstance when nursing staff can be contracted.
b. If we are allowed to contract we can then develop relationships with specific agencies and provide ongoing training to their staff. These very agencies can then serve many hospices.

1. (b) Standard: Nursing services
   a. There is not a clear definition of what is included in nursing services-RN, LPN, and LVN. Please include a definition in the definition section?
2. (d) Standard: Counseling Services
   a. We provide bereavement services to facilities who have taken care of patients through debriefing sessions, a special remembrance service just for staff in honor of that patient (especially our children who have died), we also send them cards and call them just like

we do for our family members. Sometimes we provide support to the facilities prior death to prepare them and give then an opportunity to talk about fears, hopes and the dying and death process. Most facilities are grateful for the calls and seminars and find them to be very helpful, educational and supportive.

b. Replace this section with "facilitate visits by local clergy, pastoral counselors, or other spiritual supports that are consistent with the patient's and family's wishes and the availability of community resources.
c. (d.1.iii) Please be clearer about how we are to do this.

418.66 Condition of Participation: Nursing services: Waiver of requirement that substantially all nursing services be routinely provided directly by a hospice

a. There is a problem of accessing the wavier for nursing throughout the country. CMS regions do not understand the process and limit access to hospices because of this. We would like the process to be more user friendly. We also would like clarification as to who is eligible for the wavier, rural/urban. With the nursing shortages there is a need for the wavier in urban areas as well as rural.

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

a. We would like dietitians added to the list of non-core services.

418.74 Condition of Participation: Waiver of requirement- Physical therapy, occupational therapy, and speech-language pathology, and dietary counseling

a. 24-hour pt/ot/speech available provided as needed?- How often do we use PT, let alone at 2 a.m.? Unrealistic! They are not available to us 24 hour a day. Even acute care centers do not have 24-hour therapies- they are not urgent nor emergent needs.

418.76 Condition of Participation: Home health aide and homemaker services

a. Change Home Health Aide to the universal label of "Certified Nursing Assistant".

1. (a) Standard: Home health aide qualifications
   a. We would like a definition of homemaker services.
2. (c) Standard: Competency evaluation
   a. We request that this standard should add the word "aide" after home health.
3. (e) Standard: Qualifications for instructor conducting classroom supervised practical training, competency evaluations and in-service training.
   a. We would propose to add the words "*...Of which must be in the hospice or home health care...*" to this standard.
4. (f) Standard: Eligible training organizations.
   a. We would propose to substitute "hospice" for the words "home health agency" in the beginning of this standard.
5. (g) Standard: Home health aide assignments and duties
   a. Hospices would like to defer to state law.
   b. We would like this to be more fluid, if the care is outcome driven there should not be a need for a physician's order. The IDT should have the authority to decide when the patient needs the services of a home health aide. We would like clarification on this standard.
   c. We would like clarification regarding home health aides assisting with administering medications.
   d. Nursing assistant's assessment, supervision and coordination should be exclusive to a registered nurse.
   e. (2.i) Either delete or change to "ordered by interdisciplinary team."
   f. (4) This statement delineates specifics the nursing assistants are not capable of prioritizing. It is safer practice for patients/families for nursing assistants report any and all changes in a patient's condition or noticeable issues with family dynamics.
6. (h) Standard: Supervision of home health aides
   a. What is meant by therapist?
   b. Home health agencies have 60 days to observe and assess each aide.

c. The length of stay should not be a factor in the assessment of the aide and not the patient. This is a human resource issue and the assessment would go in the personnel file rather than the clinical record. Ongoing competency assessments should take care of this issue.
d. Human resources function to monitor competency of CNA. Change "on-site" and "direct" to "*indirect supervision*".
e. Use the standard of the Health Agency COPs; have 6 months to observe and assess each HHA.
f. Delete qualified therapists.
g. Make evaluate CNAs' delivery of care.
h. Delete every 28 day on site visit and we recommend yearly competency assessment. On the every 14-day nursing onsite visit, evaluate services provided.
i. Can a physician do a CNA supervisory visit as well as an RN? Any employee can act perfect while you are there; what are we trying to find out with these visits? If you have had a CNA several years, why do you need to supervise every 2 weeks? Could we do the proposed for the first months or year of employment, and spot check later or as needed if there are problems (problems defined by Medical Director, RN, Executive Director or other supervisory staff as well as family complaint).

7. (j) Standard: Homemaker qualifications
   a. Delete home health aide from the paragraph.
   b. Reword Homemaker qualifications to read, "A qualified homemaker has successfully completed orientation addressing the needs and concerns of patients and families coping with terminal illness".

418.78 Condition of Participation: Volunteers

1. (e) Standard: Level of activity
   a. Maintaining volunteer involvement is important but a 5% requirement is arbitrary, based on unknown factors, and at times difficult to achieve.

418.100 Condition of Participation: Organization and administration of services

1. (a) Standard: Serving the hospice patient and family
   a. (2) That each patient experience hospice care that is consistent with patient and family needs and desires. Change the word "desires" to "goals" to emphasize the role goals play in developing and implementing the plan of care.
   b. (3) Where the patient and family are not in agreement as to the election and plan of treatment, the hospice will identify and list the group of individuals to whom (1) shall apply.
2. (e) Standard: Professional management responsibility
   a. We suggest that the language of the preamble, particularly "supervisory responsibility for services" [not staff] and "by qualified personnel" rather than personnel having "at least the same qualifications as hospice employees." The language "supervision of staff" and "at least the same qualifications of hospice staff" is an onerous responsibility for hospices and will be difficult to implement. How broadly will this be interpreted, i.e. supervise staff in nursing homes, contracted hospital, etc.
   b. From the preamble: This standard would require written agreements for services furnished under arrangement, and would require that the hospice retain professional management and supervisory and financial responsibility for all services that are provided to the patient and family. The hospice would be required to ensure that all services provided are authorized by the hospice, are furnished in a safe and effective manner by qualified personnel, and that items and/or services specified in the plan of care are provided. We request the language in the first sentence be changed to read "must retain administrative and financial management, and supervision oversight of staff and services for all arranged services...because the actual supervision of staff would be done by the contracting agency.
   c. (w)(1) The term "arrangements" is limited to arrangements under which receipt of payment by the hospital, critical access hospital, skilled nursing facility, home health

agency, or hospice program (whether in its own right or as agent), with respect to services for which an individual is entitled to have payment made under this title, discharges the liability of such individual or any other person to pay for the services.

d. Replace "supervision" with "oversight" under the notion that the actual supervision of the employees would be by the employer with whom the arrangement is made and the oversight would include the employer and employees.

3. (f) Hospice satellite locations.
   a. We request that a CMS satellite location standard be implemented consistently across CMS regions.
4. (g) Standard: In- service training
   a. Assess competency of PT and contracted? That's why we hire them; we are not competent to do it.

418.102 Condition of Participation: Medical director

a. The condition states, "Who is either employed by, or under contract with, the hospice." Is it an oversight that medical directors who are volunteers were not included? Would a volunteer medical director also need to be under contract?
b. We propose that when the medical director is not available that a physician is designated by the hospice.
c. The last sentence is an example of how the role of the medical director/physician seems to supersede the IDT of which the medical director is a member. Please replace the last sentence with "the medical director is a member of the IDT and participates in ensuring that each patient received hospice care that is consistent with evidence based practice and reflects hospice policy."
d. Medical director does not need to be a separate condition of participation. These responsibilities can be incorporated into physician services in the core services section.

1. (a) Standard: Initial certification of terminal illness
   a. We ask for clarification/discussion of criteria for determining appropriateness and eligibility.
   b. We request that the hospice be responsible for designating who will take the medical director's place when he or she is not available
2. (b) Standard: Recertification of the terminal illness
   a. We ask for clarification on what documentation the medical director would look at to review "the patient's and family's expectations and wishes for the continuation of hospice care."
3. (c) Standard: Coordination of medical care
   a. Please make the difference between a patient's medical care and a patient's hospice care.
   b. In light of the scope of the QAPI requirements and the fact that many medical directors are part time or volunteers, what is expected in terms of the medical director "directing" the hospice's QAPI program? Why not expand this to "or other qualified professional" so that a full time employee could be hired to do most of the work. Please delete the last sentence of this section and substitute with "the medical director participates with the interdisciplinary team in the hospice QAPI program which is directed by a qualified professional designated by the hospice governing body"

418.104 Condition of Participation: Clinical Records

a. How will our records mesh with hospitals, Nursing Homes, etc once EMR (electronic med record) is here?
b. Patient access to whole medical record? Could negatively affect patients emotionally.
c. Logistically, updated care plans for family and facilities will be a problem once RNs are laptops unless they carry a printer along…?
d. We would like a clarification for "accurate."

1. (a) Standard: Content
   a. Since the patient's rights condition of participation is intended to replace the current informed consent condition, could you clarify what is required here?

b. Please clarify what "authorization" is in (2). The only authorization currently required from patients may fall under HIPAA privacy regulations but this is not something that would be required of every patient and therefore not included in every clinical record.

c. Copy of the entire medical record would many times be two inches thick; from a practical standpoint if we can show we sent the critical information to show an adequate picture of the condition of patient (discharge summary, most recent plan of care, med list, last nursing visit, advanced directives is any, face sheet with reimbursement (Medicare, Medicaid, etc) numbers and info sent to us should be enough. Wasting paper and time to send back to physician what was originally sent to us. We should not forward any of the chart that is not our documents re: hospice.

2. (b) Standard: Authentication
   a. The preamble states that a similar requirement is in the conditions of participations for hospitals. Our concern is that home care is so broad that it may not be feasible to completely comply with this standard. For example, does this standard apply to all consulting or covering physicians? NF and HHA do not have such a standard, only hospitals, whose rule says: 482.24(c)Standard: Content of record. The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services. All entries must be legible and complete, and must be authenticated and dated promptly by the person (identified by name and discipline) who is responsible for ordering, providing, or evaluating the service furnished. The author of each entry must be identified and must authenticate his or her entry. (ii) Authentication may include signatures, written initials or computer entry. We recommend that we use the COPs of Home Health Agencies regarding signature acceptance.
3. (d) Standard: Retention of Records
   a. We would like this to follow the HIPAA requirement for records retention.
4. (e) Standard: Discharge or transfer of care
   a. Sending a copy of the patient's clinical record if the patient transfers, revokes or is discharged is particularly onerous, not necessary since the discharge summary requirements are comprehensive and receipt of the entire printed clinical record (sometimes hundreds of pages) is not likely to be welcomed by facilities or attending physicians.
   b. The release of information should follow the Minimum Necessary Standard in HIPAA. Please change the language to require a discharge summary and other records available as needed in accordance with HIPAA.
   c. Please add: When electronic medical records are available, sharing of the discharge summary and/or medical record through an electronic format will be preferable. The electronic sharing of records may include access to the record through secure internet access or other electronic access available through transferable data storage media. The record should be in an industry standard file format. If the recipient is unable to utilize the electronic files, a paper copy will be provided.
   d. Please delete "forward a copy of patient's clinical records to receiving hospice" and also delete at DC- the MD is to be provided a copy of the clinical record.
5. (f) Standard: Retrieval of clinical records
   a. Please define access parameters for electronic and paper retrieval.

<u>418.106 Condition of Participation: Drugs, controlled drugs and biologicals, medical supplies, and durable medical equipment</u>

a. Put the language from 418.110(m) in here—so the more comprehensive language would apply the behavior of the hospice as a whole (and so the hospice could import the service into an inpatient setting instead of having to establish it there.

1. (a) Standard: Administration of drugs and biologicals
   a. To document if patient is able to safely administer drugs at every team meeting is cumbersome; how about documenting if problems with drug administration are identified.

2. (b) Standard: Controlled drugs in the patient's home
    a. Delete the word "collecting" and "tracking" in this sentence.
    b. We also question using the term "potential dangers" with controlled substances. Hospice has worked for years to dispel myths associated with narcotic use with terminally ill patients. Please delete terms "POTENTIAL DANGERS" and focus on education on "SAFE USAGE".
    c. Delete discussion or education of controlled substance on initial hospice assessment visit.
3. (c) Standard: Use and maintenance of equipment and supplies
    a. When a hospice contracts for DME isn't it the vendor's responsibility to have repair and routine maintenance policies? And where it is a dealer with a CMS supplier number, can't the hospice assume it meets this requirement since it is a general CMS requirement, too? We recommend the following language: *The hospice, either directly or through contractual agreement, ensures that there is a process for providing routine and preventive maintenance of equipment and that the equipment is safe and works as intended for use in the patient's environment. This may occur directly or through contractual arrangement.* (Addition: "either directly or through contractual agreement" clarifies the responsibilities of contractors if they are used to supply medical equipment.).
    b. Hospices should be required to "write up" unusual occurrences in DME when it happened and report to DME companies.

<u>418.108 Condition of Participation: Short-term inpatient care</u>

a. Define the care as "*care provided by the hospice on an inpatient basis in a facility that meets the requirements of*...and then lists the provider standards in (a) and (b). Then it should say that inpatient care for symptom management and pain control and respite may be provided in any of these facilities. Paragraph (a) should note that pain control and symptom management would be done on an inpatient basis either because of the specific need for the staff and equipment available there or because of the inability of the hospice and/or the patient's caregivers to assure that the services are properly provided in the home. Paragraph (b) would discuss respite and the five-day limit.
b. We are required to train? What authority do we have to train them? Does CMS mean in-service? We are putting them where they will get a higher level of care; in-servicing them on hospice care should be sufficient training.
c. We are supposed to educate hospital staff where we admit our hospice patient. We educate but have no control over them; how can we be held responsible for oversight and can't use that staff more than the patients family members (then why put them in the hospital if the family can do it?? They go inpatient because they have problems we can't even manage at home.
d. Include "psychosocial/family/caregiver crisis" as criteria for inpatient care.

1. (a) Standard: Inpatient care for symptom management and pain control
    a. The word "approved" should be replaced with "certified."
    b. Please clarify the requirements for nursing services for this inpatient level of care. Aren't the proposed regulations changing the requirement for 24 hour RN staffing for the general inpatient level of care as well as respite and replacing it with 24 hour "nursing" care?
    c. Inpatient care must be available for pain control and symptom management and family/caregiver crisis and must be provided in participating Medicare or Medicaid facility.
    d. Respite care must be provided in participating Medicare or Medicaid facility.
    e. 24 RN services available for inpatient care- Respite care does not need 24 hr RN
    f. State specifically that RN services are required in patient level of care, but not for respite care.
2. (b) Standard: Inpatient care for respite purposes
    a. Please define Medicare/Medicaid approved nursing facility. Does this mean, "certified?"
    b. Please clarify the definition of nursing services, i.e. RN, LPN/LVN?
    c. DO NOT require 24 hr/day RN for respite care stays.
3. (c) Standard: In patient care provided under arrangements

a. Please clarify whether or not the hospice is required to have a copy of the patient's entire inpatient clinical record in its possession or whether it can arrange with the inpatient provider to retain the records on its behalf until required. Why require duplication of records if not needed? If a surveyor needed them, they could be requested.
b. Hospices would be able to provide continuity of care by receiving the discharge summary from the hospital and the inpatient record could always be available on request.

418.110 Condition of Participation: Hospices that provide inpatient care directly

a. Include "homelike" in definition.

1. (a) Standard: Staffing
   a. Is it permissible for hospices to ensure the 24-hour coverage in a nursing facility by providing nurses for shifts not covered by the nursing facility? Doesn't this violates the anti-kick back law, and should NOT be allowed.
2. (b) Standard: Twenty-four hour nursing services
   a. There is a general concern that the 24-hour RN requirement has been removed for both the general inpatient levels of care and respite care. Please clarify what "nursing services" means. We suppose that it means services of both RN and LPN/LVN as it does in the NF requirements.
   b. Is there a minimum requirement of services or qualifications?
3. (c)Standard: Physical Environment
   a. Define and provide examples of "equipment failures" that would be required to be reported?
   b. Define what is considered equipment failure that requires repairing. Should be repaired if it results in a serious injury or life-threatening.
4. (f) Standard: Patient Rooms
   a. Please add this to the end of (iv):, *except during community disasters and/or evacuations*
   b. Clarifying how it should be equipped- DEFINE and provide for equipment incorporated into home-like environment.
   c. Space requirements should be omitted from the standard.
5. (l) Standard: Meal Service and menu planning
   a. Thank you CMS for recognizing the nutritional needs of terminally ill patients and also the need for flexibility in this standard.
6. (m) Standard: Pharmaceutical services
   a. Section (m) should also be included in 418.106 as an indication that these are requirements laid on the hospice as a whole, not just on an inpatient basis. (m) Should cross-refer to the earlier standard.
   b. Could you clarify whether or not patients are allowed to bring prescription drugs from home into a facility?
   c. Please add the word *"unpredicted"* before death so that the phrase reads *"regional office any unpredicted death..."*
7. (n) Standard: Pharmacist: 4 Drug Management Procedures
   a. Add "if required by law" to the end of this paragraph.
8. (o) Standard: Seclusion and restraint
   a. The langue in section (o)(i) should be revised to allow hospices to develop evidence-based policies that specify the unique circumstances and interventions of hospice care and the conditions under which they can be implemented r/t restraints. This should be in all settings, not just facilities. Suggested language changes are underlined: Bed rails are not included in this definition of restraint if used for the safety of the patient or to assist the patient in independent functioning. A drug used, as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard treatment for a hospice patient's hospice medical or psychiatric condition. Seclusion is the restricted confinement of a person alone in a room or an area where a person is physically prevented from leaving.
   b. Add the word "unpredicted" before death.
   c. Please clarify on (7) as to why this has to be reported to CMS and to what office at CMS.

d. Physician orders for restraints should cover a 24-hour period with the requirement of a nursing assessment every 8 hours to assess the need to continue or discontinue the restraints. The nurse can choose to continue or discontinue and give supporting documentation. Physician orders required every 24 hours.
e. Modify CMS regional office with patient's death cause by strangulation from a restraint.

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

a. Clarify the term "facility" This section should specifically apply only to Medicare and Medicaid participating facilities. Also, this condition cannot successfully be implemented until there is in the SNF/NF requirements a parallel condition that conforms their requirements. We recommend that the effective date of this section be delayed until the companion section is enacted or that it be at least incorporated by reference into the SNF/NF requirements. We understand that the nursing home COPs will add a section on nursing homes and hospice care. Does this condition match the requirements that will be proposed for nursing homes?
b. We ask that CMS work with surveyors on this issue and that hospices be allowed some leniency until the nursing facility regulations are complete.

1. (b) Standard: Professional management
   a. We would like the word "*hospice*" inserted before inpatient so the phrase reads "*arrangements necessary for hospice inpatient care...*"
   b. Hospice to be responsible for the coordination of the patient's care. Both hospice and NF regulations should reflect coordination of care between both agencies' services.
   c. Please provide some information regarding how this standard is or is not related to nursing home regulations. We assume that this means that the hospice must avoid making assumptions about care provisions and specify the services to be provided by the facility and the ones to be provided by the hospice and the processes for management and routine communication.
2. (d) Standard: Medical Director
   a. We are concerned that the requirements of this standard may cause unnecessary strain in the relationship between the hospice and the facility. Rather care coordination between members of the hospice IDG and the nursing home team who are likely to have more daily contact with the patient should be encouraged.
   b. Please explain why in this instance (as well as elsewhere in the proposed regulations) the Medical Director appears to be separated out from the rest of the IDT. We believe that the best language would be to require that the IDT assume this duty through a designee of its choice, either an physician or a nurse.
   c. Is it permissible for the NF Medical Director to also be the Hospice Medical Director?

3. (e) Standard: Written agreement
   a. Is the written consent of the patient to be part of the facility/hospice contract?
   b. Clarify a "life threatening" condition other than the patient's hospice terminal diagnosis.
   c. Omit the need for consent to be in the contract with the facility. We have the consent in the individual record.
   d. We are concerned that this does not belong in the written agreement between the hospice and the facility and should be moved to another section.
   e. States vary in what they consider included in the room and board rate and what their responsibility is in the provision of room and board. How does this impact this Standard? Will the room and board definition in the State Operation Manual be changing in relation to the hospice regulations?
   f. Remove (iii) because (i) would ensure that the hospice team is notified of any change which is most important.
4. (f) Standard: Hospice plan of care
   a. We would like a definition or clarification on what is meant by "all caregivers".
   b. Change (f.4) to say, "...any change in the plan of care must be discussed among hospice interdisciplinary team and NF caregivers and must be approved by the interdisciplinary team.

c. We are concerned that this does not belong in the written agreement between the hospice and the facility and should be moved to another section.

5. (g) Standard: Coordination of Services
   a. Are we correct in assuming that "physician orders" refer to the hospice physician orders?
6. (h) Standard: Transfer, revocation, or discharge from hospice care
   a. For some facilities, discharge from the hospice could mean the person may no longer reside in the facility. Please provide some clarification of this standard including how compliance would be audited. Why not change *"does not directly impact"* to *"may not affect"?*
7. (i) Standard: Orientation and training of staff
   a. We are concerned that facilities may be inundated with hospice in-services if they have contracts with multiple hospice providers.

418.114 Condition of Participation: Personnel qualifications for licensed professionals

a. Is the implication here that non-degreed social workers can be hired and work as social workers because they are licensed by the State? If so, the effect of going to State licensure here is to lower the requirement for social workers that has been in this rule up to now. We question whether this is appropriate, given the importance of social workers in this context and we believe CMS should consider reinstating the current requirement.
b. We request that the following language be use: *"All Professionals who furnish services directly, under an individual contract, or under arrangements with a hospice must meet minimum qualifications as specified in paragraph (c) of this section and must be legally authorized (licensed, certified, or registered) to practice by the State in which he or she performs such functions or actions, and must act only within the scope of his or her State license, or State certification, or registration. All personnel qualifications must be kept current at all times."*

1. (c) Standard: Personnel qualifications when no state licensing, certification, or registration requirements exist.
   a. The minimum qualifications for a hospice social worker should be at least a BSW from a CSWE accredited school of social work. This qualification should take precedence over any state regulation allowing non social work degreed individuals to be licensed as social workers. In addition, the individual with at least a BSW degree from a CSWE accredited school of social work must be licensed according to laws of the state in which the social worker practices. Keep the Condition of Participation as it is currently: "A person who has at least a baccalaureate degree from a school of social work accredited by the Council on Social Work Education."
2. (d) Standard: Criminal background checks
   a. Clarification is needed regarding if criminal background checks are required for volunteers, contract staff, etc.
   b. Hospices should be required to do criminal background checks on all paid staff and patient care volunteers.
   c. Criminal background checks should be the responsibility of the contracted agency per the written agreement.
   d. Another area of concern is the phrase "before employment at the hospice". There should be some flexibility in hospice policy about what the hospice can do with the employee until the results of the background check is returned, if the process in the state is length.

89. Conditions of Participation: Entire Document
   a. Replace the word drugs with medication through out the regulation.
   b. Change "Medicare-approved" to "Medicare certified" throughout COPs.

We appreciate this opportunity to provide comments to CMS regarding the proposed changes in the Conditions of Participation for Hospice. The comments provided are from our members—hospice providers, hospice professionals, and individuals supporting our mission of providing optimum end of life care to the citizens of Illinois. The comments were made to assure quality service to consumers and open access for all to hospice services.

Thank you for your consideration of our comments.

Sincerely,

Harriet O'Connor
President/CEO
Illinois Hospice & Palliative Care Organization

July 22, 2005

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

Dear Sir or Madam:

The Hospice and Palliative Care Association of New York State (HPCANYS) is pleased to submit comments on the Medicare and Medicaid programs: Hospice Conditions of Participation: Proposed Rule published on May 27, 2005 in the Federal Register. Thank you for this opportunity. Our comments were developed based on input from hospices throughout New York State, as well as in coordination with the National Hospice and Palliative Care Organization (NHPCO). HPCANYS hosted three audio conferences on the Proposed COPs in an effort to coordinate and prioritize comments. **The comments in Bold have been determined to be the most critical.** *Proposed language changes are in italics.*

Section 418.3 Definitions
We request the following changes in this section:

- **Attending physician – add: *(3) The hospice medical director, hospice physician or nurse practitioner may also act as the patient's attending physician.***
- Clinical note – add spiritual, to read "Clinical note means a notation of a contact with the patient that is written and dated by any person providing treatments and medications administered, including the patient's reaction and/or response, and any changes in physical, emotional or *spiritual* condition."
- Add definition of Counseling Services: *Counseling Services means services that assist the patient/family to minimize the stress and problems that arise from the terminal illness or from the dying process.*
- Add definition of Dietitian: *Dietitian means a person who is registered by the Commission of Dietetics Registration or the American Dietetic Association.*
- ***Drug restraint* should be amended as follows: means a medication used to control behavior or to restrict the patient's freedom of movement, *which is not a standard hospice treatment or not requested by the patient or the patient's surrogate.***

  This is a critical concern. Hospice commonly uses psychoactive medications for therapeutic use; e.g. Haldol which is used to control symptoms. In other settings, Haldol is considered a drug restraint. Further, patients on hospice may request or need terminal sedation – yet such medication in another setting would be considered a drug restraint. The issue here is patient's rights. Our concern is that in trying to protect

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patient's rights, <u>this will actually restrict a hospice patient's right to control of anxiety, terminal restlessness, pain, etc.</u> Unlike a nursing home, hospital, or other institutional setting, hospice provides most care in the patient's home where there would be no benefit to hospice staff to have the patient restrained.

- Licensed Professional – amend to include *dietary therapy* after occupational therapy.
- Add definition for Nursing Services: *Nursing Services mean care provided by a licensed nurse or under the supervision of a licensed nurse as allowed by law.*
- Palliative Care – add *interdisciplinary group* to the definition: Palliative care means patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care *uses an interdisciplinary group* to address physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice.
- Add definition for patient's residence: *Patient's residence means where the patient lives.*
- *Representative* should be amended to add *"or common law within the State"* after "...courts of the State..."

PATIENT RIGHTS

Section 418.52 Condition of Participation: Patient's Rights

Section (a) Standard: Notice of Rights

- Section (a) (3) This is the first section where "tracking" of drugs is mentioned. It will be virtually impossible for hospice to "track" drugs as is understood for other more institutional healthcare providers. This will be discussed further under Section 418.106.
- Section (a) (3) needs to be reworded to reflect the CMS understanding of what is meant by "inform the patient". We would suggest revising this section to read, "*The hospice must inform the patient and family of the hospice's drug policies and procedures regarding management and disposal of controlled substances during the comprehensive assessment.*" During discussion with CMS, this was restated to mean including in the admission packet or booklet, which is reviewed during admission and then left with the patient and family to review and refer to as hospice care progresses. The hospice admission process is already lengthy and often difficult for the dying patient and his or her family. Just as with hospital discharge, hospice admission is a barrage of information that is often barely remembered so it is more important that the information is available and reviewed with the patient when pertinent.

Section (b) Exercise of Rights and Respect for Property or Person

- (b) (1) (v.)The right of the patient to be involved in his or her plan of care should be added.
- (b) (1) (vi.)The right of the patient to refuse treatment should be added.
- (b) (3) should be amended to include "*and practice*" after "...by State law." at the end of the sentence.
- Section (b) (4) should be revised to be consistent with Home Health Agency Conditions of Participation by stating: "*The hospice must investigate complaints made by a patient or the patient's family or guardian regarding treatment or care that is (or fails to be) furnished, or regarding the lack of respect for the patient's*

property by anyone furnishing services on behalf of the hospice, and must document both the existence of the complaint and the resolution of the complaint."

Section (e) Patient Liability

- **We recommend that this standard be amended to read, "*Before care is initiated, the patient must be informed, verbally and in writing, and in a language that he or she can understand, if payment may be expected from the patient as well as hospice's intention to bill Medicare or Medicaid, third-party payers, or other resources of funding known to the hospice...*" While we agree that, ideally, the patient and family should be informed of personal liability before services are provided, it is virtually unworkable for evening and weekend admissions because the staff will not be able to verify insurance coverage. This is typically not a problem for Medicare or Medicaid (other than nursing home room and board – particularly for new nursing home admission), but will be a critical issue for other insurers. If admission is desired by the patient and family, it will not be delayed due to inability to determine insurance coverage. If the patient chooses to elect hospice before insurance coverage can be confirmed, it should be acceptable if the patient and family is informed that coverage has not been determined and, therefore, the patient may be personally responsible for the cost of hospice services.**

Section 418.54 Condition of Participation: Comprehensive Assessment

- In opening paragraph, change "care" to "assessment" in the last sentence so that hospice can include items not related to the terminal illness that the hospice might still wish to assess. For example, a hospice patient admitted for Cancer of the Pancreas may also have Chronic Obstructive Pulmonary Disease (COPD). While the COPD would need to be assessed and the medications taken for the COPD would be important to note as decisions are made concerning medication for pain management, etc., the COPD is unrelated to the terminal diagnosis and is not part of the plan of care for the terminal diagnosis.

Section (a) Standard: Initial Assessment:

- **There is no such thing as a physician's admission order for care in Hospice. We believe this language was taken from home care CoPs. We strongly recommend that this be changed to Physician's certification to be consistent with Hospice statute. Inclusion of "physician's admission order for care" would add another administrative layer to the admissions process, and thus, would limit access to the hospice benefit.**
- **We recommend the following language be added to the initial assessment: "...unless otherwise ordered by the physician *or requested by the patient or family...*"**

ASSESSMENT TIMEFRAMES

Section (b) Standard: Timeframe for completion of the comprehensive assessment

- **7 days is requested for the completion of the comprehensive assessment. We feel strongly that 4 calendar days could be intrusive upon the patient and family.** For example, a debilitated, very private individual is admitted to hospice. The admission nurse does the initial assessment, an LPN begins

routine, daily care on the day following admission and the case manager RN also visits. The patient and family wonders if the Social Worker visit might be delayed until the following week as an additional LPN will be covering the weekend and they really are struggling with so many new people coming into their home. The admission nurse has not identified any urgent psychosocial needs and the case manager RN concurs. If the comprehensive assessment must be completed within 4 days clearly, the Social Worker would need to visit within the next two days, but with 7 days the visit could wait a few more days. This is really a common occurrence. A hospice admission is very involved and the nurse and HHA or LPN usually begin the day after admission. It is not hard to imagine how a family can feel overwhelmed by the new people coming into their home and all the questions that need to be asked and answered – thoughtful questions and answers that can be emotional and draining. If a true, interdisciplinary, comprehensive assessment is desired, 7 days would be much kinder for the patient and family.

- Recommend language to read "...attending physician, *if he/she is willing to participate*..." It is current practice to invite the attending physician to participate in IDG. This practice works well and does not require change.

Section (c) Standard: Content of the comprehensive assessment,
(3) Factors to be considered...(ii), Drug Therapy

- It needs to be recognized that hospice is dependent upon the patient/family/physican regarding the use of drugs other than for the terminal illness. At a minimum it is imperative that the interpretive guidelines clearly state that hospice cannot be held responsible for being aware of drugs that hospice is not informed of by the patient, family, physician or other health care provider.

Section (d) Standard: Update of the comprehensive assessment.

- **We strongly urge that "every 14 days" be changed to "*every two weeks*," or "*15 days*." This change would 1) provide the flexibility needed to accommodate holidays and emergencies and 2) synchronize with Hospice's 90/90/60 day cert. periods.**

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

Section (a) Standard: Approach to Service Delivery

- **(1) (i)This should be changed to "*the hospice Medical Director or physician designee*" to be consistent with other sections of the Conditions of Participation. This change will also eliminate a potential problem when the Medical Director or hospice physician is a patient's attending physician.**
- **(2) This should be removed or changed to read, "*If a hospice has more than one interdisciplinary group, there will be consistency across teams and an inclusive process for developing policies that represent all disciplines and teams, with final authority resting with the governing body and senior management.*" It is clearly the role of the governing body to establish policy for an organization so the existing language is not only contrary to common practice, but also to corporate law.**

Section (c) Standard: Content of the Plan of Care:

- Suggest replace "problem" with "*desired outcomes*" to be consistent with philosophy of new proposed COPs.
- **(c) (6) regarding family agreement....We strongly recommend that "agreement" be deleted. Often there is disagreement within the family about care. It is not uncommon for one or more members of the family to be opposed to hospice care for the patient rather than curative treatment. Hospice will also seek to bring all participating members of the family into the plan of care through consensus, but clearly, there will be instances when this is not possible. Further, at times, a patient and/or family member is encouraged to accept a plan of care that is safer than the plan they wish. How often does one member of the family clearly disagree with the patient receiving immediate release morphine for comfort – pain relief, suppression of rapid respiration, etc.? Does CMS really want hospice to delay such needed comfort measures while family agreement is sought? What if agreement is never reached? Clearly, a competent patient can refuse a treatment, but should one of five daughters objections mean that the patient suffers?**

Section (d) Standard: Review of plan of care:

- **We strongly urge that "every 14 days" be changed to "*every two weeks*," or "*15 days*." This change would 1) provide the flexibility needed to accommodate holidays and emergencies and 2) synchronize with Hospice's 90/90/60 day cert. periods. Again, this seems minor, but is critical. In smaller hospices, there is often a team where members are part-time and are only available one day a week or even one day every other week for the several hours needed for Interdisciplinary Team meeting. If this day is Thursday, what happens on Thanksgiving when the members who can get together, do so on Wednesday? Two weeks later when they meet it will be Thursday, and that will be 15 rather than 14 days.**
- **The medical director or physician designee being separated from the rest of the hospice interdisciplinary team at the beginning of the standard would be very destructive to the structure of the team and the very philosophy of hospice. This change would be a step backward for hospice. The Medical Director is not the team leader nor is he or she viewed as more important than the Home Health Aide, nurse, or social worker. Do you understand how difficult it has been for hospice to take physicians who are accustomed to being in charge and make them part of a true team? Yet we have done that with the backing of the law and regulations. If you take this away, there will no longer be an interdisciplinary team, but at best a multi-disciplinary team with tumultuous leadership between the Patient Care coordinator and the medical director as well as all other members of the team.**

OUTCOME MEASURES

418.58 Condition of Participation: Quality assessment and performance improvement.

The hospice industry is in the development stage of identifying and measuring data for improvement. We urge CMS to recognize that full development of a

hospice QAPI will occur over an extended period of time although the preliminary pieces are in place in many hospices.

The increased demands in quality assessment and performance will add significant cost burdens for hospice. This needs to be recognized and addressed in the hospice reimbursement system.

418.62 Condition of Participation: Licensed professional services.

- Section (b) Add the word "*hospice*" after "patient's."
- Section (c) should be revised to add at the end of the sentence, "with contracted licensed professionals encouraged to participate whenever possible." Contracted therapists are often utilized infrequently, particularly in smaller hospices, and it may well prevent access to such therapies if they are required to participate as outlined in this section.

CORE SERVICES

418.64 Condition of Participation: Core Services.

We strongly recommend that hospices be allowed to contract for continuous care staff on a routine basis. Without this change, patients are being denied access to continuous care. We recognize that CMS does not want this change, but does CMS realize how this is negatively affecting patient care? Continuous care is a key component of hospice allowing many patients to stay at home rather than go to a hospital or nursing home. However, the need for continuous care is sporadic and most often needed at night - the time most difficult to staff. Requiring that hospice staff be used routinely for this service makes it virtually impossible, particularly for smaller hospices. Most hospices have gone to great lengths to hire staff that are willing to provide this care, yet most find they can only secure a small number of nurses who may well be unavailable when the need actually arises, usually with only several hours of notice at most.

Section (b) Standard: Nursing Services

- Definition of nursing services needs to be in the definition section (see comment on p.2 above). In addition, this section should mirror the Medicare Modernization Act.

Section (d) (2)Standard: Nutritional counseling.

- We concur. Thank you for including this.

STATUTORY NURSING WAIVER

418.66 Condition of Participation: Nursing services.

It is requested that this section be made consistent with MMA language concerning a nurse practitioner being eligible to serve as a hospice patient's attending physician.

418.72 Condition of Participation: Therapies...

We recommend that dietitians be added to the list of non-core services.

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

Section (c) Standard: Competency evaluation

- We request that *aide* be added after home health

- Requiring that competency evaluation be determined solely by observing the aide's performance providing care to a real patient rather than in a skills laboratory setting is contrary to New York State statute. New York permits state approved home health aide training programs to determine aide competence in either setting. Changing the requirement to the more stringent one of observation while the worker is providing care in a patient home may impact the availability of both paraprofessional personnel and the RNs who must supervise and evaluate them.

Section (e) Standard: Qualifications for instructors

- Revise to say: "...supervision of a registered nurse who possess a minimum of two years nursing experience, at least one year of which must be *hospice* or home health care."

Section (g) Standard: Home health aide assignments and duties

- **Delete "the appropriate qualified therapist," because it is not consistent with hospice practice, which is to have an RN make assignments. It appears that this language is taken directly from Certified Home Health Care CoP.**

Section (h) Standard: Supervision of home health aides.

- **(i) Remove "qualified therapist." This is from Home Care Conditions of Participation (CoP) and does not apply to hospice practice, which is to have the RN provide supervision.**
- **We strongly urge that "every 14 days" be changed to "*every two weeks*," or "*15 days*." This change would 1) provide the flexibility needed to accommodate holidays and emergencies and 2) synchronize with Hospice's 90/90/60 day cert. periods.**

Section (j) Standard: Homemaker qualifications - Recommend use definition of homemaker in NYS statute. New York State has specific requirement for homemakers that are different from home health aides. To require a home health aide be used for homemaker services is inefficient use of very limited resources, which will only worsen with time.

Section 418.78 Conditions of Participation: Volunteers.

(e) Standard: Level of Activity:

- We support the content of this section and the opportunity to include administrative volunteer time in the 5% standard. In light of the importance of both administrative and clinical volunteer support to hospice operations, this provision is beneficial. The automatic increase in volunteer time needed as patient census rises could be burdensome for hospices where there is strong competition among entities utilizing volunteers in their operations. We recommend that the 5% formula be applied to the previous year's patient care hours rather than concurrent patient census.

ORGANIZATION AND ADMINISTRATION

Section 418.100 Condition of Participation: Organization and Administration of Services

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

- (2) should be amended to state: "...consistent with patient and family needs and *goals wherever possible*." Clearly, if there are unresolved conflicts between the patient's goals and the family's goals, the patient or patient surrogate will take precedence.

Section (e) Standard: Professional management responsibility.

- The wording of Section (e) (2) should be revised to: "Furnished in a safe and effective manner *by qualified personnel*";

Section 418.102 Condition of Participation: Medical Director

- Section 418.102 first paragraph needs to be amended by adding "*or the hospice*" after "....by the medical director" in the third sentence. Usually the hospice secures a physician to provide coverage for the medical director. Again, there seems to be some focus on the medical director as a part of hospice that is not factual.
- Section (a) Standard: Initial certification of terminal illness
- The hospice needs to be able to contract with an entity for a physician to serve as a medical director or a coverage physician. More and more physicians are employed by hospitals, health centers, systems, etc. and to restrict this could prohibit availability of a hospice physician.

Section (b) Standard: Recertification of the terminal illness

- presumably this can be done during IDT with the entire team participating as the comprehensive assessment is updated to determine eligibility for re-certification. This needs to be clearly stated in the interpretive guidelines.

Section (c) Standard: Coordination of medical care

- **It is STRONGLY recommended that the last sentence of this section be revised as follows: "*The medical director or physician designee is also responsible for participating in the hospice's quality assessment and performance improvement program. The program may be directed by the medical director, physician designee or other qualified professional.*" This is a critical issue as most hospice medical directors are part-time or even volunteer and clearly are not prepared to direct the hospice's quality assessment and performance improvement program. If this is left in place, it will not actually occur in most instances, and it is doubtful that this is what CMS is looking to accomplish.**

CLINICAL RECORDS

Section 418.104 Condition of Participation: Clinical Records

Section (a) Standard: Content

- This section includes an informed consent and authorization, but does not include the patient's rights. The election statement basically covers this, with the exception of a HIPAA authorization, which is not a general form, but rather a specific form explicitly stating what is authorized to be released to whom and during what timeframe. Thus (a) (2) should be amended to reference the election statement, which is required to include a consent to start hospice service as well as the patient rights.

Section (b) Standard: Authentication

- **This section is applicable for a hospital setting, but not for hospice. It is STRONGLY recommended that this section be excluded as neither Nursing**

Facilities nor Home Health Agencies have such a standard. At a minimum, it must be recognized that hospices have no mechanism to authenticate a signature of a covering physician beyond the initial verbal order taken by a registered nurse.

Section (d) Standard: Retention of records

- This section should be revised to follow the HIPAA requirement for records retention.

Section (e) Standard: Discharge or transfer of care

- **This section needs to be revised. It is imperative that the requirement for hospice to provide a copy of the clinical record to the patient's attending physician in the case of a revocation or discharge be removed. The discharge summary is a good addition and will provide all the information that most physicians will accept. If CMS feels strongly about this, the most that should be required is that hospice will *offer* the attending physician or, in the case of a transfer, the accepting facility, a copy of the complete clinical record *or any parts of the record which the physician or facility feel are needed.* This requirement is contrary to the HIPAA standard of "minimum necessary information." Also, the family is the unit of care for hospice and clearly the patient's attending physician, who would not be dealing with other family members, may not need the family information. Mandating that the entire clinical record be sent would be unduly burdensome on the hospice—both cost wise and staff wise. This mandate is also counter to federal efforts to reduce paperwork in the health care system.**

DRUGS, SUPPLIES, AND DME

Section 418.106 Condition of Participation: Drugs, Controlled Drugs and Biologicals

Section (b) Standard: Controlled drugs in the patient's home

- **Recommend the following language change: "*The hospice must have written policy for disposing of controlled drugs in the hospice plan of care that are maintained in the patient's home...*" Hospice is not legally able to collect controlled drugs in a patient's home – it is illegal to transport a controlled substance without a prescription and this would typically be done when the patient has died so the prescription is no longer valid. The word "collecting" MUST BE REMOVED. The term tracking is also of concern. Again, this is a home rather than an institutional setting. Hospice can track what medications are put in the home to the extent that medications are only provided at the level ordered by a physician. However, hospice cannot track in the sense that this word is used in hospital and nursing facility regulations where the facility is administering the medications. This should be stated in the standard. Clearly, this can only apply to hospice provided controlled drugs rather than all controlled drugs in the patient's home since a family or patient who is abusing drugs would often hide medication not provided by hospice. What would happen when the family refuses to allow for disposal of the controlled substances?**

Section (c) Standard: Use and maintenance of equipment and supplies

- This section must be revised to state that in the instances where DME is provided through arrangement, the arrangement must specify that the vendor will comply with this standard.

SHORT-TERM INPATIENT CARE
Section 418.108 Condition of Participation: Short-term inpatient care.

We strongly urge revision of the introduction to this section as follows:

- ***"Short-term General Inpatient Care and Respite Care are provided by the hospice in a participating Medicare or Medicaid facility."***

- **The provider standards for general inpatient care and respite care should be listed in sections (a) and (b). As currently worded, caregiver collapse is not included as an eligible service on short-term GIP. There are many instances when psycho-social crises demand a short in-patient stay and this is currently allowed in existing hospice regulations.**

Section (a) Standard: Inpatient care for symptom management, pain control *and psycho-social issues*.

- **It is imperative that psycho-social issues/caregiver collapse be covered under general inpatient care. Paragraph (a) should note that pain control and symptom management would be done on an inpatient basis either because of the specific need for the staff and equipment available there or because of the inability of the hospice and/or the patient's caregivers to assure that the services are properly provided in the home.**
- **In addition, we recommend that the CMS Hospice Manual, Chapter 2, Coverage of Services, be amended as follows: The first sentence of the final paragraph of 230.1 be revised to read, "*General inpatient care may be required for procedures necessary for pain control or acute or chronic symptom management, which cannot feasibly be provided in the home.*"**
- **We strongly advocate the need for RN presence on a 24-hour basis for the general inpatient level of care. The critical issues encountered with the hospice patient in this setting facing end-stage changes call for the assessment and treatment skills of an RN. RN presence on a 24-hour basis for respite care is not seen as presenting the equivalent need.**
- **It is also recommended that the word "approved" should be replaced with *"certified"* in item (a) (1).**

Section (b) Standard: Inpatient care for respite purposes.

- (2) Recommend change "approved" to *"participating"*: "A Medicare/Medicaid *participating* nursing facility that also meets the standards specified in 418.110(b) and (f)."

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

Section (a) Standard: Staffing.

- With reference to the statement, that hospice is responsible for ensuring staffing levels reflecting patient volume; hospice is requesting clarification regarding

provision of staff. Allowing hospices to provide nurses on appropriate shifts for 24 hr. RN coverage in facilities, including nursing homes, where such coverage may not be mandated under other regulations, would help meet this requirement. The ability to provide this coverage supplement would, naturally, be dependent upon availability of the necessary staff.

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

- **As noted previously, Hospice strongly recommends retention of the 24-hr. RN requirement for the general inpatient level of care while allowing flexibility in the RN staffing for respite.**

Section (c) Standard: Physical environment.

- Reference to reporting of equipment failures (ii) to appropriate State and local bodies. Clarification is requested regarding the definition of "equipment failure" as well as providing some examples. Would this occur within the interpretative guidelines when they are published?

Section (f) Standard: Patient rooms.

- Standards with minimum square footage requirements indicated appear to be appropriate for application to new construction situations.

- It is also recommended that the following be added to the end of (iv): *"except during community disasters and/or emergencies."*

Section (l) Standard: Meal service and menu planning.

- We concur with the proposed changes. Content that allows increased flexibility in the delivery of meal service to hospice patients is highly desirable. It is important that meal service, when possible, adapt to the needs of the resident with less emphasis on the number of hours between meals.

Section (m) Standard: Pharmaceutical services.

- Section (m) should also be included in 418.106 as an indication that these are requirements for the hospice as a whole, not just on an inpatient basis. (m) should cross-refer to the earlier standard.

Section (n) Pharmacist.

- It is recommended that "*if required by law*" be added to the end of paragraph (4) (iii) in this section regarding investigation and reporting requirements.

Section (o) Standard: Restraint and seclusion.
It is imperative that this section be removed. Restraint and seclusion are perceived so differently in hospice that inclusion of this section will irreparably harm the foundations of a program designed for end-of-life care. The problem here lies in the fundamental differences between hospice and any other part of the health care continuum. Hospice patients are dying and, therefore, often benefit from "seclusion" although we would call it privacy. Hospice patients need aggressive symptom control which often warrants medication that in another setting would be used for restraint. While the need for this provision in other settings is clearly understood and, while hospice would never want a patient to be restrained or secluded if this were not necessary and the patient's wish, if this

section is not removed it will likely result in avoidance of some of the most precious benefits of hospice care. Patients often choose to remove themselves from their environment as they die; it is almost a transition from this life to whatever lies beyond it. Patients often choose comfort over alertness, particularly as life is ending. Please remember the uniqueness of the hospice benefit and remove this section completely.

While it is imperative to remove this section totally, it is reluctantly recognized that CMS may not agree. In this instance, over our strong protests, this section must be dramatically revised. The following revisions are critical to mitigate the very real negative impact of this standard:

- **The term "seclusion" should be removed from this section. Hospice does not seclude patients; however, most hospice inpatient rooms are private rooms to allow the family 24 hour access and privacy for needed conversations and comfort. This is not done to seclude the patient, but rather to respect the special needs of patients at end of life for privacy and intimate surroundings with family. Inclusion of the term "seclusion" could lead to confusion and, potentially, to removal of the environmental gains that hospices have made in inpatient settings for both privacy and family access.**
- **As noted in the previous section "Definitions" Hospice has great concern over the potential impact on end-of-life care when use of a medication to control some symptoms such as terminal agitation or restlessness, is perceived as imposition of a chemical restraint. The hospice concern, whatever the setting within which care is being given, is with the use of the most appropriate method of ensuring palliative care is made available.**
- **Whether the care setting is the patient's home, a nursing home or an inpatient setting the goal is control of the anxiety, restlessness, pain or other symptom negatively impacting quality of life in the last stage. Forced perception of certain drug use, such as Haldol, as a restraint by others including nursing homes will restrict the ability of Hospice to meet those specialized end-of-life needs. Utilization of a standard for chemical restraints utilized in nursing homes does not always correspond with standards commonly accepted by Hospice medical staff regarding utilization of some medications. The proven, specialized expertise and experience of hospice medical staff must be given consideration as standards of medication use are applied to the restraint issue.**
- Suggested change for inclusion in (o) (1) is the addition after "...normal access to one's body" is "Bed rails are not included in this definition of restraint if used for the safety of the patient or to assist the patient in independent functioning." The concept of the side rail as an "enabler" is of value here.
- Section (o) (3) (d) refers to time limitations for restraints. Suggested language proposes the following schedule: *"change the hours to 8-hour intervals over a 24-hour period for adults, while sleeping, and 4-hour intervals while awake; 6-hour intervals while sleeping for 9-17 year olds, 2 hours intervals over 24-hours while awake; 2-hour intervals while sleeping for under age 9 and 1-hour while awake."*
- **Section (o) (7). Request that the word "unpredicted" be added before "death" in that sentence referring to reporting of any death that occurs while the patient is restrained.**

RESIDENTS RESIDING IN A FACILITY

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

Clarify what is meant by "other facility," and define "nursing facility." Also clarify that this section should specifically apply only to Medicare and Medicaid participating facilities. This condition cannot successfully be implemented until there is in the SNF/NF requirements a parallel condition that confirms their requirements. We recommend that the effective date of this section be delayed until the companion section is enacted or that it be at least incorporated by reference into the SNF/NF requirements. We understand that the nursing home COPs will add a section on nursing homes and hospice care. Does this condition match the requirements that will be proposed for nursing homes?

It is also requested that CMS work with surveyors on this issue and that hospices be allowed some leniency until the nursing facility regulations are complete. Can this Condition be phased in?

Section (b) Standard: Professional management.

Recommend that "hospice" be inserted after "inpatient" in this standard: "...make any arrangements necessary for *hospice* inpatient care in a participating Medicare/Medicaid facility according to 418.100."

In a number of cases, Hospice relationships with nursing homes can be described as tenuous. Concern on the part of nursing home staff, which is also held responsible for care of their resident, is sometimes related to the held perception that the nursing facility loses total control of the resident care plan. It is essential to emphasize that a collaborative relationship is the goal, not domination of the care plan. Certainly, Hospice must bear responsibility for the coverage it approves and the services it offers, but the expertise of hospice in provision of specialized end-of-life care is not always made available due to perception of regulations. It is not unheard of to hear nursing facility personnel say they do not want hospice to come in because they lose control of their care plan process. Stressing the relative responsibility of both parties, while recognizing the collaborative and integrative nature of the relationship, will enhance opportunities for meeting the varied and complex needs of the terminal patient.

Section (d) Standard: Medical Director

We request that this standard be re-titled: Interdisciplinary Group and that the text be revised as follows: The Hospice Interdisciplinary Group must provide overall coordination of the care of the hospice resident that resides in an SNF, NF, or other facility. Members of the interdisciplinary group will regularly communicate and coordinate care with SNF/NF staff to ensure quality care for the patient and family. The hospice Medical Director or physician designee will communicate with the Medical Director of the SNF/NF, the patient's attending physician, and other physicians participating in the provision of care for the terminal and related conditions as necessary."

We are concerned that the requirements of this standard could be a real impediment to hospice-nursing facility collaboration. As written, it may

cause unnecessary strain in the relationship between the hospice and the facility. Communication issues arise on many levels. What appears to be a focus on medical director/physician communication leaves the remainder of the IDT team, which has the consistent and integrated relationship with the facility, out of the loop. Certainly, physician-to-physician communication is an extremely important element in the care of the patient, but experience has shown that good internal communication between hospice medical director/physician designee through the IDT team works well for most interactions in the nursing home. In cases where conflict between IDT members and facility staff, including the physician occur, the hospice medical director is brought in to facilitate resolution. In addition, the relative complexity of certain patient situations may mandate closer physician-to-physician communication, but this should remain as a decision the IDT members make, as patient needs change. Contact with the facility should remain with the designee of the IDT, either the MD or a nurse.

Logistical issues are of concern also on both sides of this communication issue. As written, the content of (d) does not indicate parameters for contact between physicians. From the hospice side, especially for those organizations with volunteer or part-time medical directors, the rather broad expectation of communication could be a detriment and place a significant burden on the hospice physician.

Hospice communication with "*the facility medical director, the patient's attending physician and other physicians participating in the provision of care*" also presents challenges. In some instances, the nursing home medical director does not carry a patient load and may be totally unfamiliar with the needs of that person. Here again, consistent focus on a case-by-case judgment regarding involvement of the facility medical director would be desirable. In addition, the non-specific mandate of physician to physician communication presents potential time and cost issues when consideration is given to the, at times, relatively large number of attending physicians in some nursing homes as well as the difficulty that may be encountered by the hospice physician in trying to reach them on a regular basis.

If this section remains unchanged or only minimally changed, it must be recognized that it will result in a dramatic increase in cost for Medical Director/physician designee services for the hospice with little to no foreseeable benefit. This will necessitate revision of the hospice Medicare reimbursement methodology to assure that these additional costs are fairly reimbursed.

Section (e) Standard: Written agreement

- (1): "written consent" should be changed to "*election* statement." This paragraph should be deleted from 418.112 (e) and moved to the appropriate section in reference to the patient record standard.
- (4) (iii). Clarification is requested regarding definition of a life threatening condition other than the patient's hospice terminal diagnosis.
- (e) (6): States vary in what they consider included in the room and board rate and

what their responsibility is in the provision of room and board. How does this impact this Standard? Will the room and board definition in the State Operation Manual be changing in relation to the hospice regulations?

Section (f) Standard: Hospice plan of care

- (3): Recommend that the 14-day requirement for care plan review be changed to *two weeks or 15 days* to be in line with the current 90/90/60 day certification periods.
- (f) (4) Recommend the following language change: "Any changes in the plan of care must be discussed *by representatives of hospice and representatives of the nursing facility* and must be approved by the hospice before implementation." Once again, expected collaboration must be the goal as IDT designated representative(s) and facility staff responsible for the supervision of care in the nursing home should both be aware of hospice care plan changes.

Section (g) Standard: Coordination of services.

- Comment: Is there a likelihood that nursing facility regulations will state that facilities can accept orders from the hospice physician? Any such outcome must consider the need to stress collaboration and not diminish the role of the attending physician who also bears a responsibility for the care of the patient in a facility. In addition, facility staff are trained and oriented to work closely with their attending physicians. Interjecting a more direct order relationship between hospice and facilities without attending input may be difficult for the facility staff.

- (6) Physician orders. Our assumption is that this refers to "hospice" physician orders.

Section (h) Standard: Transfer, revocation or discharge from hospice care.

- We recommend that "does not directly impact" be changed to *"may not affect"*: "Discharge from or revocation of hospice care *may not affect* the eligibility to continue to reside in a SNF, NF, ICF/MR, or other facility."

  A concern here is, while discharge from hospice does not always mean discharge from a facility, this may be an issue in some cases and patients should not experience the trauma of an external move because they have perhaps stabilized for the moment and may not be eligible for hospice.

- Please provide some clarification of this standard including how compliance would be audited.

Section (i) Standard: Orientation and training of staff.

- Recommend revision to read: "Hospice must *assure orientation* of facility staff..." As written, facilities that have contracts with multiple hospices could be inundated with hospice in-services. It would be preferable if hospices were expected to meet with facilities, offer appropriate in-services (and document the attempt) and make every effort to ensure this education is made available.

  One must also consider the needs and resources of the contracted facilities. Focus for in-service should be on those elements most important to the coordinated provision of care for the terminally ill patient.

PERSONNEL QUALIFICATIONS
418.114. Condition of participation: Personnel qualifications for licensed professionals.

Section (c) Personnel qualifications, (7) Social Worker

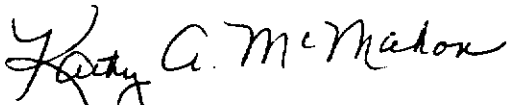
- The use of State licensure as a standard for social workers is of concern to many hospices. End-of-life patient and family needs present an extremely intense and demanding set of variables and require skills and training that are often more than a non-Masters prepared Social Worker will possess. Every effort should be made by hospice to employ this level of professional worker and regulatory support for such a course is important.

Section (d) Standard: Criminal background check

- This requirement would place a great financial burden on hospices. The hospice reimbursement rate must be adjusted to accommodate this significant new expense.
- Please clarify that the criminal background check requirement applies to prospective, not current employees and contracted staff.

In closing, I urge you give serious, thoughtful consideration to our comments as you finalize the Proposed Hospice Conditions of Participation. Again, we appreciate the opportunity to provide these comments. If you have any questions or require additional information, please contact me at 518/446-1483 or kmcmahon@hpcanys.org.

Sincerely,



Kathy A. McMahon
President and CEO

July 25, 2005

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 or Madam:

Thank you for this opportunity to comment on the Medicare and Medicaid programs: Hospice Conditions of Participation: Proposed Rule published on May 27, 2005 in the Federal Register. These comments are a collaborative effort from the Southern Tier Hospice and Palliative Care management team in coordination drawing on input from the Hospice and Palliative Care Association of New York State and the National Hospice and Palliative Care Organization. These comments are personalized with examples from the over fifty-five years of STHPC experience represented by the four members of this management team who worked together on these comments. This is not a bureaucratic effort on our part, but a realization that this is the legacy that we will leave the next generation of hospice management, as most of us will retire before these regulations are next revised. Two of the collaborators remember when the Conditions of Participation for hospice were first released twenty-two years ago and all of us understand that this is our opportunity to influence these regulations to reflect what is needed in actual operations by patients, families and staff.

While clearly all of these changes are needed, **the comments in Bold have been determined to be the most critical.** *Proposed language changes are in italics.* We ask you to read our requests with an open mind and our examples with an open heart. This is not an exercise in manipulation, but persuasion with a clear focus on assuring that first and foremost, the regulations support quality care for patients and families.

Section 418.3 Definitions
We request the following changes in this section:
Section (a) Standard: Notice of Rights

- **(3) Attending physician – add:** ***(3) The hospice medical director, hospice physician or nurse practitioner may also act as the patient's attending physician.*** This will be discussed in another section, but it is important that CMS realize that many hospices use community doctors as the medical director or hospice physician and these physicians have often been a patient's attending physician for years. It is imperative that these relations be allowed to continue. Moreover, there are times when patients are coming to hospice from another area and do not have a local attending physician so the medical director or hospice physician is willing to meet this need when necessary also.
- Clinical note – add spiritual, to read "Clinical note means a notation of a contact with the patient that is written and dated by any person providing treatments and medications administered, including the patient's reaction and/or response, and any changes in physical, emotional or *spiritual* condition.

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- Add definition of Counseling Services: *Counseling Services means services that assist the patient/family to minimize the stress and problems that arise from the terminal illness or from the dying process.*
- Add definition of Dietitian: *Dietitian – a person who is registered by the Commission of Dietetics Registration or the American Dietetic Association.*
- ***Drug restraint* should be amended as follows: means a medication used to control behavior or to restrict the patient's freedom of movement, *which is not a standard hospice treatment or not requested by the patient or the patient's surrogate.***

  This is a critical concern. Hospice commonly uses psychoactive medications for therapeutic use; e.g. Haldol which is used to control symptoms. In other settings, Haldol is considered a drug restraint.

  Further, patients on hospice may request or need terminal sedation – yet such medication in another setting would be considered a drug restraint. The issue here is patient's rights. Our concern is that in trying to protect patient's rights, <u>this will actually restrict a hospice patient's right to control of anxiety, terminal restlessness, pain, etc.</u> Unlike a nursing home, hospital, or other institutional setting, hospice provides most care in the patient's home where there would be no benefit to hospice staff to have the patient restrained.
- Licensed Professional – amend to include *dietary therapy* after occupational therapy.
- Add definition for Nursing Services: *Nursing Services mean care provided by a licensed nurse or under the supervision of a licensed nurse as allowed by law.*
- Palliative Care – add *interdisciplinary group* to the definition: Palliative care means patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care *uses an interdisciplinary group* to address physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice.
- Add definition for patient's residence: *Patient's residence means where the patient lives.*
- *Representative* should be amended to add *"or common practice within the State"* after "...courts of the State..."
- ***Restraint* should be revised by deleting as a restraint after drug at the end of the definition and replacing it with, *primarily for restraining the patient against the patient and family wishes.*** This is discussed in other sections, but is a critical issue. Hospice patients are in a very different situation from most other patients in the health care system. These patients are aware that they are dying and have chosen hospice seeking comfort and the ability to participate in the decisions that will affect their dying process. For example, bed rails in a nursing facility are considered a restraint. However, in hospice they are generally used to assist the patient – something the patient can grab to help with turning in bed so they can maintain at least this little piece of independence or to help in getting up from the bed for a pivot transfer to a commode. This is why it is imperative that the patient and family wishes be considered here. Please also understand that while the CMS intention is to promote patients rights rather than hinder them, regulations are out there and open to interpretation by the new hospice director or nurse coming from a setting where

restraint, drug restraint and many other terms have clear meanings with stiff penalties for infractions. Can you not imagine staff coming from a nursing facility steering clear of Haldol or bed rails because both were virtually forbidden in their experience and these regulations seem to be using the same language?

- **The definition of seclusion should be removed.** In nursing facilities, the desire is to socialize the patient while in hospice, the desire is to meet the needs of the dying patient. A patient may have little active family participation in his or her life and may be seeking company, but most hospice patients are seeking privacy to be with family and, towards imminent death, even to remove themselves totally from interacting with his or her surroundings as he or she prepares for death. Again, while well-intentioned, highlighting seclusion and bringing forth the specter of guilt from other parts of health care, may actually hinder a hospice patient's right and need for privacy. If CMS refused to remove this definition over our strong objections, at a minimum the definition should be revised to add, *against the wishes of the patient and family,* at the end of the definition.

Section 418.52 Condition of Participation: Patient's Rights

Section (a) Standard: Notice of Rights

- Section (a) (3) This is the first section where "tracking" of drugs is mentioned. It will be virtually impossible for hospice to "track" drugs as is understood for other more institutional healthcare providers. This will be discussed further under Section 418.106.
- Section (a) (3) needs to be reworded to reflect the CMS understanding of what is meant by "inform the patient." We would suggest revising this section to read, "***The hospice must inform the patient and family of the hospice's drug policies and procedures regarding management and disposal of controlled substances during the comprehensive assessment or when a controlled substance is first ordered..***" During discussion with CMS, this was restated to mean including in the admission packet or booklet, which is reviewed during admission and then left with the patient and family to review and refer to as hospice care progresses. The hospice admission process is already lengthy and often difficult for the dying patient and his or her family. Just as with hospital discharge, hospice admission is a barrage of information that is often barely remembered so it is more important that the information is available and reviewed with the patient when pertinent.
- (a) (1) (v.)The right of the patient to be involved in his or her plan of care should be added.
- (a) (1) (vi.)**The right of the patient to refuse treatment should be added**.

Section (b) Exercise of Rights and Respect for Property or Person

- (b) (3) should be amended to include "*and practice*" after "...by State law." at the end of the sentence.
- Section (b) (4) should be revised to be consistent with Home Health Agency Conditions of Participation by stating: "***The hospice must investigate complaints made by a patient or the patient's family or guardian regarding treatment or care that is (or fails to be) furnished, or regarding the lack of respect for the patient's property by anyone furnishing services on behalf of the hospice, and must document both the existence of the complaint and the resolution of the***

complaint." The standard as proposed is overly restrictive and could result in hospices avoiding some of the confrontational issues that can be essential to patients and their families preparing for and accepting end of life. Clearly, if there are complaints that allege violation of law, these should be reported. However, families have alleged "abuse" because staff has reviewed the election statement with the patient and the family feels it was "abusive" to inform the patient that he or she has six months to live if the disease runs it normal course. Complaints of "abuse" have been made because a social worker has asked the patient's plan for care when the patient can no longer be left alone. Does CMS really want these reported to the State and treated like a criminal offense? Hospice often deals with complaints that end up being simply the patient or family's anger at the illness, prognosis or situation. Hospice actually seeks to encourage these complaints so that feelings can be expressed and denial dealt with through to acceptance when possible. Will hospice really encourage these complaints when the hospice and staff are made to feel like suspects in a crime? Please require that potential criminal behavior be reported as most local law currently requires, but avoid criminalizing all behavior that may result in a complaint.

Section (e) Patient Liability

- **We recommend that this standard be amended to read, "*Before care is initiated, the patient must be informed, verbally and in writing, and in a language that he or she can understand, if payment may be expected from the patient as well as hospice's intention to bill Medicare or Medicaid, third-party payers, or other resources of funding known to the hospice...*" While we agree that, ideally, the patient and family should be informed of the exact personal liability before services are provided, it is virtually unworkable for evening and weekend admissions because the staff will not be able to verify insurance coverage. This is typically not a problem for Medicare or Medicaid (other than nursing home room and board – particularly for a new nursing home admission), but will be a critical issue for other insurers. If the patient and family desire admission, it will not be delayed due to inability to determine insurance coverage. If the patient chooses to elect hospice before insurance coverage can be confirmed, it should be acceptable if the patient and family is informed that coverage has not been determined and, therefore, the patient may be personally responsible for the cost of hospice services.**

Section 418.54 Condition of Participation: Comprehensive Assessment

- In opening paragraph, change "care" to "assessment" in the last sentence so that hospice can include items not related to the terminal illness that the hospice might still wish to assess. For example, a hospice patient admitted for Cancer of the Pancreas may also have Chronic Obstructive Pulmonary Disease (COPD). While the COPD would need to be assessed and the medications taken for the COPD would be important to note as decisions are made concerning medication for pain management, etc., the COPD is unrelated to the terminal diagnosis and is not part of the plan of care for the terminal diagnosis.

Section (a) Standard: Initial Assessment:

- **There is no requirement for a physician's admission order for care in Hospice. We believe this language was taken from home care CoPs. We strongly**

recommend that this be changed to Physician's certification to be consistent with Hospice statute. Inclusion of "physician's admission order for care" would add another administrative layer to the admissions process, and thus, would limit access to the hospice benefit.

- **We recommend the following language be added to the initial assessment: *"...unless otherwise ordered by the physician or requested by the patient or family..."*** It is not uncommon for the patient or family to request that the admission/assessment be delayed until a convenient time for all of the family to be there or because the patient has things he or she wishes to consider before discussing admission to hospice (a physician's visit to assure that no further treatment is available, a trip, etc.).

Section (b) Standard: Timeframe for completion of the comprehensive assessment

- **7 days is requested for the completion of the comprehensive assessment. We feel strongly that four calendar days could be intrusive upon the patient and family.** For example, a debilitated, very private individual is admitted to hospice. The admission nurse does the initial assessment, an LPN begins routine, daily care on the day following admission and the case manager RN also visits. The patient and family wonders if the Social Worker visit might be delayed until the following week as an additional LPN will be covering the weekend and they really are struggling with so many new people coming into their home. The admission nurse has not identified any urgent psychosocial needs and the case manager RN concurs. If the comprehensive assessment must be completed within 4 days clearly, the Social Worker would need to visit within the next two days, but with 7 days, the visit could wait a few more days. This is really a common occurrence. A hospice admission is very involved and the nurse and HHA or LPN usually begin the day after admission. It is not hard to imagine how a family can feel overwhelmed by the new people coming into their home and all the questions that need to be asked and answered – thoughtful questions and answers that can be emotional and draining. If a true, interdisciplinary, comprehensive assessment were desired, 7 days would be much kinder for the patient and family. The short length of stay in hospice has been sited in discussions about extending this timeframe. For imminently dying patients, the comprehensive assessment is usually done by the nurse at the initial assessment, because it is recognized that the patient needs that level of assessment immediately. Therefore, the short length of stay should not be an issue since those patients with the shortest length of stay will generally be assessed comprehensively on admission or at worst when the imminence of death is assessed.
- Recommend language to read "...attending physician, *if he/she is willing to participate...*" It is current practice to invite the attending physician to participate in IDG. This practice works well and does not require change.

Section (c) Standard: Content of the comprehensive assessment,
(3) Factors to be considered...(ii). Drug Therapy

- It needs to be recognized that hospice is dependent upon the patient/family/physican regarding the use of drugs other than for the terminal illness. At a minimum it is imperative that the interpretive guidelines clearly state that hospice cannot be held

responsible for being aware of drugs that hospice is not informed of by the patient, family, physician or other health care provider.

Section (d) Standard: Update of the comprehensive assessment.

- **We strongly urge that "every 14 days" be changed to "*every two weeks*," or "*15 days*." This change would 1) provide the flexibility needed to accommodate holidays and emergencies and 2) synchronize with Hospice's 90/90/60 day cert. periods.** The examples of problems with holidays are perhaps best understood by example. In smaller hospices, there is often a team where members are part-time and are only available one day a week or even one day every other week for the several hours needed for Interdisciplinary Team meeting. If this day is Thursday, what happens on Thanksgiving when the members who can get together, do so on Wednesday? Two weeks later when they meet it will be Thursday in order to allow everyone to be there and that will be 15 rather than 14 days. Isn't it clearly better that the team have fifteen days between meetings, but have the whole team together?

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

Section (a) Standard: Approach to Service Delivery

- (1) We disagree with the change in the requirement for leadership of the IDG. We feel strongly that an RN should be the member of the IDG to provide coordination of care and to ensure continuous assessment of each patient's and family's needs.
- **(1) (i)This should be changed to "*the hospice Medical Director or physician designee*" to be consistent with other section of the Conditions of Participation. This change will also eliminate a potential problem when the Medical Director or hospice physician is a patient's attending physician.**
- **(2) This should be removed or changed to read, "*If a hospice has more than one interdisciplinary group, there will be consistency across teams and an inclusive process for developing policies that represent all disciplines and teams, with final authority resting with the governing body and senior management.*" It is clearly the role of the governing body to establish policy for an organization.** It is recommended that a statement be added, *patient care procedures and guidelines for care should be established in cooperation with the IDGs.*

Section(c) Standard: Content of the Plan of Care:

- Suggest replace "problem" with "*desired outcomes*" to be consistent with philosophy of new proposed COPs.
- **(c) (6) Re. family agreement....We strongly recommend "agreement "be deleted.** Often there is disagreement within the family about care. It is not uncommon for one or more members of the family to be opposed to hospice care for the patient rather than curative treatment. Hospice will always seek to bring all participating members of the family into the plan of care through consensus, but clearly, there will be instances when this is not possible. Further, at times, a patient and/or family member are encouraged to accept a plan of care that is safer than the plan they wish. How often does one member of the family, clearly disagree with the patient receiving immediate release morphine for comfort – pain relief, suppression of rapid respiration, etc.? Does

CMS really want hospice to delay such needed comfort measures while family agreement is sought? What if agreement is never reached? Clearly, a competent patient can refuse a treatment, but should the objections of one of five daughters mean that the patient suffers? Understanding and involvement by the family is enough, agreement goes too far.

Section (d) Standard: Review of plan of care:

- **We strongly urge that "every 14 days" be changed to "*every two weeks*," or "*15 days*." This change would 1) provide the flexibility needed to accommodate holidays and emergencies and 2) synchronize with Hospice's 90/90/60 day cert. periods.** Again, this seems minor, but is critical. In smaller hospices, there is often a team where members are part-time and are only available one day a week or even one day every other week for the several hours needed for Interdisciplinary Team meeting. If this day is Thursday, what happens on Thanksgiving when the members who can get together, do so on Wednesday? Two weeks later when they meet it will be Thursday in order to allow everyone to be there and that will be 15 rather than 14 days.
- **The medical director or physician designee being separated from the rest of the hospice interdisciplinary team at the beginning of the standard would be very destructive to the structure of the team and the very philosophy of hospice. This change would be a step backward for hospice.** The Medical Director is not the team leader nor is he or she viewed as more important than the Home Health Aide, nurse, social worker, or any other member of the team. Do you understand how difficult it has been for hospice to take physicians who are accustomed to being in charge and make them part of a true team? Yet we have done that with the backing of the law and regulations. If you take this away, there will no longer be an interdisciplinary team, but at best a multi-disciplinary team with tumultuous leadership between the Patient Care coordinator and the medical director as well as all other members of the team. The medical director and patient's attending physician are relied on for their medical expertise just as the social worker is relied on for expertise with psychosocial issues or the spiritual coordinator with spiritual issues.

418.58 Condition of Participation: Quality assessment and performance improvement. The hospice industry is in the development stage of identifying and measuring data for improvement. We urge CMS to recognize that full development of a hospice QAPI will occur over an extended period although the preliminary pieces are in place in many hospices. It is hoped that CMS and surveyors will take a mentoring role with hospices as this development occurs.

The increased demands in quality assessment and performance will add significant cost burdens for hospice. This needs to be recognized and addressed in the hospice reimbursement system.

418.62 Condition of Participation: Licensed professional services.

- Section (b) Add the word "*hospice*" after "patient's."
- **Section (c) should be revised to add at the end of the sentence, "with contracted licensed professionals encouraged to participate whenever possible."**

Contracted therapists are often utilized infrequently, particularly in smaller hospices, and it may well prevent access to such therapies if they are required to participate as outlined in this section. Many hospices have experienced difficulty in securing needed contracts for therapies. In smaller hospices, the use of these therapies is infrequent and often the contracting process is seen by the therapist as more trouble than it is worth. A requirement for inservice attendance could push the therapist to refuse to sign a hospice contract. There will be instances where a therapist wants to participate, our physical therapist is a Board member and a patient care and fund-raising volunteer, by these instances are rare. We literally had to beg to get an occupational therapist to sign an agreement and you can be certain that the person we coerced would not have signed if she were required to attend hospice inservices.

418.64 Condition of Participation: Core Services.
PLEASE READ THIS SECTION CAREFULLY. While it is understood that CMS is strongly opposed to contracting for continuous care, it is important that the patient's voice be heard. We strongly recommend that hospices be allowed to contract for continuous care staff on a routine basis. Without this change, patients are being denied access to continuous care. We recognize that CMS does not want this change, but does CMS realize how this is negatively affecting patient care? Continuous care is a key component of hospice allowing many patients to stay at home rather than go to a hospital or nursing home. However, the need for continuous care is sporadic and most often required at night - the time most difficult to staff. Requiring that hospice staff be used routinely for this service makes it virtually impossible, particularly for smaller hospices. Our hospice has gone to great lengths to hire staff that is willing to provide this care, yet we still find that there are many instances where continuous care is urgently needed, but there is no staff to provide this care. How does this happen – we employ 10 part-time/per-diem LPNs and 7 part-time per-diem RNs (one of whom only wishes to do continuous care) still when a continuous care need arises we often find this is at a time when much of the staff is unavailable for a wide variety of reasons – people have busy lives and often have commitments when asked if they can spend the night with a patient while we attempt to adjust medications for symptom control. Our case managers volunteered for continuous care, and some still do, but how can a nurse carry ten patients, work from 7:30 in the morning often until the evening to complete documentation and then pull even another 4 hours let alone 15 hours and be ready to work again the next day? We have specifically targeted staff for this, but they find work elsewhere when there might not be a need for continuous care for a month or longer. Look at continuous care utilization; it is down not because the need does not exist, but because the staff that is needed does not exist. On the other side of this issue, what is happening to these patients? They are going for short-term inpatient care because this is the only alternative. This is more costly than continuous care for CMS so why is it being encouraged over continuous care? Most hospices do not have a dedicated hospice inpatient unit so when the patient goes for inpatient care they are cared for by a nurse employed by the hospital not the hospice, how is this better than hospice contracting through an agency for a nurse to provide continuous care? Do you realize how often most hospitals use traveling nurses who are barely familiar with the hospital let alone hospice? Continuous care should be promoted rather than impeded.

Please picture yourself in the middle of this situation. The patient is an independent woman whose primary wish is to be at home, to die in her own home. The case has been difficult

because the women has no family and lives alone. However, she has remained at home and is living and dying as she wishes. Suddenly, she begins vomiting uncontrollably. Her nurse spends much of the day with her trying one medicine after another, with little success. At noon, she calls into the office to see if there is anyone who could do continuous care that evening and night so that the patient can stay at home while medication continues to be tried. The patient is getting weaker and less able to care for herself from the vomiting, but cries whenever the possibility of a hospital admission is discussed. The team coordinator, LPN scheduler, volunteer coordinator, and director of patient care are all calling frantically to secure continuous care staffing, but everyone is unable to do it that evening with the exception of one nurse who could do three hours in the evening. The patient's nurse volunteers to do at least eight hours although the social worker who has visited reports that the nurse is already exhausted from her constant attention to the patient while juggling her caseload. The nurse stops in the office in the early afternoon, crying with frustration because she knows how much it means for the patient to stay at home. Another nurse who worked 12 hours the day before and has had a particularly busy day offers to do a couple of hours because she feels the distress. However, even with these pieces there is not the 15 hours of coverage that is really needed, so at the end of the day the patient is taken by ambulance to the hospital. Will you fly to our hospice the next time this occurs so you can explain why CMS would rather pay more for an inpatient admission to a hospital which probably has a traveling nurse on the unit for the night shift than allow us to use any one of our contracted licensed home care agencies to provide nursing staff to cover the remaining hours on this case? It feels as if there is some issue that CMS has with continuous care that is not public knowledge because CMS's stance on this seems to have everyone losing – CMS pays more for at best equivalent care; the patient is forced to a setting that he or she may not want and suffers stress, sorrow, loss of control – all the things we try to avoid putting on the patient in hospice; the hospice staff suffers trying to understand why a good care plan decision is being thwarted; if there is a family, the family suffers knowing that they are not complying with the wishes of the patient. Who is winning in this situation? With all the horror that is resulting, what horror is being avoided? Require that hospices show that aggressive recruitment for continuous care has taken place, that hospice staff is always offered the opportunity to provide continuous care hours even if this means overtime is needed, but allow contracted staff when it is the last alternative. This is the only logical course; it is the only ethical course.

Section (b) Standard: Nursing Services

- Definition of nursing services needs to be in the definition section (see comment on p.2 above). In addition, this section should mirror the Medicare Modernization Act.

Section (d) (2) Standard: Nutritional counseling.

- Thank you for including this. We agree.

418.66 Condition of Participation: Nursing services.
It is requested that this section be made consistent with MMA language concerning a nurse practitioner being eligible to serve as a hospice patient's attending physician.

418.72 Condition of Participation: Therapies...
We recommend that dietitians be added to the list of non-core services.

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

Section (c) Standard: Competency evaluation

- We request that *aide* be added after home health
- Requiring that competency evaluation be determined solely by observing the aide's performance providing care to a real patient rather than in a skills laboratory setting is contrary to New York State statute. New York permits state approved home health aide training programs to determine aide competence in either setting currently. Changing the requirement to the more stringent one of observation while the worker is providing care in a patient home may affect the availability of both paraprofessional personnel and the RNs who must supervise and evaluate them.

Section (e) Standard: Qualifications for instructors

- should say *hospice* or home health care.

Section (g) Standard: Home health aide assignments and duties

- **Delete "the appropriate qualified therapist," because it is not consistent with hospice practice, which is to have an RN make assignments. It appears that this language is taken directly from Certified Home Health Care CoP.**

(h) Standard: Supervision of home health aides.

Section (i) Remove "qualified therapist." This is from Home Care CoP and does not apply to hospice practice, which is to have the RN provide supervision.

- **We strongly urge that "every 14 days" be changed to "*every two weeks*," or "*15 days*." This change would 1) provide the flexibility needed to accommodate holidays and emergencies and 2) synchronize with Hospice's 90/90/60 day cert. periods.**

Section (j) Standard: Homemaker qualifications - Recommend use definition of homemaker in NYS statute. New York State has specific requirement for homemakers that are different from home health aides. To require a home health aide be used for homemaker services is inefficient use of very limited resources, which will only worsen with time. It may also impede the appropriate use of homemakers. We frequently use homemakers to supplement home health aide time. The Home Health Aide provides personal care while the homemaker does laundry and cleans the home to provide support for the caregiver or the patient living alone. A Home Health Aide is not needed for the support and given the limited availability of Home Health Aides; it is scandalous to waste this precious resource. Through conversations on the condition of participation, it appears that many hospices do not use homemakers because they are not available in their area or because the hospice focuses on personal care. Our experience is that many families want to care for the patient, but it is hard to balance care of the patient with care of the home. A few hours of homemaker time each week eliminates this conflict when the patient and family desire it. Conversely, when the patient lives alone, a homemaker can delay a patient's need to go into a nursing home since it is often the strain of housekeeping that first becomes impossible for the patient.

Section 418.78 Conditions of Participation: Volunteers.
(e) Standard: Level of Activity:

- We support the content of this section and the opportunity to include administrative volunteer time in the 5% standard. In light of the importance of both administrative and clinical volunteer support to hospice operations, this provision is beneficial. The automatic increase in volunteer time needed as patient census rises could be burdensome for hospices where there is strong competition among entities utilizing volunteers in their operations. We recommend that the 5% formula be applied to the previous year's patient care hours rather than concurrent patient census.

Section 418.100 Condition of Participation: Organization and Administration of Services
Section (a) Standard: Serving the hospice patient and family

- (2) should be amended to state: "...consistent with patient and family needs and *goals wherever possible.*" Clearly, if there are unresolved conflicts between the patient's goals and the family's goals, the patient or patient surrogate will take precedence. While this standard as proposed is well intentioned, it evidences a lack of understanding of the complexity of hospice care. As noted in the comments on Section 418.56 (c) (6), the family often disagrees with the patient or members of the family disagree amongst themselves. Hospice does not wish to cause this disagreement to go unspoken nor to deal care planning while consensus is sought. Rather, hospice wishes to allow the family and patient to openly express feelings, but to base care planning on the patient wishes as family consensus is sought.

Section (e) Standard: Professional management responsibility.

- We request that the word "supervision" of staff in the opening paragraph of this section be changed to "*oversight*". Hospice does not supervise the staff for all arranged services, i.e. the deliveryman for the DME company, but rather provides oversight of the service including the staff. If there were a problem related to the performance of the deliveryman, we would work through the DME provider rather than directly with the deliveryman.
- The wording of Section (e) (2) should be revised to: Furnished in a safe and effective manner *by qualified personnel;*

Section 418.102 Condition of Participation: Medical Director
Section 418.102 first paragraph needs to be amended by adding "*or the hospice*" after "....by the medical director" in the third sentence. Usually the hospice secures a physician to provide coverage for the medical director. Again, there seems to be some focus on the medical director as a part of hospice that is not factual. Does CMS really want the medical director selecting his partner for coverage rather than a hospice-trained physician secured by the hospice? Who is employing this physician, credentialing this physician, assuring that this physician receives needed training?
Section (a) Standard: Initial certification of terminal illness

- The hospice needs to be able to contract with an entity for a physician to serve as a medical director or a coverage physician. More and more physicians are employed by hospitals, health centers, systems, etc. and to restrict this could prohibit availability of a hospice physician.

Section (b) Standard: Recertification of the terminal illness

- Presumably this can be done during IDT with the entire team participating as the comprehensive assessment is updated to determine eligibility for re-certification. This needs to be clearly stated in the interpretive guidelines.

Section (c) Standard: Coordination of medical care

- **This is a critical issue as most hospice medical directors are part-time or even volunteer and clearly not prepared to direct the hospice's quality assessment and performance improvement program. If this is left in place, it will not actually occur in most instances, and it is doubtful that this is what CMS is looking to accomplish. It is STRONGLY recommended that the last sentence of this section be revised as follows: *"The medical director or physician designee is also responsible for participating in the hospice's quality assessment and performance improvement program. The program may be directed by the medical director, physician designee or other qualified professional."***

Section 418.104 Condition of Participation: Clinical Records

Section (a) Standard: Content

- This section includes an informed consent and authorization, but does not include the patient's rights. The election statement basically covers this, with the exception of a HIPAA authorization which is not a general form, but rather a specific form explicitly stating what is authorized to be released to whom and during what timeframe. Thus (a) (2) should be amended to state the election statement, which is required to include a consent to start hospice service as well as the patient rights.

Section (b) Standard: Authentication

- **This section is applicable for a hospital setting, but not for hospice. It is STRONGLY recommended that this section be excluded as neither Nursing Facilities nor Home Health Agencies have such a standard. At a minimum, it must be recognized that hospices have no mechanism to authenticate a signature of a covering physician beyond the initial verbal order taken by a registered nurse.**

Section (d) Standard: Retention of records

- This section should be revised to follow the HIPAA requirement for records retention.

Section (e) Standard: Discharge or transfer of care

- **This section needs to be revised. It is imperative that the requirement for hospice to provide a copy of the clinical record to the patient's attending physician in the case of a revocation or discharge or to the facility in the case of transfer be removed. The discharge summary is a good addition and will provide all the information that most physicians will accept. If CMS feels strongly about this, the most that should be required is that hospice will *offer* the attending physician or, in the case of a transfer, the accepting facility a copy of the complete clinical record *or any parts of the record which the physician or facility feel are needed.* It would be almost impossible to justify that the minimum necessary information in either case would be the entire clinical record, and this is the HIPAA standard. The family is the unit of care for hospice and clearly, the patient's attending physician, who would not be dealing with other family members, may not need the family information. Mandating that the entire clinical record be sent would be unduly burdensome on the hospice—**

both cost wise and staff wise. This mandate is also counter to federal efforts to reduce paperwork in the health care system. Couple this with the fact that receiving physician or facility will not want all of this information and also have expense in maintaining this unnecessary information and the fact that a patient's and potentially family's is being sent needlessly, and this change is critical.

Electronic Record

STHPC has converted to a primarily electronic record. Our patient care staff that work more than half time each has his or her own tablet or laptop computer, while staff working less either use a loaner or come into the office to use a computer. The positive points of the electronic record are:

1. For the first time, the patient care staff really has access to the entire medical record when they need it. Our staff subscribes the patients they are working with and can replicate from home through a secure VPN. This means that the on-call nurse can see all the documentation on that patient admitted on the weekend, the patient's case manager can replicate and see what happened with the patient while on-call. STHPC also has a voice mail report line that is password protected for report, but computers give access to historical as well as current information.
2. It reduces duplication of information.
3. It is easy for staff to look back to see what happened at the last visit and compare status much more readily.
4. While currently STHPC records do not allow for input from all sources – attending physician, etc. Therefore, this part of the record is maintained on paper, in the future an electronic record will allow for greater sharing of information electronically with attending physicians, hospitals, nursing facilities, etc.
5. It is easier for management to access the record. When a manager receives a call about the patient, he or she can immediately access the record at his or her desk from the computer – and quickly go to the specific part of the record that is needed rather than having to go to the record room, find the chart, then search the chart for the needed information.
6. The STHPC record is tied to the staff person's time sheet. This has made the time sheet much more reflective of what the staff member is actually doing and easily records time in and out.
7. The electronic record is going to be easy to modify to comply with these conditions of participation once finalized.
8. It is wonderful to be able to look at the patient's record during IDG meeting – most staff bring their computers to the meetings and there is a base computer in the room connected to a projected so everyone can look at the same thing at the same time.

Of course, not everything about the electronic record is positive. The following are some of the negatives STHPC has experienced:

1. It has been difficult for some of the staff to adjust to using a computer. Remember the age of many of our nurses and the fact that they may never have used a computer before this. Clearly, education is critical and the more individualized and hands-on, the better.
2. Very few staff members are comfortable using the computer in the home.
3. The format of the record as originally designed did not meet our needs and customization of forms continues.

4. It seemed difficult for staff to understand that what they were inputting in the computer was legal documentation just as it was when he or she was handwriting documentation. This was fairly easy to rectify with education, but was unexpected.
5. There are parts of the records that remain on paper – documents signed by the patient, information from the attending physician, history and physical, test results, etc. Hopefully, some of this will be corrected in the future as systems become integrated and the opportunity to accept handwriting – specifically signatures, through the computer screen.
6. The glitches of computers. STHPC has a wireless system, but has found that staff can often lose connection briefly through the wireless system and thus lose documentation so generally staff is hardwired in the office. There has also been the disconnect between the mobile and the production system and staff remembering to replicate before leaving the office or at the beginning and end of the day from home. Of course, there have been hardware glitches. Tablets were the computer of choice when STHPC began this process, but now many staff prefer the laptop because it is more reliable hardware.
7. Setting up a system to assure that records are compliant was a challenge, but workable. It is almost like learning a language fluently – you have to think in the language rather than translate. It is similar with an electronic record – you have to think in electronic record parameters instead of trying to convert a paper record to electronic.

STHPC is committed to the transition to an electronic record and hopes that as the software and hardware advances, the electronic record will be fine-tuned to take full advantage for the benefit of the patient and staff.

Section 418.106 Condition of Participation: Drugs, Controlled Drugs and Biologicals
Section (a) Standard: Administration of drugs and biologicals

- Section (a) (2) requires that hospice determine the ability of the patient and/or family to safely self-administer drugs and biologicals. While this is something that hospices, including STHPC, do regularly, the concern is the intention here and how it might be interpreted. What is the intention if it is determined that the patient is not safe, but generally competent and demanding to manage his or her own medication? This is not institutional care so if the patient or family is unsafe, a prn medication is needed, and the patient refuses to move to a setting where medications can be controlled, what is expected? This cannot be left open-ended like this. A sentence should be added as follows: *If the patient and/or family are determined to be unable to safely administer drugs and biologicals, hospice will be expected to provide reasonable assistance (pre-pouring medications, provision and filling of pill seven day pillbox, etc.) Hospice will not be expected to restrict the provision of medications unless there is a blatant safety issue for non-competent adults or children in the home. If applicable, hospice will encourage the patient to seek a setting where assistance with administration can be provided such as the home of a family member, a family moving into the patient's home, a nursing home, etc.*

Section (b) Standard: Controlled drugs in the patient's home

- **Recommend the following language change: "*The hospice must have written policy for disposing of controlled drugs in the hospice plan of care that are maintained in the patient's home...*" Hospice is not legally able to collect controlled drugs in a patient's home – it is illegal to transport a controlled substance without a prescription and this would typically be done when the patient has died so the prescription is no longer valid. The word "collecting" MUST BE REMOVED. The term tracking is also of concern. Again, this is a home rather than an institutional setting. Hospice can track what medications are put in the home to the extent that medications are only provided at the level ordered by a physician. However, hospice cannot track in the sense that this word is used in hospital and nursing facility regulations where the facility is administering the medications. This should be stated in the standard. Clearly, this can only apply to hospice provided controlled drugs rather than all controlled drugs in the patient's home since a family or patient who is abusing drugs would often hide medication not provided by hospice. What would happen when the family refuses to allow for disposal of the controlled substances?**

Section (c) Standard: Use and maintenance of equipment and supplies

- This section must be revised to state that in the instances where DME is provided through arrangement, the arrangement must specify that the vendor will comply with this standard. If the hospice is not providing the equipment directly, the hospice will not have policies on repair and routine maintenance of equipment, for example.

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

WE STRONGLY URGE REVISION OF THE INTRODUCTION TO THIS SECTION AS FOLLOWS:

"SHORT-TERM GENERAL INPATIENT CARE AND RESPITE CARE ARE PROVIDED BY THE HOSPICE IN A PARTICIPATING MEDICARE OR MEDICAID FACILITY."

The provider standards for general inpatient care and respite care should be listed in sections (a) and (b). As currently worded, caregiver collapse is not included as an eligible service on short-term GIP. There are many instances when psychosocial crises demand a short in-patient stay and this is currently allowed in existing hospice regulations.

(A) STANDARD: INPATIENT CARE FOR SYMPTOM MANAGEMENT, PAIN CONTROL *AND PSYCHOSOCIAL ISSUES*.

IT IS IMPERATIVE THAT PSYCHOSOCIAL ISSUES/CAREGIVER COLLAPSE BE COVERED UNDER GENERAL INPATIENT CARE. Caregiving has become the highest area of concern at STHPC. Over the years, it has changed from the majority of patients having competent caregiving to the majority have no caregiver or compromised caregiving. Even in an ideal situation, if the caregiving system collapses, an inpatient admission is often

needed. Take the example of patient at home, virtually bed-bound, living with her husband who is providing care. There is no other caregiver, but the husband is an excellent caregiver and there is no caregiving problem identified....until the LPN visits the home to find the husband experiencing severe chest pain, calls 911 and the husband is taken to the hospital with an MI. The patient cannot be left home alone, there is no alternative caregiver, and the patient needs prn meds regularly. The patient would also be admitted for hospice inpatient care for caregiver breakdown with immediate discharge planning. If this option were not available, what would happen to this patient? Respite might be a possibility, but often the patient is anxious and needy when this occurs and respite does not quite provide the level of care needed either. It is virtually impossible to get a patient admitted to a nursing home within hours of determined a need, it is almost impossible to get an admission in less than two days. Inpatient care is truly the only viable alternative when the patient has no other caregiving system and cannot safely be left alone.

Paragraph (a) should note that pain control and symptom management would be done on an inpatient basis either because of the specific need for the staff and equipment available there or because of the inability of the hospice and/or the patient's caregivers to assure that the services are properly provided in the home.

We strongly advocate the need for RN presence on a 24-hour basis for the general inpatient level of care. The critical issues encountered with the hospice patient in this setting facing end-stage changes call for the assessment and treatment skills of an RN. RN presence on a 24-hour basis for respite care is not seen as presenting the equivalent need.

It is also recommended that the word "approved" should be replaced with *"certified"* in item (a) (1).

(b) Standard: Inpatient care for respite purposes.
(b) (2) Recommend change "approved" to *"participating"*: "A Medicare/Medicaid *participating* nursing facility that also meets the standards specified in 418.110(b) and (f)."

(c) Standard: Inpatient care provided under arrangements.
Item (c) (1) refers to hospice supplying "the inpatient provider a copy of the patients' plan of care and specifies the inpatient services to be furnished." It is the belief of hospice personnel, based on experience, that the hospital discharge summary would contain sufficient information to ensure the continuity of care. In addition, the volume of paperwork that could be potentially involved would present extreme time and cost pressures on both the hospice and receiving entity. Patient records and information are available, if necessary, beyond the discharge summary.

418.110 Condition of Participation: Hospices that provide inpatient care directly.
Item (a) Standard: Staffing.

- With reference to the statement, that hospice is responsible for ensuring staffing levels reflecting patient volume; hospice is requesting clarification regarding provision of staff. Allowing hospices to provide nurses on appropriate shifts for 24 hr. RN coverage in facilities, including nursing homes, where such coverage may not be mandated

under other regulations, would help meet this requirement. The ability to provide this coverage supplement naturally would be dependent upon availability of the necessary staff.

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

- As noted previously, Hospice strongly recommends retention of the 24-hr. RN requirement for the general inpatient level of care while allowing flexibility in the RN staffing for respite.

Item (c) Standard: Physical environment.

- Reference to reporting of equipment failures (ii) to appropriate State and local bodies. Clarification is requested regarding the definition of "equipment failure" as well as providing some examples. Would this occur within the interpretative guidelines when they are published?

Item (f) Standard: Patient rooms.

- Standards with minimum square footage requirements indicated appear to be appropriate for application to new construction situations.
- It is also recommended that the following be added to the end of (iv): "except during community disasters and/or emergencies."

Item (l) Standard: Meal service and menu planning.

- We concur with the proposed changes. Content that allows increased flexibility in the delivery of meal service to hospice patients is highly desirable. It is important that meal service, when possible, adapt to the needs of the resident with less emphasis on the number of hours between meals.

Item (m) Standard: Pharmaceutical services.

- Section (m) should also be included in 418.106 as an indication that these are requirements for the hospice as a whole, not just on an inpatient basis. (m) should cross-refer to the earlier standard.

Item (n) Pharmacist.

- It is recommended that "*if required by law*" be added to the end of paragraph
- (4) (iii) in this section regarding investigation and reporting requirements.

Item (o) Standard: Restraint and seclusion.

It is imperative that this section be removed. Restraint and seclusion are perceived so differently in hospice that inclusion of this section will irreparably harm the foundations of a program designed for end of life care. The problem here lies in the fundamental differences between hospice and any other part of the health care continuum. Hospice patients are dying and, therefore, often benefit from "seclusion" although we would call it privacy. Hospice patients need aggressive symptom control, which often warrants medication that in another setting would be used for restraint. While the need for this provision in other settings is clearly understood and, while hospice would never want a patient to be restrained or secluded if this were not necessary and the patient's wish, if this section is not removed it will likely result in

avoidance of some of the most precious benefits of hospice care. Patients often choose to remove themselves from their environment as they die; it is almost a transition from this life to whatever lies beyond it. Patients often choose comfort over alertness, particularly as life is ending. Please remember the uniqueness of the hospice benefit and remove this section completely.

While it is imperative to remove this section totally, it is reluctantly recognized that CMS may not agree. In this instance, over our strong protests, this section must be dramatically revised. The following revisions are critical to mitigate the very real negative impact of this standard:

- **The term "seclusion" should be removed from this section. Hospice does not seclude patients; however, most hospice inpatient rooms are private rooms to allow the family 24-hour access and privacy for needed conversations and comfort. This is not done to seclude the patient, but rather to respect the special needs of patients at end of life for privacy and intimate surroundings with family. Inclusion of the term "seclusion" could lead to confusion and, potentially, to removal of the environmental gains that hospices have made in inpatient settings for both privacy and family access.**

- **As noted in the previous section "Definitions" Hospice has great concern over the potential impact on end-of-life care when use of a medication to control some symptoms such as terminal agitation or restlessness, is perceived as imposition of a chemical restraint. The hospice concern, whatever the setting within which care is being given, is that the use of the most appropriate method of ensuring palliative care is made available.**

- **Whether the care setting is the patient's home, a nursing home or an inpatient setting the goal is control of the anxiety, restlessness, pain or other symptom negatively affecting quality of life in the last stage. Forced perception of certain drug use, such as Haldol, as a restraint by others including nursing homes will restrict the ability of Hospice to meet those specialized end-of-life needs. Utilization of a standard for chemical restraints utilized in nursing homes does not always correspond with standards commonly accepted by Hospice medical staff regarding utilization of some medications. The proven, specialized expertise and experience of hospice medical staff must be given consideration as standards of medication use are applied to the restraint issue.**

- Suggested change for inclusion in (o) (1) is the addition after"...normal access to ones' body" is "Bed rails are not included in this definition of restraint if used for the safety of the patient or to assist the patient in independent functioning." The concept of the side rail as an "enabler" is of value here.

- Item (o) (3) (d) refers to time limitations for restraints. Suggested language proposes the following schedule:
    - "change the hours to 8-hour intervals over a 24-hour period for adults, while sleeping, and 4-hour intervals while awake; 6-hour intervals while

sleeping for 9-17 year olds, 2 hours intervals over 24-hours while awake; 2-hour intervals while sleeping for under age 9 and 1-hour while awake."

- **Item (o) (7). Request that the word "unpredicted" be added before "death" in that sentence referring to reporting of any death that occurs while the patient is restrained.**

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

Clarify what is meant by "other facility," and define "nursing facility." Also clarify that this section should specifically apply only to Medicare and Medicaid participating facilities. This condition cannot successfully be implemented until there is in the SNF/NF requirements a parallel condition that confirms their requirements. We recommend that the effective date of this section be delayed until the companion section is enacted or that it be at least incorporated by reference into the SNF/NF requirements. We understand that the nursing home COPs will add a section on nursing homes and hospice care. Does this condition match the requirements that will be proposed for nursing homes?

It is also requested that CMS work with surveyors on this issue and that hospices be allowed some leniency until the nursing facility regulations are complete.

Can this Condition be phased in?

(b) Standard: Professional management.

Recommend that "hospice" be inserted after "inpatient" in this standard: "...make any arrangements necessary for *hospice* inpatient care in a participating Medicare/Medicaid facility according to 418.100."

In a number of cases, Hospice relationships with nursing homes can be described as tenuous. Concern on the part of nursing home staff, which is also held responsible for care of their resident, is sometimes related to the held perception that the nursing facility loses total control of the resident care plan. It is essential to emphasize a collaborative relationship is the goal, not domination of the care plan. Certainly, Hospice must bear responsibility for the coverage it approves and the services it offers, but the expertise of hospice in provision of specialized end-of-life care is not always made available due to perception of regulations. It is not unheard of to hear nursing facility personnel say they do not want hospice to come in because they lose control of their care plan process. Again, the importance of stressing the relative responsibility of both parties but of a collaborative and integrative nature will enhance opportunities for meeting the varied and complex needs of the terminal patient.

(d) Standard: Medical Director

We request that this standard be re-titled: Interdisciplinary Group and that the text be revised as follows: The Hospice Interdisciplinary Group must provide overall coordination of the care of the hospice resident that resides in an SNF, NF, or other facility. Members of the interdisciplinary group will regularly

communicate and coordinate care with SNF/NF staff to ensure quality care for the patient and family. The hospice Medical Director or physician designee will communicate with the Medical Director of the SNF/NF, the patient's attending physician, and other physicians participating in the provision of care for the terminal and related conditions as necessary.

We are concerned that the requirements of this standard could be a real impediment to hospice-nursing facility collaboration. As written, it may cause unnecessary strain in the relationship between the hospice and the facility. Communication issues arise on many levels. What appears to be a focus on medical director/physician communication leaves the remainder of the IDT team, which has the consistent and integrated relationship with the facility, out of the loop. Certainly, physician-to-physician communication is an extremely important element in the care of the patient but experience has shown that good internal communication between hospice medical director/physician designee through the IDT team works well for most interactions in the nursing home. In cases where conflict between IDT members and facility staff, including the physician occur, the hospice medical director is brought in to facilitate resolution. In addition, the relative complexity of certain patient situations may mandate closer physician-to-physician communication but this should remain as a decision the IDT members make, as patient needs change. Contact with the facility should remain with the designee of the IDT, either the MD or a nurse.

Logistical issues are of concern also on both sides of this communication issue. As written, the content of (d) does not indicate parameters for contact between physicians.

From the hospice side, especially for those organizations with volunteer or part-time medical directors, the rather broad expectation of communication could be a detriment and place a significant burden on the hospice physician.

Hospice communication with "*the facility medical director, the patient's attending physician and other physicians participating in the provision of care*" also presents challenges. In some instances, the nursing home medical director does not carry a patient load and may be totally unfamiliar with the needs of that person. Here again, consistent focus on a case-by-case judgment regarding involvement of the facility medical director would be desirable. In addition, the non-specific mandate of physician to physician communication presents potential time and cost issues when consideration is given to the, at times, relatively large number of attending physicians in some nursing homes as well as the difficulty that may be encountered by the hospice physician in trying to reach them on a regular basis.

If this section remains unchanged or only minimally changed, it must be recognized that it will result in a dramatic increase in cost for Medical Director/physician designee services for the hospice with little to no foreseeable benefit. This will necessitate revision of the hospice Medicare reimbursement methodology to assure that these additional costs are fairly reimbursed.

(e) Standard: Written agreement

- (1): "written consent" should be changed to "*election* statement." This paragraph should be deleted from 418.112 (e) and moved to the appropriate section in reference to the patient record standard.
- (4) (iii). Clarification is requested regarding definition of a life threatening condition other than the patient's hospice terminal diagnosis.
- (e) (6): States vary in what they consider included in the room and board rate and what their responsibility is in the provision of room and board. How does this impact this Standard? Will the room and board definition in the State Operation Manual be changing in relation to the hospice regulations?

(f) Standard: Hospice plan of care

- (3): Recommend that the 14-day requirement for care plan review be changed to *two weeks or 15 days* to be in line with the current 90/90/60 day certification periods.
- (f) (4) Recommend the following language change: "Any changes in the plan of care must be discussed *by representatives of hospice and representatives of the nursing facility* and must be approved by the hospice before implementation." Once again, expected collaboration must be the goal as IDT designated representative(s) and facility staff responsible for the supervision of care in the nursing home should both be aware of hospice care plan changes.

(g) Standard: Coordination of services.

- Comment: Is there a likelihood that nursing facility regulations will state that facilities can accept orders from the hospice physician? Any such outcome must consider the need to stress collaboration and not diminish the role of the attending physician who also bears a responsibility for the care of the patient in a facility. In addition, facility staff are trained and oriented to work closely with their attending physicians. Interjecting a more direct order relationship between hospice and facilities without attending input may be difficult for the facility staff.
- (6) Physician orders. Our assumption is that this refers to "hospice" physician orders.

(h) Standard: Transfer, revocation or discharge from hospice care.

- We recommend that "does not directly impact" be changed to *"may not affect"*: "Discharge from or revocation of hospice care *may not affect* the eligibility to continue to reside in a SNF, NF, ICF/MR, or other facility."

A concern here is, while discharge from hospice does not always mean discharge from a facility, this may be an issue in some cases and patients should not experience the trauma of an external move because they have perhaps stabilized for the moment and may not be eligible for hospice.

- Please provide some clarification of this standard including how compliance would be audited.

(i) Standard: Orientation and training of staff.

- Recommend revision to read: "Hospice must *assure orientation* of facility staff..." As written, facilities that have contracts with multiple hospices could be inundated with

hospice in-services. It would be preferable if hospices were expected to meet with facilities, offer appropriate in-services (and document the attempt) and make every effort to ensure this education is made available.

One must also consider the needs and resources of the contracted facilities. Focus for in-service should be on those elements most important to the coordinated provision of care for the terminally ill patient.

418.114. Condition of participation: Personnel qualifications for licensed professionals.

(c) Personnel qualifications, (7) Social Worker

- The use of State licensure as a standard for social workers is of concern to many hospices. End-of-life patient and family needs present an extremely intense and demanding set of variables and require skills and training that are often more than a non-Masters prepared Social Worker will possess. Every effort should be made by hospice to employ this level of professional worker and regulatory support for such a course is important.

(d) Standard: Criminal background check

- This requirement would place a great financial burden on hospices. The hospice reimbursement rate must be adjusted to accommodate this significant new expense.

There are many suggestions and comments that need to be made relative to the interpretive guidelines, which will follow the CoPs once finalized. This will be handled under separate cover at a later date as it will not be necessary to consider as CMS reviews the CoPs.

If you have any questions or need further clarification on any issue, please feel free to contact me at any time. STHPC wishes you well as you review all of the comments you receive and finalize the Conditions of Participation for Hospice.

Cordially,

Mary Ann Starbuck
Executive Director

July 25, 2005

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 or Madam:

Thank you for this opportunity to comment on the Medicare and Medicaid programs: Hospice Conditions of Participation: Proposed Rule published on May 27, 2005 in the Federal Register. **Our comments in Bold are the most critical to us.**

Section 418.3 Definitions
We request the following changes in this section:
Section (a) Standard: Notice of Rights
(a) (3) Attending physician – add: (3) The hospice medical director, hospice physician or nurse practitioner may also act as the patient's attending physician.

- Clinical note – add spiritual, to read "Clinical note means a notation of a contact with the patient that is written and dated by any person providing treatments and medications administered, including the patient's reaction and/or response, and any changes in physical, emotional or spiritual condition.
- Add definition of Counseling Services: Counseling Services means services that assist the patient/family to minimize the stress and problems that arise from the terminal illness or from the dying process.
- Add definition of Dietitian: Dietitian – a person who is registered by the Commission of Dietetics Registration or the American Dietetic Association.
- Drug restraint should be amended as follows: means a medication used to control behavior or to restrict the patient's freedom of movement, **which is not a standard hospice treatment or not requested by the patient or the patient's surrogate.**

This is a critical concern. Hospice commonly uses psychoactive medications for therapeutic use; e.g. Haldol which is used to control symptoms. In other settings, Haldol is considered a drug restraint. Further, patients on hospice may request or need terminal sedation – yet such medication in another setting would be considered a drug restraint. The issue here is patient's rights. Our concern is that in trying to protect patient's rights, <u>this will actually restrict a hospice patient's right to control of anxiety, terminal restlessness, pain, etc.</u> Unlike a nursing home, hospital, or other institutional setting, hospice provides most care in the patient's home where there would be no benefit to hospice staff to have the patient restrained.

- Licensed Professional – amend to include dietary therapy after occupational therapy.
- Add definition for Nursing Services: Nursing Services mean care provided by a licensed nurse or under the supervision of a licensed nurse as allowed by law.

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• Palliative Care – add interdisciplinary group to the definition: Palliative care means patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care uses an interdisciplinary group to address physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice.
• Add definition for patient's residence: Patient's residence means where the patient lives.
• Representative should be amended to add "or common law within the State" after "...courts of the State..."

Section 418.52 Condition of Participation: Patient's Rights

Section (a) Standard: Notice of Rights

• Section (a) (3) This is the first section where "tracking" of drugs is mentioned. It will be virtually impossible for hospice to "track" drugs as is understood for other more institutional healthcare providers. This will be discussed further under Section 418.106.
• Section (a) (3) needs to be reworded to reflect the CMS understanding of what is meant by "inform the patient". We would suggest revising this section to read, "The hospice must inform the patient and family of the hospice's drug policies and procedures regarding management and disposal of controlled substances during the comprehensive assessment." During discussion with CMS, this was restated to mean including in the admission packet or booklet, which is reviewed during admission and then left with the patient and family to review and refer to as hospice care progresses. The hospice admission process is already lengthy and often difficult for the dying patient and his or her family. Just as with hospital discharge, hospice admission is a barrage of information that is often barely remembered so it is more important that the information is available and reviewed with the patient when pertinent.
• (a) (1) (v.)The right of the patient to be involved in his or her plan of care should be added.
• (a) (1) (vi.)The right of the patient to refuse treatment should be added.

Section (b) Exercise of Rights and Respect for Property or Person

• (b) (3) should be amended to include "and practice" after "...by State law." at the end of the sentence.
• Section (b) (4) should be revised to be consistent with Home Health Agency Conditions of Participation by stating: "The hospice must investigate complaints made by a patient or the patient's family or guardian regarding treatment or care that is (or fails to be) furnished, or regarding the lack of respect for the patient's property by anyone furnishing services on behalf of the hospice, and must document both the existence of the complaint and the resolution of the complaint."

Section (e) Patient Liability

• **We recommend that this standard be amended to read, "Before care is initiated, the patient must be informed, verbally and in writing, and in a language that he or she can understand, if payment may be expected from the patient as well as hospice's intention to bill Medicare or Medicaid, thirdparty payers, or other resources of funding known to the hospice..." While we agree that the patient and family should be informed of personal liability before services are provided, it is virtually unworkable for evening and weekend admissions because the staff will not be able to verify insurance coverage. This is typically not a problem for Medicare or Medicaid (other than nursing home room and board – particularly for new nursing home admission), but will be a critical issue for other insurers. Is it CMS's intention that admission desired by the patient and family should be delayed due to inability to determine insurance coverage? If the patient chooses to elect hospice before insurance coverage can be confirmed, is it acceptable if the patient and family is informed that coverage has not been determined and, therefore, the patient may be personally responsible for the cost of hospice services?**

Section 418.54 Condition of Participation: Comprehensive Assessment

• In opening paragraph, change "care" to "assessment" in the last sentence so that hospice can include items not related to the terminal illness that the hospice might still wish to assess. For example, a hospice patient admitted for Cancer of the Pancreas may also have Chronic Obstructive Pulmonary Disease (COPD). While the COPD would need to be assessed and the medications taken for the COPD would be important to note as decisions are made concerning medication for pain management, etc., the COPD is unrelated to the terminal diagnosis and is not part of the plan of care for the terminal diagnosis.

Section (a) Standard: Initial Assessment:

• There is no such thing as a physician's admission order for care in Hospice. We believe this language was taken from home care CoPs. We strongly recommend that this be changed to Physician's certification to be consistent with Hospice statute. Inclusion of "physician's admission order for care" would add another administrative layer to the admissions process, and thus, would limit access to the hospice benefit. • We recommend the following language be added to the initial assessment: "...unless otherwise ordered by the physician or requested by the patient or family..."

Section (b) Standard: Timeframe for completion of the comprehensive assessment

• 7 days is requested for the completion of the comprehensive assessment.

We feel strongly that 4 calendar days could be intrusive upon the patient and family. For example, a debilitated, very private individual is admitted to hospice. The admission nurse does the initial assessment, an LPN begins routine, daily care on the day following admission and the case manager RN also visits. The patient and family wonders if the Social Worker visit might be delayed until the following week as an additional LPN will be covering the weekend and they really are struggling with so many new people coming into their home. The admission nurse has not identified any urgent psychosocial needs and the case manager RN concurs. If the comprehensive assessment must be completed within 4 days clearly, the Social Worker would need to visit within the next two days, but with 7 days the visit could wait a few more days. This is really a common occurrence. A hospice admission is very involved and the nurse and HHA or LPN usually begin the day after admission. It is not hard to imagine how a family can feel overwhelmed by the new people coming into their home and all the questions that need to be asked and answered – thoughtful questions and answers that can be emotional and draining. If a true, interdisciplinary, comprehensive assessment is desired, 7 days would be much kinder for the patient and family.

• Recommend language to read "...attending physician, if he/she is willing to participate..." It is current practice to invite the attending physician to participate in IDG. This practice works well and does not require change.

Section (c) Standard: Content of the comprehensive assessment,

(3) Factors to be considered...(ii). Drug Therapy

• It needs to be recognized that hospice is dependent upon the patient/family/physican regarding the use of drugs other than for the terminal illness. At a minimum it is imperative that the interpretive guidelines clearly state that hospice cannot be held responsible for being aware of drugs that hospice is not informed of by the patient, family, physician or other health care provider.

Section (d) Standard: Update of the comprehensive assessment.

• We strongly urge that "every 14 days" be changed to "every two weeks," or "15 days." This change would 1) provide the flexibility needed to accommodate holidays and emergencies and 2) synchronize with Hospice's 90/90/60 day cert. periods.

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

Section (a) Standard: Approach to Service Delivery

• **(1) (i)This should be changed to "the hospice Medical Director or physician**
Section(c)Standard: Content of the Plan of Care:
• **Suggest replace "problem" with "desired outcomes" to be consistent with designee" to be consistent with other section of the Conditions of Participation. This change will also eliminate a potential problem when the Medical Director or hospice physician is a patient's attending physician.**

• **(2) This should be removed or changed to read, "If a hospice has more than one interdisciplinary group, there will be consistency across teams and an** inclusive process for developing policies that represent all disciplines and teams, with final authority resting with the governing body and senior management." It is clearly the role of the governing body to establish policy for an organization so the existing language is not only contrary to common practice, but also to corporate law.

Section(c)Standard: Content of the Plan of Care:
• Suggest replace "problem" with "desired outcomes" to be consistent with philosophy of new proposed COPs.

• **(c) (6) Re. family agreement....We strongly recommend "agreement "be deleted.** Often there is disagreement within the family about care. It is not uncommon for one or more members of the family to be opposed to hospice care for the patient rather than curative treatment. Hospice will also seek to bring all participating members of the family into the plan of care through consensus, but clearly, there will be instances when this is not possible. Further, at times, a patient and/or family member is encouraged to accept a plan of care that is safer than the plan they wish. How often does one member of the family, clearly disagree with the patient receiving immediate release morphine for comfort – pain relief, suppression of rapid respiration, etc.? Does CMS really want hospice to delay such needed comfort measures while family agreement is sought? What if agreement is never reached? Clearly, a competent patient can refuse a treatment, but should one of five daughters objections mean that the patient suffers?

Section (d) Standard: Review of plan of care:
• **We strongly urge that "every 14 days" be changed to "every two weeks," or "15 days." This change would 1) provide the flexibility needed to accommodate holidays and emergencies and 2) synchronize with Hospice's 90/90/60 day cert. periods.** Again, this seems minor, but is critical. In smaller hospices, there is often a team where members are part-time and are only available one day a week or even one day every other week for the several hours needed for Interdisciplinary Team meeting. If this day is Thursday, what happens on Thanksgiving when the members who can get together, do so on Wednesday? Two weeks later when they meet it will be Thursday in order to allow everyone to be there and that will be 15 rather than 14 days.

• **The medical director or physician designee being separated from the rest of the hospice interdisciplinary team at the beginning of the standard would be very destructive to the structure of the team and the very philosophy of hospice. This change would be a step backward for hospice.**

The Medical Director is not the team leader nor is he or she viewed as more important than the Home Health Aide, nurse, social worker. Do you understand how difficult it has been for hospice to take physicians who are accustomed to being in charge and make them part of a true team? Yet we have done that with the backing of the law and regulations. If you take this away, there will no longer be an interdisciplinary team, but at best a multi-disciplinary team with tumultuous leadership between the Patient Care coordinator and the medical director as well as all other members of the team.

418.58 Condition of Participation: Quality assessment and performance improvement.
The hospice industry is in the development stage of identifying and measuring data for improvement. We urge CMS to recognize that full development of a hospice QAPI will occur over an extended period of time although the preliminary pieces are in place in many hospices.

The increased demands in quality assessment and performance will add significant cost burdens for hospice. This needs to be recognized and addressed in the hospice reimbursement system.

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

Section (c) Standard: Competency evaluation
- We request that aide be added after home health

Section (e) Standard: Qualifications for instructors
- should say hospice or home health care.

Section(g) Standard: Home health aide assignments and duties
- Delete "the appropriate qualified therapist," because it is not consistent with hospice practice. It appears that this language is taken directly from Certified Home Health Care CoP.

(h) Standard: Supervision of home health aides.

- (i) Remove "qualified therapist." This is from Home Care CoP and does not apply to hospice practice.
- **We strongly urge that "every 14 days" be changed to "every two weeks," or "15 days." This change would 1) provide the flexibility needed to accommodate holidays and emergencies and 2) synchronize with Hospice's 90/90/60 day cert. periods.**

Section (j) Standard: Homemaker qualifications - Recommend use definition of homemaker in NYS statute. New York State has specific requirement for homemakers that are different from home health aides. To require a home health aide be used for homemaker services is inefficient use of very limited resources, which will only worsen with time.

Section 418.102 Condition of Participation: Medical Director
- Section 418.102 first paragraph needs to be amended by adding "or the hospice" after "....by the medical director" in the third sentence. Usually the hospice secures a physician to provide coverage for the medical director. Again, there seems to be some focus on the medical director as a part of hospice that is not factual. Does CMS really want the medical director selecting his partner for coverage rather than a hospice-trained physician secured by the hospice?

Section (a) Standard: Initial certification of terminal illness
- The hospice needs to be able to contract with an entity for a physician to serve as a medical director or a coverage physician. More and more physicians are employed by hospitals, health centers, systems, etc. and to restrict this could prohibit availability of a hospice physician.

Section (b) Standard: Recertification of the terminal illness
- presumably this can be done during IDT with the entire team participating as the comprehensive assessment is updated to determine eligibility for re-certification. This needs to be clearly stated in the interpretive guidelines.

Section (c) Standard: Coordination of medical care
- **This is a critical issue as most hospice medical directors are part-time or even volunteer and clearly not prepared to direct the hospice's quality assessment and performance**

improvement program. If this is left in place, it will be a sham in most instances and it is doubtful that this is what CMS is looking to accomplish. It is STRONGLY recommended that the last sentence of this section be revised as follows: "The medical director or physician designee is also responsible for participating in the hospice's quality assessment and performance improvement program. The program may be directed by the medical director, physician designee or other qualified professional."

Section 418.104 Condition of Participation: Clinical Records

Section (a) Standard: Content

• This section includes an informed consent and authorization, but does not include the patient's rights. The election statement basically covers this, with the exception of a HIPAA authorization which is not a general form, but rather a specific form explicitly stating what is authorized to be released to whom and during what timeframe. Thus (a) (2) should be amended to state the election statement, which is required to include a consent to start hospice service as well as the patient rights.

Section (b) Standard: Authentication

• **This section is applicable for a hospital setting, but not for hospice. It is STRONGLY recommended that this section be excluded as neither Nursing Facilities nor Home Health Agencies have such a standard. At a minimum, it must be recognized that hospices have no mechanism to authenticate a signature of a covering physician beyond the initial verbal order taken by a registered nurse.**

Section (d) Standard: Retention of records

• This section should be revised to follow the HIPAA requirement for records retention.

Section (e) Standard: Discharge or transfer of care

• **This section needs to be revised. It is imperative that the requirement for hospice to provide a copy of the clinical record to the patient's attending physician in the case of a revocation or discharge be removed. The discharge summary is a good addition and will provide all the information that most physicians will accept. If CMS feels strongly about this, the most that should be required is that hospice will <u>offer</u> the attending physician or, in the case of a transfer, the accepting facility a copy of the complete clinical record <u>or any parts of the record which the physician or facility feel are needed.</u> It would be almost impossible to justify that the minimum necessary information in either case would be the entire clinical record and this is the HIPAA standard. The family is the unit of care for hospice and clearly the patient's attending physician who would not be dealing with other family members may not need the family information.**

Section 418.106 Condition of Participation: Drugs, Controlled Drugs and Biologicals

Section (a) Standard: Administration of drugs and biologicals

• Section (a) (2) requires that hospice determine the ability of the patient and/or family to safely self-administer drugs and biologicals. What is the intention if it is determined that the patient is not safe, but generally competent and demanding to manage his or her own medication? This is not institutional care so if the patient or family is unsafe, a prn medication is needed, and the patient refuses to move to a setting where medications can be controlled, what is expected? This cannot be left open-ended like this. A sentence should be added as follows: If the patient and/or family are determined to be unable to safely administer drugs and biologicals, the patient and family will be encouraged to relocate the patient to a setting where administration assistance can be routinely offered. However, it is recognized that the patient, if competent, and the patient's surrogate if the patient is not competent, can refuse to relocate. Given patient rights and the home

setting, hospice will be expected to provide reasonable assistance (prepouring medications, provision and filling of pill seven day pillbox, etc.) Hospice will not be expected to restrict the provision of medications unless there is a blatant safety issue for non-competent adults or children in the home.

Section (b) Standard: Controlled drugs in the patient's home

- **Recommend the following language change: "The hospice must have written policy for disposing of controlled drugs in the hospice plan of care that are maintained in the patient's home..." Hospice is not legally able to collect controlled drugs in a patient's home – it is illegal to transport a controlled substance without a prescription and this would typically be done when the patient has died so the prescription is no longer valid. The word "collecting" MUST BE REMOVED. The term tracking is also of concern. Again, this is a home rather than an institutional setting. Hospice can track what medications are put in the home to the extent that medications are only provided at the level ordered by a physician. However, hospice cannot track in the sense that this word is used in hospital and nursing facility regulations where the facility is administering the medications. This should be stated in the standard. Clearly, this can only apply to hospice provided controlled drugs rather than all controlled drugs in the patient's home since a family or patient who is abusing drugs would often hide medication not provided by hospice. What would happen when the family refuses to allow for disposal of the controlled substances?**

Section (c) Standard: Use and maintenance of equipment and supplies

- This section must be revised to state that in the instances where DME is provided through arrangement, the arrangement must specify that the vendor will comply with this standard.

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

We strongly urge revision of the introduction to this section as follows:

"Short-term General Inpatient Care and Respite Care are provided by the hospice in a participating Medicare or Medicaid facility."

The provider standards for general inpatient care and respite care should be listed in sections (a) and (b). As currently worded, caregiver collapse is not included as an eligible service on short-term GIP. There are many instances when psycho-social crises demand a short in-patient stay and this is currently allowed in existing hospice regulations.

(a) Standard: Inpatient care for symptom management, pain control <u>and psychosocial issues.</u>

It is imperative that psycho-social issues/caregiver collapse be covered under general inpatient care. Paragraph (a) should note that pain control and symptom management would be done on an inpatient basis either because of the specific need for the staff and equipment available there or because of the inability of the hospice and/or the patient's caregivers to assure that the services are properly provided in the home.

We strongly advocate the need for RN presence on a 24-hour basis for the <u>general inpatient level of care</u>. The critical issues encountered with the hospice patient in this setting facing end-stage changes call for the assessment and treatment skills of an RN. RN presence on a 24-hour basis for respite care is not seen as presenting the equivalent need.

It is also recommended that the word "approved" should be replaced with <u>"certified"</u> in item (a) (1).

(b) Standard: Inpatient care for respite purposes.

(b) (2) Recommend change "approved" to "participating": "A Medicare/Medicaid participating nursing facility that also meets the standards specified in 418.110(b) and (f)."

(c) Standard: Inpatient care provided under arrangements.
Item (c) (1) refers to hospice supplying "the inpatient provider a copy of the patients' plan of care and specifies the inpatient services to be furnished." It is the belief of hospice personnel, based on experience, that the hospital discharge summary would contain sufficient information to ensure the continuity of care. In addition, the volume of paperwork that could be potentially involved would present extreme time and cost pressures on both the hospice and receiving entity. Patient records and information are available, if necessary, beyond the discharge summary.

418.110 Condition of Participation: Hospices that provide inpatient care directly.
Item (a) Standard: Staffing.

- With reference to the statement, that hospice is responsible for ensuring staffing levels reflecting patient volume; hospice is requesting clarification regarding provision of staff. Allowing hospices to provide nurses on appropriate shifts for 24 hr. RN coverage in facilities, including nursing homes, where such coverage may not be mandated under other regulations, would help meet this requirement. The ability to provide this coverage supplement would, naturally, be dependent upon availability of the necessary staff.

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

- As noted previously, Hospice strongly recommends retention of the 24-hr. RN requirement for the general inpatient level of care while allowing flexibility in the RN staffing for respite.

Item (c) Standard: Physical environment.

- Reference to reporting of equipment failures (ii) to appropriate State and local bodies. Clarification is requested regarding the definition of "equipment failure" as well as providing some examples. Would this occur within the interpretative guidelines when they are published?

Item (f) Standard: Patient rooms.

- Standards with minimum square footage requirements indicated appear to be appropriate for application to new construction situations.
- It is also recommended that the following be added to the end of (iv): "except during community disasters and/or emergencies."

Item (l) Standard: Meal service and menu planning.

- We concur with the proposed changes. Content that allows increased flexibility in the delivery of meal service to hospice patients is highly desirable. It is important that meal service, when possible, adapt to the needs of the resident with less emphasis on the number of hours between meals.

Item (m) Standard: Pharmaceutical services.

- Section (m) should also be included in 418.106 as an indication that these are requirements for the hospice as a whole, not just on an inpatient basis. (m) should cross-refer to the earlier standard.

Item (n) Pharmacist.

- It is recommended that "if required by law" be added to the end of paragraph
- (4) (iii) in this section regarding investigation and reporting requirements.

Item (o) Standard: Restraint and seclusion.
It is imperative that this section be removed. Restraint and seclusion are perceived so differently in hospice that inclusion of this section will irreparably harm the foundations of a program designed for end of life care. The problem here lies in the fundamental differences between hospice and any

other part of the health care continuum. Hospice patients are dying and, therefore, often benefit from "seclusion" although we would call it privacy. Hospice patients need aggressive symptom control which often warrants medication that in another setting would be used for restraint. While the need for this provision in other settings is clearly understood and, while hospice would never want a patient to be restrained or secluded if this were not necessary and the patient's wish, if this section is not removed it will likely result in avoidance of some of the most precious benefits of hospice care. Patients often choose to remove themselves from their environment as they die; it is almost a transition from this life to whatever lies beyond it. Patients often choose comfort over alertness, particularly as life is ending. Please remember the uniqueness of the hospice benefit and remove this section completely.

While it is imperative to remove this section totally, it is reluctantly recognized that CMS may not agree. In this instance, over our strong protests, this section must be dramatically revised. The following revisions are critical to mitigate the very real negative impact of this standard:

- **The term "seclusion" should be removed from this section. Hospice does not seclude patients, however, most hospice inpatient rooms are private rooms to allow the family 24 hour access and privacy for needed conversations and comfort. This is not done to seclude the patient, but rather to respect the special needs of patients at end of life for privacy and intimate surroundings with family. Inclusion of the term "seclusion" could lead to confusion and, potentially, to removal of the environmental gains that hospices have made in inpatient settings for both privacy and family access.**

- **As noted in the previous section "Definitions" Hospice has great concern over the potential impact on end-of-life care when use of a medication to control some symptoms such as terminal agitation or restlessness, is perceived as imposition of a chemical restraint. The hospice concern, whatever the setting within which care is being given, is with the use of the most appropriate method of ensuring palliative care is made available.**

- **Whether the care setting is the patient's home, a nursing home or an inpatient setting the goal is control of the anxiety, restlessness, pain or other symptom negatively impacting quality of life in the last stage. Forced perception of certain drug use, such as Haldol, as a restraint by others including nursing homes will restrict the ability of Hospice to meet those specialized end-of-life needs. Utilization of a standard for chemical restraints utilized in nursing homes does not always correspond with standards commonly accepted by Hospice medical staff regarding utilization of some medications. The proven, specialized expertise and experience of hospice medical staff must be given consideration as standards of medication use are applied to the restraint issue.**

- Suggested change for inclusion in (o) (1) is the addition after "...normal access to ones' body" is "Bed rails are not included in this definition of restraint if used for the safety of the patient or to assist the patient in independent functioning." The concept of the side rail as an "enabler" is of value here.

- Item (o) (3) (d) refers to time limitations for restraints. Suggested language proposes the following schedule:
  - "change the hours to 8-hour intervals over a 24-hour period for adults, while sleeping, and 4-hour intervals while awake; 6-hour intervals while sleeping for 9-17 year olds, 2 hours intervals over 24-hours while awake; 2-hour intervals while sleeping for under age 9 and 1-hour while awake."

- **Item (o) (7). Request that the word "unpredicted" be added before "death" in that sentence referring to reporting of any death that occurs while the patient is restrained.**

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

Clarify what is meant by "other facility," and define "nursing facility." Also clarify that this section should specifically apply only to Medicare and Medicaid participating facilities. This condition cannot successfully be implemented until there is in the SNF/NF requirements a parallel condition that confirms their requirements. We recommend that the effective date of this section be delayed until the companion section is enacted or that it be at least incorporated by reference into the SNF/NF requirements. We understand that the nursing home COPs will add a section on nursing homes and hospice care. Does this condition match the requirements that will be proposed for nursing homes?

It is also requested that CMS work with surveyors on this issue and that hospices be allowed some leniency until the nursing facility regulations are complete.

Can this Condition be phased in?

(b) Standard: Professional management.

Recommend that "hospice" be inserted after "inpatient" in this standard: "...make any arrangements necessary for hospice inpatient care in a participating Medicare/Medicaid facility according to 418.100."

In a number of cases, Hospice relationships with nursing homes can be described as tenuous. Concern on the part of nursing home staff, which is also held responsible for care of their resident, is sometimes related to the held perception that the nursing facility loses total control of the resident care plan. It is essential to emphasize a collaborative relationship is the goal, not domination of the care plan. Certainly, Hospice must bear responsibility for the coverage it approves and the services it offers, but the expertise of hospice in provision of specialized end-of-life care is not always made available due to perception of regulations. It is not unheard of to hear nursing facility personnel say they do not want hospice to come in because they lose control of their care plan process.

Again, the importance of stressing the relative responsibility of both parties but of a collaborative and integrative nature will enhance opportunities for meeting the varied and complex needs of the terminal patient.

(d) Standard: Medical Director

We request that this standard be re-titled: Interdisciplinary Group and that the text be revised as follows: The Hospice Interdisciplinary Group must provide overall coordination of the care of the hospice resident that resides in an SNF, NF, or other facility. Members of the interdisciplinary group will regularly communicate and coordinate care with SNF/NF staff to ensure quality care for the patient and family. The hospice Medical Director or physician designee will communicate with the Medical Director of the SNF/NF, the patient's attending physician, and other physicians participating in the provision of care for the terminal and related conditions as necessary.

We are concerned that the requirements of this standard could be a real impediment to hospice-nursing facility collaboration. As written, it may cause unnecessary strain in the relationship between the hospice and the facility. Communication issues arise on many levels. What appears to be a focus on medical director/physician communication leaves the remainder of the IDT team, which has the consistent and integrated relationship with the facility, out of the loop. Certainly, physician-to-physician communication is an extremely important element in the care of the patient but experience has shown that good internal communication between hospice medical director/physician designee through the IDT team works well for most interactions in the nursing home. In cases where conflict between IDT members and facility staff, including the physician occur, the hospice medical director is brought in to facilitate resolution. In addition, the relative complexity of certain patient situations may mandate closer physician-to -physician communication but this should remain as a decision the IDT members make, as patient needs

change. Contact with the facility should remain with the designee of the IDT, either the MD or a nurse.

Logistical issues are of concern also on both sides of this communication issue.
As written, the content of (d) does not indicate parameters for contact between physicians.

From the hospice side, especially for those organizations with volunteer or parttime medical directors, the rather broad expectation of communication could be a detriment and place a significant burden on the hospice physician.

Hospice communication with *"the facility medical director,* the patient's attending physician and other physicians participating in the provision of care" also presents challenges. In some instances, the nursing home medical director does not carry a patient load and may be totally unfamiliar with the needs of that person. Here again, consistent focus on a case-by-case judgment regarding involvement of the facility medical director would be desirable. In addition, the non-specific mandate of physician to physician communication presents potential time and cost issues when consideration is given to the, at times, relatively large number of attending physicians in some nursing homes as well as the difficulty that may be encountered by the hospice physician in trying to reach them on a regular basis.

If this section remains unchanged or only minimally changed, it must be recognized that it will result in a dramatic increase in cost for Medical Director/physician designee services for the hospice with little to no foreseeable benefit. This will necessitate revision of the hospice Medicare reimbursement methodology to assure that these additional costs are fairly reimbursed.
should be deleted from 418.112 (e) and moved to the appropriate section in reference to the patient record standard.
• (4) (iii). Clarification is requested regarding definition of a life threatening condition other than the patient's hospice terminal diagnosis.
• (e) (6): States vary in what they consider included in the room and board rate and what their responsibility is in the provision of room and board. How does this impact this Standard? Will the room and board definition in the State Operation Manual be changing in relation to the hospice regulations?
care must be discussed by representatives of hospice and representatives of the nursing facility and must be approved by the hospice before implementation."
Once again, expected collaboration must be the goal as IDT designated representative(s) and facility staff responsible for the supervision of care in the nursing home should both be aware of hospice care plan changes.
• (6) Physician orders. Our assumption is that this refers to "hospice" physician

(e) Standard: Written agreement
• (1): "written consent" should be changed to "election statement." This paragraph

(f) Standard: Hospice plan of care
• (3): Recommend that the 14-day requirement for care plan review be changed to
15 days to be in line with the current 90/90/60 day certification periods.
• (f) (4) Recommend the following language change: "Any changes in the plan of

(g) Standard: Coordination of services.
• Comment: Is there a likelihood that nursing facility regulations will state that facilities can accept orders from the hospice physician? Any such outcome must consider the need to stress collaboration and not diminish the role of the attending physician who also bears a responsibility for the care of the patient in a facility. In addition, facility staff are trained and oriented to work closely with their attending physicians. Interjecting a more direct order relationship between hospice and facilities without attending input may be difficult for the facility staff.
orders.

(h) Standard: Transfer, revocation or discharge from hospice care.

• We recommend that "does not directly impact" be changed to *"may not affect"*:
"Discharge from or revocation of hospice care may not affect the eligibility to continue to reside in a SNF, NF, ICF/MR, or other facility."

A concern here is, while discharge from hospice does not always mean discharge from a facility, this may be an issue in some cases and patients should not experience the trauma of an external move because they have perhaps stabilized for the moment and may not be eligible for hospice.

• Please provide some clarification of this standard including how compliance would be audited.

(i) Standard: Orientation and training of staff.

• Recommend revision to read: "Hospice must assure orientation of facility staff..."
As written, facilities that have contracts with multiple hospices could be inundated with hospice in-services. It would be preferable if hospices were expected to meet with facilities, offer appropriate in-services (and document the attempt) and make every effort to ensure this education is made available.
One must also consider the needs and resources of the contracted facilities.
Focus for in-service should be on those elements most important to the coordinated provision of care for the terminally ill patient.

Please advise if any of these comments are unclear. We have joined with a number of hospices and hospice organizations in preparing these comments, and we have identified those of greatest significance to us for inclusion in this letter. As a general note, there are a number of these comments that arise out of an overarching perception, that being that many of the draft regulations were imported wholesale from those applicable to the home care setting. While many of these regulations can legitimately make the transition form home care to hospice care, it is critical that the unique nature of hospice care be treated differently for regulatory purposes in those situations in which hospice care and home care lack a shared set of common clinical or holistic values. The hospice patient presents a more complex set of concerns that are acknowledged by the inclusion in the existing statutory regime of the mandated psychosocial, spiritual and bereavement aspects of care. Likewise, the dying patient's clinical needs are fundamentally different than those presented by patients being treated with a curative intent. I believe that in contrast to the proposed regulations published on May 27th, the comments presented above will be both substantially more apt in responding to patient needs and considerably more faithful to both the spirit and the letter of the statutory standards that they seek to implement.

Yours,

Dale B. Johnson
Chief Executive Officer

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Working to improve quality of life for all Missourians since 1980

MHPCA

Missouri Hospice & Palliative Care Association

July 25, 2005

Centers for Medicare and
Medicaid Services
Department of Health and Human Services
ATTN: CMS-3844-P
PO Box 80100
7500 Security Boulevard
Baltimore, MD 21244-1850

FILE CODE: CMS-3844-P

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

Gentlemen:

The Missouri Hospice & Palliative Care Association (MHPCA) is very pleased to have been a part of the response prepared by National Hospice and Palliative Care Organization on the Hospice Conditions of Participation. Three Missouri representatives participated in the Baltimore meeting on June 9-10, 2005. A statewide meeting was then held in which comments from 41 Missouri hospice programs were collected and sent to be included in the NHPCO industry-wide response.

MHPCA has one strong area of concern that warrants a separate letter. It is our understanding that the proposed Hospice Conditions of Participation for the section referenced above were written to clarify areas of responsibility for hospices and nursing facilities. MHPCA feels that the language in this section sets up barriers by reflecting that hospice is "in charge" or has more responsibility than the nursing homes. It is feared that this will cause more reluctance on the part of the nursing home to contract with hospices. We would prefer language that focuses on communication and identifies specific responsibilities for each provider without diminishing the role of either.

Also MHPCA is hopeful that any changes to the Hospice CoP's will be implemented at the same time as changes to the nursing facility regulations. The timing of implementation of both regulations is important to minimize confusion and ultimately to create collaboration.

A CD copy of the manual, "**Guidelines for End of Life Care in LTC Facilities,**" is enclosed to provide examples of ways hospice and nursing homes can collaborate. The

MHPCA, 3905 Stonewall Avenue, Independence, MO 64055, Ph: 816-350-7702

manual was written by members of MHPCA, the Missouri End of Life Coalition and Missouri Department of Health to enhance the delivery of hospice and palliative care for patients residing in nursing facilities Through the Missouri Department of Health, a collaborative team of hospice, nursing facility, nursing home survey and hospice survey staff developed a manual for providers to help identify patients appropriate for palliative care and to provide guidelines for end of life care. The Hospice section of this manual focus's specifically on collaboration and provides clear examples of the areas of responsibility for nursing facilities and hospice.

Thank you for giving us the opportunity to provide input on this very important project. We are hopeful that this manual will be helpful. If you have questions or if we can be of further assistance, please feel free to contact the MHPCA office.

Yours truly.

Cindy Baird
Executive Director

Yvonne Schwandt
President

"Guidelines for End of Life Care in LTC Facilities"

"Guidelines" wins AHFSA Promising Practice Award

The "Guidelines for End of Life Care in LTC Facilities" wins the American Health Facility Survey Agencies' Promising Practices Award. The Association of Health Facility Survey Agencies (AHFSA) maintains a website where interested persons can learn about licensing, certifying, and inspecting health care providers. AHFSA is a not-for-profit organization that provides a forum for health care regulatory agency directors and managers to address common interests, concerns, and health care program issues. Today, AHFSA actively participates with the U.S. Department of Health and Human Services through its Centers for Medicare and Medicaid Services, providers, and advocacy groups in planning, implementing, and assessing the quality and effectiveness of health care programs. The state licensing and certification agencies in all 50 States and the District of Columbia are members of this association.

Betty Markway, Missouri Department of Health and Senior Services will present information on the project to other states at a workshop at the AHFSA's Annual Training Conference is October 17, 2004 in St. Petersburg.

Innovative State-Approved Training Seeks To Improve End-of-Life Care in Missouri Nursing Homes

After nearly three years of work, the Missouri End of Life Coalition (MEOLC) and the Missouri Department of Health and Senior Services (DHSS) release "Guidelines for End of Life Care in LTC Facilities." The Coalition brought together a group of representatives from the state Department of Health and Senior Services, provider groups, and the Missouri Association of Long Term Care Physicians, to create a document to serve as the basis for palliative care in Missouri's nursing facilities.

The Guideline calls for attention to goals of care, pain management, nutrition and hydration, spiritual and psychosocial issues, and collaborations with hospice. There are also numerous helpful appendices, including care plan interventions, pain assessment tools, and hospice guidelines.

"The training centers on a new manual co-authored by both organizations," noted Betty Markway, a program manager at DHSS, "The manual has just been published and a copy is being made available to every licensed skilled and intermediate care facility in the state."

"In addition, nursing home surveyors have been using the manual with the expectation that they will have a better understanding of palliative care and will be prepared to consider end-of-life issues during the survey process."

Current statistics show that from 25-32% of deaths in Missouri occur in nursing homes, while the national average is 24%. Some sources estimate that by 2020, 40% of deaths in this country will occur in nursing homes. Yet, just as is the case for Missourians who die at home or in the hospital, palliative care and hospice services remain underutilized in long-term facilities.

"Thirty percent of nursing home residents will die within one year of their admission because they come to care facilities already near the end of life" says Debbie Oliver, chair of the MEOLC task force that co-authored the manual.

"These workshops seek to ensure that more Missourians receive the highest standard of end-of-life care by educating LTC staff about current options and state standards."

The Coalition conducted training programs for medical directors, nursing facility staff, and surveyors across the state.

Ohio
Hospice &
Palliative Care Organization

July22, 2005

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

RE: Comments related to the Hospice proposed Conditions of Participation, CMS-3844-P

To Whom It May Concern:

The Ohio Hospice & Palliative Care Organization (OHPCO), an association in Ohio working to "Promote the development and delivery of highest quality of end of life care," held a series of face to face meetings around the state, one conference call to seek hospice industry input as well as conversations and comments from our colleagues in home health industry, the extended care facility industry, and regulatory bodies on the proposed rules - **CMS-3844-P**. We have worked closely with our National Organization, the National Hospice and Palliative Care Organization (NHPCO) and agree with most of their comments. In this response we will highlight our pertinent areas of concerns brought up during our meetings and conversations.

However, before getting into the sections specifically, OHPCO wanted to comment on parts of the Introduction and preamble. While we are in agreement with the ideas and discussion in regard to the Palliative Care and Quality Standards, Patients Rights and Quality Outcomes, we feel the CoPs and preamble are in conflict at different points. We are taking this opportunity to speak more generally and philosophically on the Proposed Rules prior to specific identified areas.

First and foremost we would like to begin discuss palliative care and end of life. Hospice is palliative care and the philosophy of palliative care is holistic in nature so that the decision making that occurs in palliative care is a shared decision making model vs. the medical model where the physician is in charge and makes the care decisions. Inherent in this is the distinguishing difference between interdisciplinary vs. multidisciplinary teams of care. Hospice has been built around an interdisciplinary model of care.

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The physician and medical care is part of this interdisciplinary care. While the physician is the figure head in ordering or prescribing treatment and medications, due to the fact that palliative care is being provided vs. traditional medical care, decision making occurs around controlling symptoms vs. curing disease or even perhaps underlying infection. The decision making involving medical care is critical to the other related items going on in the patient's life and through the interdisciplinary model, the physician uses information from the team, and working with the team to determine the most appropriate care to prescribe. Throughout the proposed rules, it appears the medical care is pulled out separate, in a traditional medical model, away from the interdisciplinary team. We will suggest this is carefully considered as it appears throughout the Proposed Rules. It creates a fundamental change in the "interdisciplinary" decision making model, looking more like "multidisciplinary" traditional medical model of care. This, we feel would be a serious and grave shift in our philosophy of care and holistic shared decision making.

Another area of concern is the lifting of language from what appears to be Home Health rules and Skilled Nursing Facility rules. It is a concern to us that there appears to be an attempt to put hospice, a very different care model than either home health or skilled nursing facility care, into a similar box. Reimbursement models are different, philosophy of care is different, and the manner in which we devise our plan of care is very different not to mention our outcome is not the outcome these other industries are trying to achieve. To this end, we believe that in some areas, linking this language too closely creates conflict and misunderstanding in the philosophy and practice of hospice care. An example here is related to the Home Health Aide and supervision changes. While this is not an area that routinely shows up on any common reported area of deficit, the proposed rule would be overly costly to implement, over burdensome to manage and doesn't appear to be based or indicated on past surveys or audits except that it is similar to what is done in other industries.

While we believe there needs to be more attention paid to the coordination of the plan of care and improvements to documenting patient outcomes of care and satisfaction, we do have concerns that there is a disconnect between the collection of "data elements" and reporting outcome measures. For hospice, outcome measures should be patient driven and thus individualized. A systematic process of data collection is neither individualized nor productive in the helping to derive outcomes data around the success of comfortable dying. In fact, lots of data collection of the dying patient may even be burdensome, increase pain, and decrease meaningful time spent preparing for death. OHPCO believes the areas to expand upon would be those related to the NHPCO outcome measures (self-determination, comfort, safety and effective grieving). However, to get to the evaluation of those measures on an individual basis, one would have to consider looking at the patient's functional ability and improvement around interactions, quality of life, communications, emotional, spiritual and psychosocial interventions which help patients and family to cope and deal with impending death.

Lastly, in overview, the language around "Drug restraint" is worrisome due to end of life symptom management and the medications hospices routinely use that have not been allowed routinely in extended care facilities along with the use of the term and

description of "behavior." If a patient is in terminal restlessness and we are using haloperidol to control restlessness and provide comfort, there is a behavioral effect. The terminal restlessness is creating a behavior and physical effects that have poor outcomes. There are other examples also, but at the end of life, to create a comfortable death and control untoward physical effects, these drugs have useful indications. Hospices have worked with nursing facilities to provide this level of care. The language in the CoPs, we are afraid, would create a chilling effect to the use of these appropriate medications for situations around the dying process. In the Last Acts report "Means to a Better End, A Report on Dying in America" published in November 2004 and in the report "Achieving Balance in State Pain Policy, A Progress Report Card" (updated in Feb. 2004) by the Pain & Policy Group from the University of Wisconsin Comprehensive Cancer Center, both these reports discuss barriers toward providing adequate pain therapy. Most areas of the country did very poorly in regard to providing appropriate care at the end of life. Due to misconceptions, fear by providers, fear from patients, poorly educated practitioners and use of bad policy and language, all theses are many of the barriers discussed. The use of the term "Dangerous Drugs" is one of the cited barriers. OHPCO would suggest CMS closely look at this language consider more appropriate language (see reports enclosed).

418.3 Definitions:
Clinical Note – We agree to add the word spiritual to the sentence "any changes in physical or emotional conditions."

Drug Restraint – Change to "Chemical" Restraint. Chemical Restraint means a chemical or medication used **with the intent** 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. However, strong language needs to be included which allows for the appropriate use of medications to control terminal symptoms which may be medications that are considered "restraints" in other situations, looking at intent vs. just the drug.

With respect to medication use, the conditions outlined in this section are often inappropriate for hospice patients. Dr. Mark Beers published the hallmark article in 1991 outlining medications that are potentially inappropriate in the elderly. The article addressed concerns over medication related falls and excessive use of medications to prevent undesirable behavior (i.e. chemical restraints). Dr. Beers subsequently updated his recommendations in a 1997 publication. Both these publications serve as the basis for CMS guidelines for surveyors for appropriate use of medication in geriatric patients in long term care facilities. Although the intent of the guidelines is to prevent the use of a medication or devices to unnecessarily restrain patients who should be managed through redirection or other non-restrictive methods, they can be construed to deter the use of medications when these interventions are necessary for the control of symptoms that can not be managed through other methods or when the patient is at risk of harming themselves or others.

More desirable language would acknowledge the appropriate use of medications in hospice patients that may not be desirable in patients who are not experiencing symptoms

of life-limiting illness. Without mention of appropriate indications for medications that might not generally be acceptable in geriatric patients, barriers to the appropriate use of medications, such as haloperidol and other antipsychotic agents, opioids, and tricyclic antidepressants, which are standard of care for the treatment of many symptoms in hospice patients, could evolve.

So this issue of "Drug restraint" and the language used is very worrisome due to end of life symptom management that hospice's routinely utilize. The example of a patient that is in terminal restlessness and using haloperidol to control the restlessness and provide comfort, there could be interpreted as a behavioral effect. The terminal restlessness is creating a behavior and physical effects that have poor outcomes for patients with terminal illness and impending death. Hospices have worked hard over the last decade with nursing facilities to educate and provide this level of care with these medications. The language in the CoPs, we are afraid, would create a chilling effect to the use of these appropriate medications for situations around the dying process.

In the Last Acts report "Means to a Better End, A Report on Dying in America" published in November 2004 and in the report "Achieving Balance in State Pain Policy, A Progress Report Card (updated in Feb. 2004) by the Pain & Policy Group from the University of Wisconsin Comprehensive Cancer Center, discuss barriers toward providing adequate pain therapy. Most areas of the country did very poorly in regard to providing appropriate care at the end of life. Due to misconceptions, fear by providers, fears from patients, poorly educated practitioners and use of bad policy and language, all theses are many of the barriers discussed. The use of the term "Dangerous Drugs" is one of the cited barriers. OHPCO would suggest CMS closely look at this language and consider more therapy friendly language. (See Reports, enclosed)

Beers MH, et.al. Explicit Criteria for Determining Inappropriate Medication Use in Nursing Home Residents. *Arch Intern Med* 151:1825-1832. Sept. 1991
Beers MH. Explicit Criteria for Determining Potentially Inappropriate Medication Use by the Elderly. *Arch Intern Med* 157:1531-1536. July 28, 1997.
McLeod PJ, et.al. Defining Inappropriate Practices in Prescribing for Elderly People: a National Consensus Panel. *Can Med Assoc J* 156(3):385-91, 1997.

Facility – Definition of facility is confusing in this growing market with the use of hospice in self sustaining independent facilities, hospice leased units in nursing facilities or hospitals, with different levels of health care facilities, assisted living facilities, extended care facilities, skilled nursing facilities and freestanding hospice inpatient facilities. Look carefully at distinguishing between the differences.

Patient's residence – We would raise the same caution as above in facility. Being careful as to the separation between a hospice residence vs. a residence in another type of facility. I would also raise a question of inquiry as to how hospices are licensed in each state. If, as in Ohio, a hospice is licensed as a service and not a facility, does this language create difficulty in defining facility or residence? Are most hospices that are licensed, licensed as a service or facility? There are technical difference in Ohio which

affects programs in some different ways. In Ohio a facility can claim they are a conscientious objector and not provide DNR or life saving treatment. As a service in Ohio, which hospice is, one can not take the position of a conscientious objector? However, some attorneys for hospice programs have determined they can take the conscientious objector position for the hospice residence vs. the service. So a program may allow someone without a DNR in their program but if they need care in the inpatient unit the patient won't be accepted unless they sign a DNR.

Physical restraint – We are concerned that this section of the Proposed Medicare Conditions of Participation restricts the use of restraints to an "emergency" situation does not acknowledge that terminal agitation is a common occurrence that may require palliative sedation as patients approach death and could persist for several days. OHPCO suggests adding "or adjacent" to the sentence "means any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's.... OHPCO would also ask that CMS consider the safety of the patient, safety to self by minimizing ones ability to harm or injury oneself.

Representative – means an individual who has the authority under State Law to authorize or terminate medical care or to elect or revoke the election of hospice care (able to sign for the beneficiary on the election form) on behalf of a hospice eligible beneficiary who is mentally or physically incapacitated. This may include a legal guardian.

Satellite location – Agree with the definition, should not have to independently meet the CoPs as a hospice.

Seclusion – Pull this definition out or question the use of a locked unit for Alzheimer's patients. We would not want this type of unit considered "seclusion" for patients with Alzheimer's or a similar disease process.

418.52 CoP: Patient's Rights:
a. Standard: Notice of rights:
1.) From an association perspective, this is critical at least in the most common basic languages, however, it is unreasonable to expect all languages be in written format.

EXAMPLE of DIFFICULTY: While working to develop Advance Directives in Spanish what we learned in Ohio was that the interpretation could occur very easily. What was lost was in the interpretative written words was the understanding and meaning in that translation. To just have the words translated doesn't equate to having the meaning translated.

It took an additional nine months to have legal authorities rewrite the document to get the correct legal interpretation. This is very concerning with some languages having many variations or dialects. To get someone to look at the intent of the language after the text interpretation was laborious, time consuming (nine months) and potentially very costly.

A hospice should provide adequate interpretation of documents and forms in a manner that most individuals of a dialect would understand, in an acceptable format, either written, visual, verbally through family or an interpreter.

2.) Clarify under the advance directive section, the sentence "including a description of applicable State Law?" Is this in regard to the state's policy on providing information to the patient or the State accepted Advance Directive forms, or the state's governing policy on the acceptance of advance directives by healthcare providers?

3.) Section concerning informing the patient and family of the hospice's drug policies especially tracking and disposing of medications. While we agree that this needs to occur, this just adds to informational overload at admission. Language should state that a hospice needs to inform but should broaden the time frame a program has to inform. As far as tracking medications, OHPCO would suggest that the interpretative guidelines state that surveyors should focus on the state's governing policy and discuss disposal specifically but with the understanding that once an order is written and filled that the medication is now within the patient's property and the hospice has limited rights in the individual's patterns or activities. The hospice should always observe for patterns of abuse, misuse or misdirected medications but only from the normal day to day activities they are associated with and with their tools, role and environment of care.
These medications in the home belong to the patient and it is a gray line in regard to tracking vs. personal property and an individual's civil rights we believe. State policy should provide guidance here.

OHPCO believes there needs to be clarification on the word "demonstrated" in this section in regards to the patient or representative has demonstrated an understanding of these rights. Is this a form or documentation under clinical notes?

b. Standard: Exercise of rights and respect for property and person:
1.) Language here should include the right of the patient to refuse treatment as determined by the Patient Self-Determination Act. While we use the NF CoPs Section 418.10 OHPCO would suggest that it is a referred to piece and that this section is used as an example is not stated verbatim. OHPCO would suggest that throughout the document, whether it is NF or HHA rule we are referring to, it is a reference and not the hospice language. It seems that the language is mixed, some places it aligns hospices' with other industry interpretations while at other areas the issue is that our patient population is different. OHPCO would suggest that the population is different and as we referred to previously, the philosophy of care is different and trying to lay another industry's language within the hospice language without individualizing it creates other problems due to the different health outcome goals and philosophy of care.

Tracking of Complaints: OHPCO agrees that hospices' should have compliance programs and complaint tracking to document concerns, issues, problem areas and areas for changes. However, OHPCO strongly encourages a division of degree in reporting. On one side is incident reporting for programs to use and on the other are issues that are more egregious. The rules need to allow for investigation, documentation and resolution

of the issue/concerns based on the degree of the issue. Incident reporting should be reported by aggregate numbers but not in detail to CMS. CMS should only review specifically those issues that present patient safety (abuse/neglect), environment of care or program violation in regards to following Medicare's rules and/or CoPs or patient abuse, neglect or potential injury.

(ii) The area of "voice grievances" would seem to fall into more of incident reporting vs. a voiced complaint and reporting to CMS. Does CMS have a better definition or explanation of this term?

3.) OHPCO believes there needs to be more specific information to discuss: "If a State Court has not adjudged a patient incompetent, any legal representative designated by the patient in accordance with State law may exercise the patient's rights to the extent allowed by State law." This statement alone speaks to anyone. OHPCO believes there is an assumption that CMS is trying to get to the issue of medical capacity to make decisions but don't say that. If an individual has capacity, then they should be able to make all decisions. However, if the beneficiary is incapacitated then their appointed durable power of attorney or an individual or individuals as defined under state law should be the one(s) that make decisions for the beneficiary.

4.) Language should be included here (i) that states "when the hospice becomes aware of the incident." Not 5 days after it occurred. The other question that is raised here is "what is the appropriate agency in the state" that one reports to? OHPCO assumes it would be the agency that has the ability to perform a survey if a complaint was made outside the hospice? However, this could be a barrier also if this agency and the industry do not have a good working relationship, an understanding and ability to accept complaints and definition of which complaints to report and not report. Or does CMS want these complaints to go to the FI or QIO?

(ii) Define abuse and neglect. Is a family member's inability to get to the beneficiary's home in a timely fashion, even though during this time frame the beneficiary was not harmed, but the plan of care is for someone to be with this individual ATC? Is this neglect? How subjective or objective does the hospice need to be here? How does one evaluate reasonable means in the home setting or "to a reasonable extent?"

(e) Patient liability: This is a growing area of concern for hospices. There is great difficulty in meeting this requirement due to the inability of CMS - Medicare/Medicaid to pass along Patient / Beneficiary liability and spin down costs information to hospices. This forces us to be held to a level of accountability that we are unable to do through normal business practice. OHPCO has asked for this information to be passed on to hospice providers for years and we have been unable to get it, it goes to the individual's residence, traditional home or nursing home. In this instance we believe CMS should provide this information to the hospice provider caring for the patient or have an information data center where a hospice provider can get this information.

Another issue here as well is the changing room and board rates which in Ohio that information goes to individual nursing facilities on a quarterly basis. While it becomes a hospice's responsibility to bill Medicaid for R&B with beneficiaries in nursing facilities, payment information follows the patients and goes to their residence, meaning the NF. Hospices have to track down this information and it is very difficult to do so. How can a hospice meet this requirement if Medicare/Medicaid won't give the information to hospices?

As for the ABN's, these questions were submitted to Palmetto GBA in May 2005. Their response was to refer to CMS Change Request 3416 dated October 22, 2004. Section 60.3.3 states that providers must decide which condition and notice requirement is appropriate to the billing situation and use only one of the options provided in each case. These questions were asked because providers are finding it difficult to determine which option best fits the hospice situation. Further guidance here would be helpful.

While we understand and support CMS' Benefit Notice Initiative's purpose of giving beneficiaries "the opportunity to timely exercise their rights and protections in a well-informed manner," it is often difficult to fit the required notice forms into hospice scenarios.

Please review the following scenarios and, for each, advise as to which notice should be used and which provider would issue it.

Scenario 1: Beneficiary is referred to hospice; already has oxygen in the home. At the time of the hospice election, the Beneficiary is informed that the hospice agency works with a different oxygen vendor and that the equipment will need switched out. The beneficiary states that she prefers to remain with the current vendor. The hospice informs her that she has the right to make that decision but that she would then be responsible for paying for the oxygen out-of-pocket; she chooses that option.

Scenario 2: Beneficiary chooses to continue obtaining medications for the terminal illness from a non-contracted pharmacy. She is informed of her right to do so and that, if she makes that choice, that she will be responsible for paying for the medications herself. She has no other prescription coverage.

Scenario 3: A hospice patient has been at general inpatient level of care. The problem that necessitated GIP has been resolved; the hospice informs the family that the patient will be discharged home the next day. Although the previous caregiving system remains intact, the family refuses to take the patient home. The hospice informs the family that, if they refuse to take the patient home, the beneficiary will be liable for payment to the inpatient facility.

Scenario 4: Although proper education has been completed and documented, family members take a patient to the emergency room for a non-emergency situation without contacting the hospice. The hospice directs the hospital to bill the beneficiary.

Scenario 5: The hospice determines that a beneficiary is no longer eligible due to lack of terminality and informs the family that the patient will be discharged. The family wishes to continue hospice care and feels that Medicare should continue to pay for it.

Should the hospice issue an ABN to the family? The wording on that document states that Medicare "probably will not pay for" the service and allows the beneficiary to request that a claim be submitted to Medicare. Both seem problematic—if the hospice has already determined that the patient no longer has the required prognosis, the use of the word "probably" is misleading. Also, what process would the hospice use to submit a claim that would provide PGBA with sufficient information about the situation?

How far does CMS expect a hospice to go in giving information regarding medications and the cost of meds that are not covered by the hospice program? How specific are hospices suppose to be in "case management" of the medications prior to admission related to the drugs related to the terminal illness and those not related to the terminal illness? Is a hospice responsible for informing a patient they need or don't need certain "other" medications that are the responsibility of the attending or specialty physician that the patient is working with to oversee those particular non-related issues?

418.54 Comprehensive assessment of the patient:
General comment here is that OHPCO doesn't see the concept of "patient's goals" referred to in this section, hopefully this is an oversight and it should be added. This is part of the foundation of the Plan of Care and is spoken to in the preamble but seems to have gotten lost here.

(a) Initial Assessment: One difference here between states and regional FI interpretation is "what is needed to start care" considering a physician's referral to evaluate a patient vs. when is the "order", or do you need an "order" to then initiate the care. Perhaps there is a difference between receiving admission orders and an order to admit to hospice. Should there be a stipulation between the two? Does a request for evaluation automatically initiate care if the evaluation determines hospice care is needed?

This standard needs to differentiate between the timing to start care vs. evaluate a patient vs. when that time frame is not within 24 hours due to circumstances related to the care of the patient or that the patient or family may not be ready for a couple of days. The assessment may be more appropriate at a later time frame. Perhaps "contact" within 24 hours would be more appropriate.

However, when patient is ready to be admitted, a patient / family initial assessment should be completed within 24 hours to ensure appropriate admission to hospice and services, 24/7, 365 days a year. The Comprehensive Assessment needs to have some flexibility in it to allow for the needed services of care for the imminently dying individual and one that will have a long LOS. Long and comprehensive assessments may be burdensome, create more suffering, and allow less time with family, this needs to be balanced and decided upon within the core team providers. It would seem the IDG could determine this need upon initial assessment and in the building of the POC. If the patient

is anticipated to die within seven days, more time and energy is spent on the immediate care needs vs. burdensome requirements.

While Ohio agrees that the vast majority of the time, an RN is the most acceptable discipline of the team to go do an initial assessment, we also discussed the need to have the ability for the Social Worker to be involved in the initial assessment depending on the identified terminal illness, needs of the patient / family, and the environment of care. In some situations it may be more appropriate to have the Social Worker do the initial assessment vs. the RN.

(b) Time frame for completion of the comprehensive assessment: OHPCO would agree that 7 days for the overarching Comprehensive Assessment is recommended. OHPCO believes the language in the first paragraph should read the "individual's attending physician and/or hospice medical director must complete the comprehensive assessment no later than 7 calendar days...."

(c) Content of the comprehensive assessment: OHPCO believes this language should read something to the effect: "The comprehensive assessment must identify the physical, psychosocial, emotional, and spiritual **needs related to the patient's terminal illness, their trajectory of illness and family care** that must be addressed in order to promote the ....." Where does the family as the unit of care come into play? This needs to be individually driven.

(3)(i) Should the category "financial" also be considered or added to this section?
(3)(ii) Drug Therapy – Language should state that when a hospice case manages a patient's prescription and over the counter drug profile, this is done due to the inherent nature of certain drug interactions and evaluating the need for continuing therapy. It is not the hospice's responsibility to cover all said medications but only those related to the terminal illness and those that are reasonable and necessary for the palliation or management of terminal illness.

What is "ineffective drug therapy?" This is very vague and depending on the disease, illness trajectory, response and multiple other variables, "ineffective" is very subjective. Effective drug therapy for an individual without a terminal illness and effective drug therapy for a terminal patient to minimizing symptoms is often not appreciated between the curative medical model and end of life model of care. Palliative vs. curative.

(d) Update of the comprehensive assessment: OHPCO would rather this read two weeks instead of every 14 days. How detailed is this comprehensive assessment, is this ensuring that each patient and their case is at least discussed every two weeks? Depending on the definition of comprehensive, this full assessment every 14 days could become extremely burdensome and not needed. The assessment should be based on patient needs and outcomes, not on a subset of standardized elements to measure.

(e) Patient outcome measures: This sounds very much like JCAHO. This section appears to lack direction towards outcome measures that one could use for benchmarking

across the hospice spectrum. OHPCO thought it would be driven more that way. Time frames are rather thin for many patients, what is the realistic expectation that hospices collect data on those that die within a short time frame? Also, the terms "must" in # (2) limits the hospices ability to compare two different parameters against each other. OHPCO would recommend removal of these terms or restructure the format of the sentences. Generally, quality improvement is measuring something to check and see if results are what we believe them to be, to correct or address issues and concerns, and to improve the outcome or develop new ways to address the area being monitored and see if improvement is made. OHPCO would hope it is the desire of CMS and the industry to measure a "quality death." And if you are successful, and there isn't any thing to improve, then it isn't quality improvement but maybe a quality outcome. OHPCO believes there is still much confusion about the direction here.

OHPCO would suggest movement towards the International Classification of Functioning as a consideration in looking at outcomes of care, improvement of care, functional changes and quality of life. This would provide a common language that at sometime could be utilized across the health care environments.

418.56 CoP – Interdisciplinary group care planning and coordination of services: OHPCO believes the RN should be the disciplined professional identified to oversee the team and we see difficulty in having other professionals assume this role. Also, consider changes to language as below:

(a) Approach to service delivery: (1) Second sentence – **Interdisciplinary group members must provide core services and care offered by the hospice, and the Interdisciplinary core members must supervise the care and services.**

One question here is the term "supervise," does this have EEOC implications, giving all core members a level of management responsibility?

(a)(1)(i) – Add language to read to allow hospice medical director to act also as the patient's attending. In (iv), remove "spiritual" before counselor. OHPCO is concerned about this change and the shift in focus this might bring to programs where the counselor is used in a more general sense.

(b) Plan of care: – Is the family/patient involved in the Plan of Care? There should be a statement in this section to that fact. "IDG in collaboration with the attending physician, patient, primary caregiver and family...."

(c) Content of the plan of care: What is the general definition of Plan of Care? This varies between hospice to hospice greatly.

(1) Interventions to facilitate the management of the beneficiaries pain and symptoms, psychosocial, emotional and spirituals needs related to the terminal illness.

(c)(2) This is too prescriptive for some of the types of care and intermittent services provided. Scope and frequency needs to be removed, PRN needs to be included. The emotional rollercoaster that the patient and family goes through related to pre-grief, grief, conflict and anticipatory morning episodes along with other emotional concerns and issues are not necessarily routine. They are individualized and the utilization of staff and disciplines at different junctions of care cannot speak to the specific services and needs on a scheduled basis. This is very acute medical care model and doesn't take into account the palliative holistic nature of hospice and our patients. This is trying to shove hospice into being "like" other medical models of care.

(c)(4) – Add language here "for the palliation and/or management of the terminal conditions or related symptoms."

(c)(6) – Would change as follows "The interdisciplinary group's documentation of patient and family understanding, involvement, agreement/**disagreement** with the plan of care." Not all family may agree with the patient's desires and plan of care. Hospice should document those concerns and identify interventions to address these issues. For example, conflict is normal in family situations period. At end of life, for many reasons, this conflict is often heightened. Part of the role of hospice providers is identifying this conflict and working to resolve the issues and concerns to help the patient and family experience a quality death.

(d) Review of the plan of care: OHPCO believes the medical director is already part of the interdisciplinary team and doesn't need to be pulled out separately here.

(e) Coordination of services: (3) remove the word all and insert "most current assessments."

418.58 CoP: Quality assessment and performance improvement:
(b)(3) – "specified by the hospice's identified Interdisciplinary Group." Remove "governing body." The governing body or the board approves the overarching plan but not the frequency and detail of data collection.

(c)(1) (i) – Hospices should use a cause and analysis approach to data collection while looking for items that improve quality of life and comfortable dying. More detailed descriptions about "adverse events" needs to be included here. Adverse event tracking and evaluation may be very different than Quality Outcome Measurements. In some areas CMS seems very vague about the data elements to monitor, here they seem to believe there is cause and affect issues that needs to be looked at, a negative approach towards improving quality outcomes. One approach is to find problems, try and fix them to improve care the other is to say this is the outcome we want, let's measure items which would demonstrate that outcome and if we aren't obtaining the outcome then let's investigate and see why not, correct the situation and re-measurer.

(e) Executive responsibilities: Does this related to the whole organization or just areas that related to patient care? Should the organization be proactive or reactive, does the process promote one direction vs. another? Is there a process generally followed?

418.62 CoP: Licensed professional services: (b) Add the word "hospice" after "patient's" so it reads "Licensed professionals must activity participate in the coordination of all aspects of the patient's hospice care, in ...."

418.64 CoP: Core Services: Consider changes to the fifth sentence – "A hospice may, under extraordinary or other non-routine circumstances, enter into a written arrangement with another healthcare organization to provide the necessary disciplinary specific services to supplement hospice employee/staff to meet the needs of patients."

This section, with all the workforce issues here and on the horizon, doesn't make sense to believe that competitors would actually work with each other in a manner such as this. In many areas, extreme competition or lack of specific providers would prohibit programs from contracting with each other. Also due to other issues identified in this section and paragraph, an aging population, workforce shortage, we need broader language here for those non-routine, high acute issues that occur from time to time and allow providers to contract occasionally with services to support the care of terminally ill patients.

(a) If contracting with an attending physician, does this section put them under the direct supervision of the medical director? Essentially, the medical director is responsible for their actions? If a patient travels to the ER due to getting anxious and the attending orders some tests, blood work, ect. Is the hospice now liable due to the supervision of the medical director over this physician by hospice contract such that the issue becomes between the medical director and attending to settle vs. the hospice saying "that wasn't related to the terminal illness?"

(a)(1) This is too broad, this section needs to specifically state "related to the terminal illness."
(a)(3) Need to specify that the physician employee is responsible for meeting the medical needs related to the terminal illness. The attending may be responsible to other medical needs of the patient and the hospice should not become responsible for these needs if the attending or covering physician is not available.

(b) Clarify, is a home health aide considered under "nursing services"? Many of their activities fall under the delegation of an RN and nursing services.

(c) Clarify qualified vs. licensed. Social workers are often involved in counseling and that should be added here. OHPCO believes that psychosocial assessment needs to be addressed in this section also. Define psychosocial support and counseling. Does the section need to consider adding non-core services specific to SW in here as well as a reference to 418.70.

(d) Counseling Services: Consider calling this section "Support Services" vs. Counseling Services.

(i) OHPCO believes this section should make sure this is covering educational experience or work experience/knowledge. Hospice is the arena where most of this education or experience is gained. Broadening this allows us to continue being a training ground for individuals in Bereavement counseling.

(ii) OHPCO would suggest considering "support" vs. counseling, under (ii), "bereavement support."

418.70 Furnishing of non-core services: Dietician should be a non-core service.

418.76 Home Health Aide and homemaker services:
(a) Pull out details of training program and list here also and list state to state differences in the training of home health aides.

(c) Add "aide" following home health in the introduction sentence.

(e) In the next to the last sentence, add "hospice" so the sentence reads "...Of which must be in hospice or home health care..."

(f) Would suggest substituting "hospice" for the words "home health agency" in the beginning of the standard.

(g) Home health aide assignment and duties: 2 (i) and (ii) – Many items here for the aide may not need a physician order, please clarified this.

(h) Remove "qualified" or define this term. Remove observation visit every 28 days. OHPCO doesn't believe there has been any reason to change the current review of the home health aide and the work they do. It does not come up in the frequently identified issues at the state or FI level of review. Has there been issues here? This change seems over burdensome and unneeded.

(iv)We oppose this provision. In states where aides have been authorized to work in this fashion there is much more education and specialization in their duties than what is prescribed here. Due to the home care environment and inability to assist aides in the home environment during this activity, we are in opposition.

(h) Supervision of home health aides:
Supervision is much too frequent and obtrusive as well as costly. Issues and concerns related to hospice care and complaints occur much less than any other provider, this should not be an area to waste time and money on. It appears to be a change to make hospice more like other providers, yet we don't have the issues identified as other heath care providers have, especially related to home health aide care. OHPOC would suggest this language stay as it currently is.

(j) & (k) Homemaker: "Homemaker services" are not a reimbursed service. Current language state that "a hospice **may** provide homemaker services but they are not reimbursed for this care." It should not be defined and if it is the language should specifically state that hospices are not necessarily responsible for this care.

418.78 Volunteers
(e) Level of activity: Spell out that 5% excludes fundraising.

418.100 Organization and administration of services:
(a) Serving the hospice patient and family. The hospice must **work towards** ensuring - (work to demonstrate a desire to reach the process of "ensuring." "Promote" would be too passive.
Under (2): That each patient experience hospice care that is consistent with patient and family needs and self-determined, individualized goals.

(b) Governing body and administrator: OHPCO questions what is meant by the term "qualified" and what are qualifications?

(e) Professional management responsibility: OHPCO supports removing the term "supervision". Also, the requirement for personnel having "at least the same qualifications as hospice employees" is troublesome when considering the care given in other settings. How does this related to an aide, volunteer, etc. in a NF with a hospice patient, when the mode of care is not related to the terminal illness? Perhaps "having the necessarily qualifications" to provide appropriate care to hospice patients.

418.102 Medical Director: Last sentence of this section starting out should read: "The medical director and physician designee **collaborate** with other physicians and health care professionals **to coordinate with** the **interdisciplinary team** to ensure that each patient experiences care that reflects the hospice **philosophy**."

(a) Initial certification of terminal illness: Does this provision change certification of illness from two physicians initially to one?

(c) Coordination of medical care: The medical director role here should not include "directing the hospice's quality assessment and performance improvement program. For many physicians this is unrealistic as their time is split between many other duties outside hospice let alone their responsibilities within the hospice program. Oversight is provided by the governing body and the IDT, of which the medical director is a part of in one or perhaps both. The hospice director should oversee or appoint a member of the program to oversee the QAPI program.

Elaborate on "another qualified professional."

418.104

(b) Authentication: What or who is a primary author? Authentication of staff and hospice personnel is doable however, obtaining consultant signatures and the multiple physician signatures would be very burdensome, costly and a logistics nightmare. Hospice care is so spread out; involving community providers and hospice programs working together, this is over burdensome.

(e) Discharge or transfer of care: Add Advance Directives to number (3). Also, we would note it is very burdensome to include the entire chart to other entities and not necessary. Suggest that a discharge summary and copy of the medical record is made available upon request. HIPAA requirement would be that hospices follow minimum six year standard.

418.106 Drugs, controlled drugs and biologicals, medical supplies, and durable medical equipment. OHPCO would recommend putting the language from 418.110 (m) in here somewhere.

(b) Controlled drugs in the patient's home: Collecting items owned by the hospice becomes an issue if the owner or responsible party doesn't want to relinquish those items. It seems inherently an overstepping of boundaries to include "collecting" in these statements when the property isn't yours to just collect. Suggest changing collect to dispose.

Would this policy and education better serve the hospice, patient and family if it were discussed near the discharge vs. admission? Perhaps, even getting the family to sign off on a form documenting the policy has been discussed and medication disposal or non-disposal noted.

Means to a Better End, a Robert Wood Johnson sponsored study looking at the issues and concerns with dying in America pointed out many state barriers to adequate pain control and the reason so many states perform so poorly in this area is related to terminology such as "potential dangers" of controlled substances. This places a negative value on controlled substances when in fact all drugs, not used correctly, have potential dangers. The placement and use of this terminology places a negative connotation on the use of and delivery of adequate pain control and needs to be removed.

(c) Use and maintenance of equipment and supplies: Work with the DME companies and language in a programs contract on how to work with concerns or issues with equipment. Remove suggested language here, over burdensome, costly and not the expertise of hospice programs.

418.108 Short-term inpatient care: Included psychosocial/emotional/dysfunctional family issues within this first paragraph.

Inpatient care for symptom management and pain control: OHPCO recommends that for GIP service 24 hours nursing coverage, on site, (RN – LPN) is required for this level of care.

Inpatient care for respite purposes: OHPCO would recommend removing the requirement for 24 hour nursing care for this patient. Perhaps if we understood what 24 hour nursing **services** meant here, this would be OK language. Also remove the requirement that for respite care this has to occur in a Medicare Certified facility.

Inpatient care provided under arrangements: Clarify the "whole clinical record." The whole hospice record is not needed within this environment. Number (4) is not under hospice's control. While it might be a part of the contract between the two parties, it is not a program piece that hospice has control over. Remove this or clarify that this entire section is related to the contract and elements within the contract.

Needs to be language in here discussing an understanding that with multiple hospice providers there is not a need to duplicate multiple similar educational programs. The hospices and NF should coordinate programming.

(f) Patient Rooms: OHPCO believes that the square foot minimum should be at 100 square feet for new construction projects.

(o) Seclusion and restraint: Hospice often uses medications to treat pain and other symptoms such as nausea. Many of these medication are not used in NF because they have been targeted related to other issues than the intended use in hospice care. The use of medications here should discuss intent vs. behavior. A cardiac drug controls behavior of the patient. Terminology here should focus on the intent and use of medication to control symptoms (e.g. Haldol for nausea, high dose narcotics for pain, etc).

(7) Insert the term "unexpected, adverse or unpredicted" prior to "any **unpredicted** death that occurs while the patient…."

418.110 Hospices that provide inpatient care directly.
(a) Staffing: How is acuity measured, suggest deleting this term, acuity.

(m) Pharmaceutical services: Hospices should be able to contract with their pharmaceutical services and bring those medications into facilities when serving their patients.

(o) Seclusion and restraint: Each hospice should have a written policy for restraints and seclusion in place.

(o)(3)(ii)(c) Delete "physician must see within 1 hour."

(o)(7) Recommend changing form CMS to Medicare state surveying body.

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

(d) Medical director: Coordination of care is OK with an oversight capacity. The attending physician should also communicate with the physician most identified as the patient's doctor in the NF, however, this is generally the attending already. Seems to OHPCO that the real collaboration is between the hospice medical director, the attending physician, hospice staff with the NF staff-team caring for patients in the NF. The outline here otherwise would be impossible to do time wise. The bulk of communications should occur between the IDT and NF staff caring for the patient. Physician to NF physician communication on a patient to patient basis here is unrealistic. This would be a barrier to care as well as a mandate trying to force a new "standard of care" practice between physicians.

Define "physician designee."
Does CMS view medical care and hospice care as the same?

(e) Written Agreement:
(1) Notation in the Written Agreement should stipulate that a written consent regarding the patient or the patient's representative that hospices services are desired should accompany each admission.

(f) Hospice plan of care:
Is there another plan of care for the patient from the facility side of things? Or, is there now an overarching plan of care? What about items not related to the terminal illness?
(g) Coordination of services: This section makes it apparent that the NF will have their own plan of care also, as it is today.

OHPCO believes the responsibility for the NF/Hospice patient falls between the two entities, and would suggest a comment in the preamble in regards to this shared responsibility. Attached is a "Roles and Responsibility" worksheet developed by NF/Hospice workgroup as well as a worksheet related to developing contracts between the two disciplines.

(i) Orientation and training of staff:
Should be a statement regarding coordination of education efforts between NF and Hospices, if more than one hospices, so duplication of educational programming is minimized, NF aren't inundated with hospice providers and appropriate topics are covered.

418.114 Personnel qualifications for licensed professionals:
Comment from providers here in Ohio overwhelmingly support the loosening of requirements in regard to Social Work, allowing state licensure to criteria to be the determining factor vs. graduation from an accredited school as currently written in the CoPs. This is one of the areas that are most difficult for us to fill in rural areas. Maintaining the current level of qualification is difficult, any attempt to increase that level of qualification would render many of our programs undue hardship in meeting the responsibilities regarding core staff members. However, we would support and believe that a Social Worker needs to be at minimum licensed, same with RNs. If state legal

authorization fell below these levels we would be concerned in regard to the education and knowledge needed to care adequately for hospice patients.

Criminal Background Check:
Concerns rose about the ability to attract volunteers in some areas. Specify that all volunteers with patient contact and/or volunteers exposed to confidential information be included.
With mandating this provision the federal government needs to describe the type of background check needed and extensiveness of the background checks. CMS also needs to ensure the resources are available for the programs doing the checks are there to ensure a timely turn around. The manual process, not uncommonly, takes more than 30 days requiring you to fire or put the individual in a non-working status until the paperwork comes through. This is a burdensome process for many of our smaller programs, which incidentally makes up about 50% of our hospice provider population.

Do Not Resuscitate:
DNR: OHPCO is surprised that somewhere in the rules CMS did not take the opportunity to discuss the philosophy of hospice and issues/concerns, conflicts in individuals not being a DNR yet choosing hospice and with the concepts of not wanting life prolonging treatment or therapy. Our suggestion would be to give hospice the ability to set their own policy around the DNR issue or be a conscientious objector.

Thank you for the opportunity to responds to CMS-3844-P, Hospice Conditions of Participation. If we can answer any questions or further explain our position(s) please don't hesitate to contact us at the address below.

Sincerely,

Jeff Lycan, President/CEO
555 Metro Place North
Suite 650
Dublin, Ohio 43017
614-763-0036
614-763-0050 Fax

Common Standards for Professional Chaplaincy

This document is one of four foundational documents affirmed by the constituent boards of the Council on Collaboration on November 7, 2004 in Portland, Maine. Collectively, these documents establish a unified voice for the six organizations that have affirmed them and describe what it means to these organizations to be a professional pastoral care provider, pastoral counselor or educator. The four documents are:

- Common Standards for Professional Chaplaincy
- Common Standards for Pastoral Educators/Supervisors
- Common Code of Ethics for Chaplains, Pastoral Counselors, Pastoral Educators and Students
- Principles for Processing Ethical Complaints

The membership of the participating groups represents over 10,000 members who currently serve as chaplains, pastoral counselors, and clinical pastoral educators in specialized settings as varied as healthcare, counseling centers, prisons or the military. The complete documents and information about each of the collaborating groups can be found on the following websites:

▪Association of Professional Chaplains (APC)
www.professionalchaplains.org
▪American Association of Pastoral Counselors (AAPC)
www.aapc.org
▪Association for Clinical Pastoral Education (ACPE)
www.acpe.edu
▪National Association of Catholic Chaplains (NACC)
www.nacc.org
▪National Association of Jewish Chaplains (NAJC)
www.najc.org
▪Canadian Association for Pastoral Practice and Education (CAPPE/ACPEP)
www.cappe.org

For more information on the foundations of professional pastoral care see *"Professional Chaplaincy: Its Role and Importance in Healthcare"* available at http://www.professionalchaplains.org/professional-chaplain-services-resources-reading-room-hc-role.htm

Qualifications of Professional Chaplaincy

The candidate for certification must:

QUA1: Provide documentation of current endorsement or of good standing in accordance with the requirements of his/her own faith tradition.

QUA2: Be current in the payment of the professional association's annual dues.

QUA3: Have completed an undergraduate degree from a college, university, or theological school accredited by a member of the Council for Higher Education Accreditation (www.chea.org); and a graduate-level theological degree from a college, university or theological school accredited by a

member of the Council for Higher Education Accreditation. Equivalencies for the undergraduate and/or graduate level theological degree will be granted by the individual professional organizations according to their own established guidelines.

QUA4: Provide documentation of a minimum of four units of Clinical Pastoral Education (CPE) accredited by the Association for Clinical Pastoral Education (ACPE), the United States Conference of Catholic Bishops Commission on Certification and Accreditation, or the Canadian Association for Pastoral Practice and Education (CAPPE/ACPEP). Equivalency for one unit of CPE may be considered.

Section I: Theory of Pastoral Care

The candidate for certification will demonstrate the ability to:

TPC1: Articulate a theology of spiritual care that is integrated with a theory of pastoral practice.

TPC2: Incorporate a working knowledge of psychological and sociological disciplines and religious beliefs and practices in the provision of pastoral care.

TPC3: Incorporate the spiritual and emotional dimensions of human development into the practice of pastoral care.

TPC4: Incorporate a working knowledge of ethics appropriate to the pastoral context.

TPC5: Articulate a conceptual understanding of group dynamics and organizational behavior.

Section II: Identity and Conduct

The candidate for certification will demonstrate the ability to:

IDC1: Function pastorally in a manner that respects the physical, emotional, and spiritual boundaries of others.

IDC2: Use pastoral authority appropriately.

IDC3: Identify one's professional strengths and limitations in the provision of pastoral care.

IDC4: Articulate ways in which one's feelings, attitudes, values, and assumptions affect one's pastoral care.

IDC5: Advocate for the persons in one's care.

IDC6: Function within the Common Code of Ethics for Chaplains, Pastoral Counselors, Pastoral Educators and Students

IDC7: Attend to one's own physical, emotional, and spiritual well-being.

IDC8: Communicate effectively orally and in writing.

IDC9: Present oneself in a manner that reflects professional behavior, including appropriate attire and personal hygiene.

Section III: Pastoral

The candidate for certification will demonstrate the ability to:

PAS1: Establish, deepen and end pastoral relationships with sensitivity, openness, and respect.

PAS2: Provide effective pastoral support that contributes to well-being of patients, their families, and staff.

PAS3: Provide pastoral care that respects diversity and differences including, but not limited to culture, gender, sexual orientation and spiritual/religious practices.

PAS4: Triage and manage crises in the practice of pastoral care.

PAS5: Provide pastoral care to persons experiencing loss and grief.

PAS6: Formulate and utilize spiritual assessments in order to contribute to plans of care.

PAS7: Provide religious/spiritual resources appropriate to the care of patients, families and staff.

PAS8: Develop, coordinate and facilitate public worship / spiritual practices appropriate to diverse settings and needs.

PAS9: Facilitate theological reflection in the practice of pastoral care.

Section IV: Professional

The candidate for certification will demonstrate the ability to:

PRO1: Promote the integration of Pastoral / Spiritual Care into the life and service of the institution in which it resides.

PRO2: Establish and maintain professional and interdisciplinary relationships.

PRO3: Articulate an understanding of institutional culture and systems, and systemic relationships.

PRO4: Support, promote, and encourage ethical decision-making and care.

PRO5: Document one's contribution of care effectively in the appropriate records.

PRO6: Foster a collaborative relationship with community clergy and faith group leaders.

Requirements for the maintenance of certification

In order to maintain status as a Certified Chaplain, the chaplain must:

MNT1: Participate in a peer review process every fifth year.

MNT2: Document fifty (50) hours of annual continuing education. (Recommendation that personal therapy, spiritual direction, supervision, and/or peer review be an acceptable options for continuing education hours.)

MNT3: Provide documentation every fifth year of current endorsement or of good standing in accordance with the requirements of his/her own faith tradition.

MNT4: Be current in the payment of the professional association's annual dues.

MNT5: Adhere to the Common Code of Ethics for Chaplains, Pastoral Counselors, Pastoral Educators and Students.

Common Code of Ethics for Chaplains, Pastoral Counselors, Pastoral Educators and Students

hereinafter referred to as: Spiritual Care Professionals

This document is one of four foundational documents affirmed by the constituent boards of the Council on Collaboration on November 7, 2004 in Portland, Maine. Collectively, these documents establish a unified voice for the six organizations that have affirmed them and describe what it means to these organizations to be a professional pastoral care provider, pastoral counselor or educator. The four documents are:

- Common Standards for Professional Chaplaincy
- Common Standards for Pastoral Educators/Supervisors
- Common Code of Ethics for Chaplains, Pastoral Counselors, Pastoral Educators and Students
- Principles for Processing Ethical Complaints

The membership of the participating groups represents over 10,000 members who currently serve as chaplains, pastoral counselors, and clinical pastoral educators in specialized settings as varied as healthcare, counseling centers, prisons or the military. The complete documents and information about each of the collaborating groups can be found on the following websites:

▪Association of Professional Chaplains (APC)
www.professionalchaplains.org
▪American Association of Pastoral Counselors (AAPC)
www.aapc.org
▪Association for Clinical Pastoral Education (ACPE)
www.acpe.edu
▪National Association of Catholic Chaplains (NACC)
www.nacc.org
▪National Association of Jewish Chaplains (NAJC)
www.najc.org
▪Canadian Association for Pastoral Practice and Education (CAPPE/ACPEP)
www.cappe.org

For more information on the foundations of professional pastoral care see *"Professional Chaplaincy: Its Role and Importance in Healthcare"* available at http://www.professionalchaplains.org/professional-chaplain-services-resources-reading-room-hc-role.htm.

The Code of Ethics for Spiritual Care Professionals:

- gives expression to the basic values and standards of the profession;
- guides decision making and professional behavior;
- provides a mechanism for professional accountability; and
- informs the public as to what they should expect from Spiritual Care Professionals.

Preamble

Spiritual Care Professionals are grounded in communities of faith and informed by professional education and training.

They are called to nurture their personal health of mind, body and spirit and be responsible for their personal and professional conduct as they grow in their respect for all living beings and the natural environment.

When Spiritual Care Professionals behave in a manner congruent with the values of this code of ethics, they bring greater justice, compassion and healing to our world.

Spiritual Care Professionals:

- affirm the dignity and value of each individual;
- respect the right of each faith group to hold to its values and traditions;
- advocate for professional accountability that protects the public and advances the profession; and
- respect the cultural, ethnic, gender, racial, sexual-orientation, and religious diversity of other professionals and those served and strive to eliminate discrimination.

1.0 Ethical Principles in Relationships with Clients

Spiritual Care Professionals understand clients to be any counselees, patients, family members, students or staff to whom they provide spiritual care. In relationships with clients, Spiritual Care Professionals uphold the following standards of professional ethics. Spiritual Care Professionals:

1.1 Speak and act in ways that honor the dignity and value of every individual.

1.2 Provide care that is intended to promote the best interest of the client and to foster strength, integrity and healing.

1.3 Demonstrate respect for the cultural and religious values of those they serve and refrain from imposing their our own values and beliefs on those served.

1.4 Are mindful of the imbalance of power in the professional/client relationship and refrain from exploitation of that imbalance.

1.5 Maintain relationships with clients on a professional basis only.

1.6 Avoid or correct any conflicts of interest or appearance of conflicting interest(s).

1.7 Refrain from any form of sexual misconduct, sexual harassment or sexual assault in relationships with clients.

1.8 Refrain from any form of harassment, coercion, intimidation or otherwise abusive words or actions in relationships with clients.

1.9 Safeguard the confidentiality of clients when using materials for educational purposes or written publication.

1.10 Respect the confidentiality of information entrusted to them by clients when communicating with family members or significant others except when disclosure is required for necessary treatment, granted by client permission, for the safety of any person or when required by law.

1.11 Understand the limits of their individual expertise and make referrals to other professionals when appropriate.

2.0 Ethical Principles in Relationships Between Supervisors/Educators and Students

Spiritual Care Professionals respect the integrity of students using the power they have as supervisors/educators in responsible ways. Spiritual Care Professionals:

2.1 Maintain a healthy educational environment free of coercion or intimidation.

2.2 Maintain clear boundaries in the areas of self-disclosure, intimacy and sexuality.

2.3 Provide clear expectations regarding responsibilities, work schedules, fees and payments.

2.4 Provide adequate, timely and constructive feedback to students.

2.5 Maintain a healthy respect for the personal growth of students and provide appropriate professional referrals.

2.6 Maintain appropriate confidentiality regarding all information and knowledge gained in the course of supervision.

3.0 Ethical Principles in Relationships with Faith Community

Spiritual Care Professionals are accountable to their faith communities, one another and other organizations. Spiritual Care Professionals:

3.1 Maintain good standing in their faith group.

3.2 Abide by the professional practice and/or teaching standards of the state/province, the community and the institution in which they are employed. If for any reason a Spiritual Care Professional is not free to practice or teach according to conscience, the Spiritual Care Professional shall notify the employer, his or her professional organization and faith group as appropriate.

3.3 Do not directly or by implication claim professional qualifications that exceed actual qualifications or misrepresent an affiliation with any institution.

4.0 Ethical Principles in Relationships with Other Professionals and the Community

Spiritual Care Professionals are accountable to the public, faith communities, employers and professionals in all professional relationships. Spiritual Care Professionals:

4.1 Promote justice in relationships with others, in their institutions and in society.

4.2 Represent accurately their professional qualifications and affiliations.

4.3 Exercise good stewardship of resources entrusted to their care and employ sound financial practices.

4.4 Respect the opinions, beliefs and professional endeavors of colleagues and other professionals.

4.5 Seek advice and counsel of other professionals whenever it is in the best interest of those being served and make referrals when appropriate.

4.6 Provide expertise and counsel to other health professionals in advocating for best practices in care.

4.7 Seek to establish collaborative relationships with other community and health professionals.

4.8 Advocate for changes in their institutions that would honor spiritual values and promote healing.

4.9 Provide other professionals with chart notes where they are used that further the treatment of the clients or patients, obtaining consent when required.

4.10 Communicate sufficient information to other care team members while respecting the privacy of clients.

4.11 Ensure that private conduct does not impair the ability to fulfill professional responsibilities or bring dishonor to the profession.

4.12 Clearly distinguish between statements made or actions taken as a private individual and those made as a member or representative of one of the cognate organizations.

5.0 Ethical Principles in Relationships with Colleagues

Spiritual Care Professionals engage in collegial relationships with peers, other chaplains, local clergy and counselors, recognizing that perspective and judgment are maintained through consultative interactions rather than through isolation. Spiritual Care Professionals:

5.1 Honor all consultations, whether personal or client–related, with the highest professional regard and confidentiality.

5.2 Maintain sensitivity and professional protocol of the employing institution and/or the certifying organization when receiving or initiating referrals.

5.3 Exercise due caution when communicating through the internet or other electronic means.

5.4 Respect each other and support the integrity and well being of their colleagues.

5.5 Take collegial and responsible action when concerns about or direct knowledge of incompetence, impairment, misconduct or violations against this code arise.

5.6 Communicate sufficient information to other care team members while respecting the privacy of clients.

6.0 Ethical Principles in Advertising

Spiritual Care Professionals engage in appropriate informational activities that educate the public about their professional qualifications and individual scopes of practice. Spiritual Care Professionals:

6.1 Represent their competencies, education, training and experience relevant to their practice of pastoral care, education and counseling in an accurate manner.

6.2 Do not use any professional identification (business cards, letterhead, Internet or telephone directory, etc.) if it is false, misleading, fraudulent or deceptive.

6.3 List and claim as evidence only degrees and certifications that are earned from educational institutions and/or training programs recognized by the certifying organizations of Spiritual Care Professionals.

6.4 Ascertain that the qualifications of their employees, supervisees and students are represented in a manner that is not false, misleading, fraudulent or deceptive.

6.5.1 Represent themselves as providing specialized services only if they have the appropriate education, training or supervised experience.

7.0 Ethical Principles in Research

Spiritual Care Professionals engaging in research follow guidelines and applicable laws that strive to protect the dignity, privacy and well-being of all participants. Spiritual Care Professionals:

7.1 Engage only in research within the boundaries of their competence.

7.2 In research activities involving human participants, are aware of and ensure that the research question, design and implementation are in full compliance with ethical principles.

7.3 Adhere to informed consent, including a clear and understandable explanation of the procedures, a description of the risks and benefits, and the duration of the desired participation.

7.4 Inform all participants of the right to withdraw consent and to discontinue involvement at any time.

7.5 Engage in research while being sensitive to the cultural characteristics of participants.

7.6 Maintain the confidentiality of all research participants and inform participants of any limits of that confidentiality.

7.7 Use any information obtained through research for professional purposes only.

7.8 Exercise conscientiousness in attributing sources in their research and writing thereby avoiding plagiarism.

7.9 Report research data and findings accurately.

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to a Better End:

A Report on Dying in America Today

November 2002

Means to a Better End:
A Report on Dying in America Today

November 2002

A Vision for Better Care at the End of Life

Death and dying are not easy to deal with. Perhaps you or someone you love is facing an illness that cannot be cured. Few of us are really ready for the hard choices that may have to be made at the end of life. It can be hard for everyone involved—the dying person, their family and loved ones, and health care providers, too.

But there is a way to ease pain and make life better for people who are dying and for their loved ones. It is called *palliative care.* Palliative care means taking care of the whole person—body, mind, spirit—heart and soul. It looks at dying as something natural and personal. The goal of palliative care is that you have the best quality of life you can have during this time.

Some health care providers—doctors, nurses, social workers, pharmacists, clergy and others—have learned how to give this special kind of care. But all health care providers should know how to give good palliative care or to help you find someone who can.

FIVE PRINCIPLES OF PALLIATIVE CARE

The following Five Principles of Palliative Care describe what care can and should be like for everyone facing the end of life. Some of these ideas may seem simple or just common sense. But all together they give a new and more complete way to look at end-of-life care.

1. **Palliative care respects the goals, likes and choices of the dying person. It . . .**
   - Respects your needs and wants as well as those of your family and other loved ones.
   - Finds out from you who you want to help plan and give you care.
   - Helps you understand your illness and what you can expect in the future.
   - Helps you figure out what is important.
   - Tries to meet your likes and dislikes: where you get health care, where you want to live and the kinds of services you want.
   - Helps you work together with your health care provider and health plan to solve problems.
2. **Palliative care looks after the medical, emotional, social and spiritual needs of the dying person. It . . .**
   - Knows that dying is an important time for you and your family.
   - Offers ways for you to be comfortable and ease pain and other physical discomfort.
   - Helps you and your family make needed changes if the illness gets worse.
   - Makes sure you are not alone.
   - Understands there may be difficulties, fears and painful feelings.
   - Gives you the chance to say and do what matters most to you.
   - Helps you look back on your life and make peace, even giving you a chance to grow.
3. **Palliative care supports the needs of the family members. It . . .**
   - Understands that families and loved ones need help, too.
   - Offers support services to family caregivers, such as time off for rest, and advice and support by telephone.
   - Knows that caregiving may put some family members at risk of getting sick themselves. It plans for their special needs.
   - Finds ways for family members to cope with the costs of caregiving, like loss of income, and other expenses.
   - Helps family and loved ones as they grieve.

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ACKNOWLEDGMENTS

The development of this *Last Acts* report was an inspiring group project. Many people contributed to this effort, which we hope will spark public discussion about the state of dying in America today. From the first brainstorming session held by the *Last Acts* Committee Conveners to the report's publication, drafts found their way into over 40 pairs of capable hands. We are grateful to all of the conveners and other experts who guided us so carefully. Special thanks to Jim Towey for "birthing" the idea that led to the report and his initial stewardship of this project. In designing specific measures, we particularly benefited from the expertise of Ira Byock, M.D., Stephen Connor, Ph.D., Elliott S. Fisher, M.D., David Joranson, M.S.S.W., Diane Meier, M.D., Christina Puchalski, M.D., Charles Sabatino, J.D., Joan Teno, M.D., and John Wennberg, M.D.

Carolen Collins and the Midwest Bioethics Center were instrumental in developing our "Momentum for Change" section. Peg Metzger developed and wrote the Action Guide which serves as a companion piece to this report. The "Islands of Hope" features describe some of the past winners of the American Hospital Association's Circle of Life Award, *www.hospitalconnect.com/aha/awards-events/circle_of_life/index.html*. Many thanks also to Jean and Dick Atcheson and Margaret Trejo, our editorial and design experts, who brought an extraordinary amount of energy, creativity and dedication to this process.

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How we die says a lot about our society. We hope this report fuels a much larger discussion of why and how America must grapple with improving the care of people nearing the end of their lives.

Karen Orloff Kaplan
Director
Last Acts

Judith R. Peres
Deputy Director
Last Acts

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During the past century, we in the United States have seen significant changes in the way we experience illness and death. A hundred years ago, people usually died from an injury or sudden illness. Farm work, factory work—even childbirth—were risky. Today, with medical and other advances, people live longer and can expect to live several years with an illness that may eventually kill them. Ultimately, many will reach a point where medical technology may be able to keep them alive but can neither restore their health nor even improve their condition. In truth, more treatment may be merely prolonging dying. At that point, patients and families face difficult choices about the kind of care they want.

While opinion polls reveal that most Americans would prefer to die at home, free from pain and with their loved ones, the reality is vastly different. Americans often die alone in hospitals or nursing homes, in pain and attached to life support machines they may not want. And this happens despite modern medicine's ability to ease most pain, the existence of good models of delivering supportive care, and the increasing availability of excellent end-of-life care through hospice and palliative care programs. All these services, however, are underused—in large part because in our death-denying culture, many Americans don't want to discuss death and dying, or because many Americans don't know about these options for good end-of-life care and thus don't ask for them.

Many Americans don't know about these options for good end-of-life care and thus don't ask for them.

The last decade saw an evolution in the way Americans think about death and dying. The debate over physician-assisted suicide, coupled with pioneering studies about patterns of end-of-life care, launched a national dialogue about how we die. In November 1995, the *Journal of the American Medical Association* published initial results from SUPPORT (Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments), the largest,

most widely publicized research project examining end-of-life care in the United States to date.[1] SUPPORT documented what the public had suspected: Dying in America was unnecessarily painful and isolating, physicians did not understand patients' wishes, and it was costly. In 1997, an Institute of Medicine report, *Approaching Death in America: Improving Care at the End of Life*, underscored that "people have come to both fear a technologically over-treated and protracted death and dread the prospect of abandonment and untreated physical and emotional stress."[2]

FAST FACT

Approximately 2.5 million people die each year—55,000 of them are children and 80 percent of them are Medicare beneficiaries.

On the heels of SUPPORT, The Robert Wood Johnson Foundation launched *Last Acts*, a multiyear, multimillion-dollar national campaign to promote improvements in care and caring near the end of life. Since 1996, *Last Acts* has been communicating with policymakers, groups representing health care professionals, and consumer organizations about the need to make sure that seriously ill and dying patients receive the best care possible and have the fullest possible understanding of the kinds of care available.

The need for serious efforts to figure out how best to care for dying people and their loved ones is becoming more urgent every day. A large aging population, increases in the incidence of chronic disease, and the reduced availability of paid and unpaid caregivers, among other factors, must soon focus more attention on ways to improve the care we offer individuals nearing the end of their lives.

Experts—and the public—generally agree that the best end-of-life care treats the whole person—body, mind and spirit. This is called *palliative care*. Palliative care works aggressively to relieve pain and other physical symptoms; it also offers emotional and spiritual support to the patient and family, while respecting their culture and traditions. Care for people near the end of life is largely financed and delivered through Medicare and Medicaid—programs that were not designed to provide comprehensive palliative care.

Palliative care is often contrasted with curative care, but the lines between cure and the relief of suffering are blurry. In fact, palliative care may be needed for many years after diagnosis of a serious illness and not just near the end of life. Palliative care can complement other therapies and can be delivered in many settings—hospitals, nursing homes, other long-term-care facilities and hospices. Although palliative care has broad applications, this report focuses on palliative care near the end of life.

In 1997, *Last Acts* published its *Precepts of Palliative Care*, which describe for health professionals five areas that are key to delivering high-quality end-of-life care.[3] Briefly stated, these core areas are:

- Respecting patient goals, preferences and choices.
- Providing comprehensive caring.
- Utilizing the strengths of interdisciplinary resources.
- Acknowledging and addressing caregiver concerns.
- Building systems and mechanisms of support.

A Vision for Better Care at the End of Life, a version of the *Precepts* for the public, appears as the endpapers of this report.

SPARKING A PUBLIC DISCUSSION

In this report, *Last Acts* rates each of the 50 states and the District of Columbia on eight criteria as a basis for assessing the state of end-of-life care in this country. Despite many recent improvements in end-of-life care and greater public awareness about it, this report shows that Americans at best have no better than a fair chance of finding good care for their loved ones or for themselves when facing a life-threatening illness. In most states, too few patients are accessing hospice and palliative care services, there are too few professionals trained in pain management and palliative care, and there are too many patients dying in hospitals and nursing homes—in pain—rather than at home with their families.

Our ratings suggest a statistical portrait of access to some facets of good end-of-life care—they are far from a perfect measuring tool. For several important aspects of end-of-life care—such as whether emotional or spiritual needs are addressed or awareness of the differences in the kind of care desired by people from different cultural backgrounds—state-by-state data simply do not exist. (Some notes on the importance of spirituality and cultural issues in health outcomes and health care decision-making are presented on pages 4 and 5.) All the data need some explanation about their strengths and weaknesses and what they are really telling us. We hope that this report will stimulate efforts to improve the availability and quality of the data needed to understand end-of-life care in this country, but meanwhile we hope to spark a public discussion that cannot wait until more refined data are developed.

For several important aspects of end-of-life care . . . state-by-state data simply do not exist.

Over time Western medicine has separated physical care from patients' spiritual needs. Increasingly, however, there is recognition of the importance of spirituality in the care of dying people.[8] Numerous studies have been done that support the important role spirituality plays in patient care.[9] When medicine confronts life-limiting illness in particular, and when cure becomes less likely, it is of paramount importance to help patients cope with their suffering and eventual dying.

As people near death they often wrestle with questions such as "Why me?" or "What will happen to me?" or "What has my life meant?" These are inherently issues of the spirit, not only of biology or chemistry. Physicians and other health care providers increasingly recognize that good care of dying people is as much or more about these questions as it is about the relief of pain and other symptoms. Spirituality is an expression of how people relate to a larger whole—something greater than themselves—and how they find meaning in the midst of their suffering. A person's purpose and meaning in life can be expressed in different ways—through specific religious traditions, a deep regard for nature, connections to family, nature, art and music, or in some other way that is uniquely personal.[10,11]

Many hospitals recognize the role of spiritual caring in their provisions for chaplains and religious services and the inclusion of chaplains or other religious advisers on hospital palliative care teams.[12] Hospice has long recognized the critical importance of involving pastoral professionals on interdisciplinary teams and always makes this service part of the total package of care available to all patients and their families.

Increasingly, medical schools are realizing that addressing spirituality can be an important and useful part of patient care and doctors' own well-being. More than 70 medical schools now include some teaching about spirituality and medicine.[13] While some doctors may hesitate to tread on spiritual ground, it seems that Americans want their doctors to ask them about spiritual concerns. In 1996, *USA Today* reported that 63 percent of people surveyed believe it is good for doctors to talk to patients about spiritual beliefs.[14] The American College of Physicians has convened two consensus conferences, which concluded

MORE INFO

See "Spirituality and End-of-Life Care" in *Innovations in End-of-Life Care*, 1(6), Nov.–Dec., 1999, and "Palliative Care in African American Communities" in *Innovations in End-of-Life Care*, 3(5), Sept.–Oct., 2001, at *www2.edc.org/lastacts/*

In a country where so much research is conducted it is remarkable that this should be the first attempt to offer a comprehensive report on a situation that ought to interest every single American. Its importance is as obvious as its urgency. Our elderly population is increasing, and as our family members and friends grow ill and die, the experience becomes vivid to every one of us. What do we know about death in this country? What are our expectations for our own care at the end of our lives? Or would we rather not think about it?

Last Acts offers this report to help every interested American start to understand how disturbing the current situation is and, at the same time, what the elements of good end-of-life care are. It is a reminder that thinking ahead about the kind of care we want for ourselves and our families, and where we might turn to find it, is critical in averting crises when an incurable illness strikes. Thinking ahead is essential in making the end of life as peaceful as possible.

that physicians are obligated to address the spiritual and existential suffering of their patients.[illegible] A spiritual assessment tool was developed that many medical schools and hospitals are now using routinely.[illegible]

In another recent survey, 45 percent of respondents indicated that spiritual or religious beliefs would influence their treatment decisions if they were seriously ill. A 1997 Gallup survey, which addressed needs people would have at the end of life, showed that the top concern of the American public was having their spiritual needs addressed. In fact, seriously ill patients and bereaved family members have rated attention to spirituality among their most important concerns at the end of life.[illegible]

People from different backgrounds have different beliefs about and approaches to almost any important issue. The challenges and dilemmas that surround serious illness and death are no exception. Increasingly, doctors, nurses and counselors are being urged to identify and respect the unique needs, wishes and views about end-of-life issues of dying patients and their families.

In recent years, the diversity of our populations preferences with respect to end-of-life care has received some long-overdue attention. Results of one study of Caucasian, African, Korean and Mexican Americans suggest that ethnicity is strongly related to attitudes toward and personal wishes for the use of life support.[illegible] Another study found that African Americans are consistently more likely than whites to prefer aggressive treatment during the terminal phase of an illness. African Americans are one-third as likely as Caucasians to have living wills and one-fifth as likely to have Do Not Resuscitate (DNR) orders. Hispanics are about one-third as likely as Caucasians to have DNR orders and are equally likely to have living wills.[illegible] Even though certain beliefs and practices may be more common in particular ethnic or cultural groups, we cannot presuppose another individuals beliefs, desires or motives based on superficial knowledge or stereotype.

The *Last Acts* Diversity Committee has published a *Statement on Diversity and End-of-Life Care*, which is accompanied by several case studies that depict the kinds of issues that arise when patients from various backgrounds deal with end-of-life decisions.[illegible]

HOW *LAST ACTS* PREPARED THIS REPORT

In May 2001, *Last Acts* brought together a group of national experts in palliative care, spirituality, pain management and the U.S. health care system. (Please see page 86 for a complete listing of the conveners' names and affiliations.) They were there to produce something that did not exist—a way to describe the status of end-of-life care in every state. Much discussion of possible means of measuring the state of care eventually focused on eight important questions:

1. Do state policies support good advance care planning?
2. What proportion of the state's deaths occur at home?
3. Is hospice care widely used in the state?
4. Do hospitals in the state offer pain and palliative care services?
5. How many elderly people spend a week or more in intensive care units during the last six months of life, meaning that they may have received over-aggressive care?

6. How well do the state's nursing homes manage their residents' pain?
7. Do state policies encourage good pain control?
8. Does the state have enough physicians and nurses who are trained and certified in palliative care?

The answers to these questions can be found in the *State Report Card Measures*—the heart of this report. We describe each measure in turn, say why it is important and how it was developed and show a map indicating state performance—A, B, C, D or E. (A much more detailed description of the data behind each measure, by state, is in the Appendix.) With each measure, we include a brief case study illustrating how this measure affects real people, in real situations, every day. We follow this section with a set of *Recommendations for Action*.

Although the *State Report Card Measures* are discouraging and show tremendous shortfalls in care, there is good news, too. In a later section of this report, titled *Momentum for Change*, we describe how state coalitions composed of diverse professional and consumer groups have recognized the serious problems with care of the dying in their states and are working actively to try to fix them. Already some of their efforts have resulted in substantial progress, described on pages 53–66. And, recently, *Last Acts* established a new project, called *Rallying Points*, to help some 350 local coalitions work to improve end-of-life care at the community level. Details about where these coalitions are located and what they are doing can be found on the project's Web site, *www.rallyingpoints.org*.

The answers to these questions can be found in the State Report Card Measures.

State Report Card Measures

See the Appendix, pages 67–85,
for the actual data, charted by state,
on which these measures are based.

? Do state policies support good advance care planning?

People use advance care planning documents (living wills and medical powers of attorney) in an attempt to determine the type of care they want if they cannot speak for themselves. These documents explain the extent to which people want life-sustaining medical treatments, and appoint someone to make those decisions for them if they cannot. Experts and consumers alike believe that honoring a terminally ill patient's treatment preferences is a critical element of high-quality end-of-life care.[25]

Although advance directive policies are determined primarily at the state level, in 1991, Congress enacted the Patient Self-Determination Act (PSDA). This act requires that all health care facilities receiving Medicare or Medicaid reimbursements must inform patients of their right to make choices about the treatment they receive and to prepare advance directives.

As an additional guide to patients' treatment wishes, most health care facilities, including nursing homes and rehabilitation centers, are required to have a Do Not Resuscitate (DNR) order policy in place if they wish to be accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). There are also some people living at home for whom resuscitation is not appropriate or is unwanted. In order to protect them from resuscitation efforts (which are mandatory if emergency personnel are called), many states have authorized "non-hospital" (or out-of-hospital) DNR orders. These are orders signed by a physician that can be presented to emergency medical personnel, which allow them *not* to begin resuscitation. Currently 44 states and the District of Columbia have authorized the use of non-hospital DNR orders.

Despite the PSDA's requirement that health care providers tell patients about advance directives, surprisingly few Americans actually complete these documents. A study published in 2002 estimated the overall prevalence of advance directives to be 15 to 20 percent in the general population.[27] Rates of completion are also low in the populations that most need them. A 2002 study of nursing home residents found that only 20 percent of them had living wills, and 48 percent had DNR orders.[28]

***Advance Directive* is a general term used to describe two types of documents—living wills and medical powers of attorney. *Living wills* (sometimes called medical directives) are written instructions for care in the event that a person is not able to make medical decisions for him- or herself. Currently, 47 states and the District of Columbia have laws authorizing living wills. Massachusetts, Michigan and New York do not.[26]**

A medical power of attorney (sometimes called a health care power of attorney) is a document that appoints a particular person (health care proxy or health care agent) to make health care decisions for a patient who is unable to do so for him- or herself (not just during a terminal illness). All 50 states and the District of Columbia have laws recognizing health care powers of attorney. Currently 28 states and the District of Columbia specify the types of decisions that health care proxies can make.

✔ How we rated state advance directive policies

For this report, we looked at the extent to which five aspects of state policies conform to key elements of the Uniform Health Care Decisions Act,[29] plus one aspect reflecting the existence of state DNR order policy. Except where indicated, the sources of these data are the legislative tracking charts produced by the American Bar Association's Commission on Law and Aging.[30] According to the Uniform Act, states should:

- Recommend a single, comprehensive advance directive, which reduces confusion (1 point).
- Avoid mandatory forms or language for medical powers of attorney or combined living wills/medical powers of attorney, giving residents the freedom to express their wishes in their own way (1 point).
- Give precedence to the agent's authority or most recent directive over the living will, recognizing that an agent has the advantage of being able to weigh all the facts and medical opinions in light of the patient's wishes at the time a decision needs to be made (½ point).[31]
- Authorize default surrogates (typically next of kin) to make health care decisions, including decisions about life support if the patient has not named someone (1 point).
- Include "close friend" in the list of permissible default surrogates, recognizing that "family" in today's world often extends beyond the nuclear family (½ point).
- Have a statewide *(non-hospital)* DNR order protocol for Emergency Medical Service personnel, to ensure that the wishes of terminally ill patients in the community can be followed by EMS personnel (1 point).[32]

This report placed states into five groups according to their overall score, which could range from 0.0 to 5.0. States receiving an A scored 4.5 to 5.0 overall, those receiving a B scored 3.5 to 4.0, and so on.

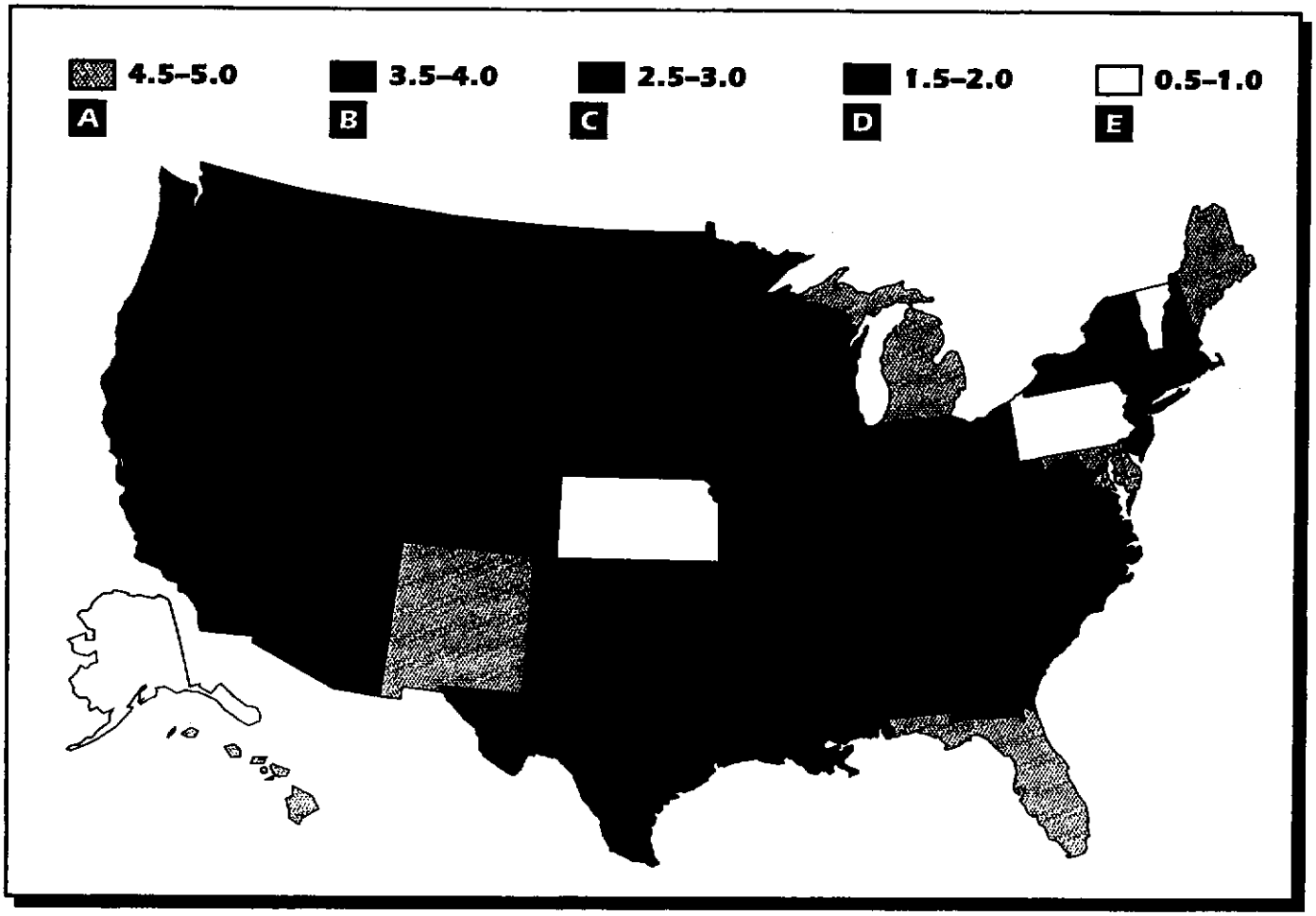
ISLAND OF HOPE

Fairview Health Services ▪ Minneapolis, Minnesota

Fairview Health Services includes seven hospitals, three physician networks, 75 clinics, three nursing homes, and 14 senior residences. All patients are asked upon admission who should make decisions for them if they become incapacitated. At one of Fairview's rural sites, advance directives and care plans are reviewed whenever patients have a history and physical exam. Patients keep the original form, as they go from setting to setting, and a copy goes into each chart.

Quality of state advance directive laws, 2002

Range 0.5 – 5.0



A Delaware, Florida, Hawaii, Maine, Maryland, Michigan, New Mexico

B Alabama, Arizona, Colorado, Connecticut, Georgia, Illinois, Massachusetts, Minnesota, Mississippi, New York, Oregon, Virginia, West Virginia

C Arkansas, California, District of Columbia, Idaho, Iowa, Kentucky, Louisiana, Missouri, Montana, New Jersey, North Dakota, Rhode Island, South Dakota, Texas, Utah, Washington, Wyoming

D Indiana, Nebraska, New Hampshire, North Carolina, Ohio, Oklahoma, Nevada, South Carolina, Tennessee, Wisconsin

E Alaska, Kansas, Pennsylvania, Vermont

Source: American Bar Association, Commission on Law and Aging. *State Health Decisions Legislative Update, 2002, www.abanet.org;* Sabatino, CP. "The Legal and Functional Status of the Medical Proxy: Suggestions for Statutory Reform." *Journal of Law, Medicine & Ethics,* 27: 552–68, 1999; Sabatino, CP, "Survey of State EMS-DNR Laws and Protocols." *Journal of Law, Medicine & Ethics,* 27: 297–315, 1999.

CASE STUDY

Planning for care makes the end of life easier

In 1998, when Margaret Lazarz was 80, she sat down with trusted relatives to orchestrate a critical stage in her life—her final medical care. With two cardiac surgeries and a pacemaker behind her, and congestive heart failure a near certainty, she knew that a time would come, not far in the future, when she would need her loved ones to act on her behalf. She created a power of attorney for health care, designating her sister-in-law, Rosella Lazarz, and her niece, Janet Aide, as her representatives in making decisions. If her breathing and heart stopped, she did not want doctors to attempt cardiopulmonary resuscitation (CPR) unless she had a good chance of survival. Her wishes were put down in writing.

Some time later, Margaret was taken to the hospital because her poorly functioning heart allowed her lungs to fill with fluid and she was unable to breathe. There she was asked whether she wanted to be resuscitated if her symptoms advanced further. Margaret's personal doctor was met with a list of questions from the family representatives: How bad was her heart? What could she expect for the future? If her breathing stopped, would CPR be successful? Would her treatment be top quality if she did not choose CPR? Could a plan be made to ensure she was comfortable, no matter what happened?

Gently, the doctor explained to Margaret that CPR would not help extend her life with any quality, if it worked at all. She then agreed to let her written directive stand. In just a few weeks, her breathing and heart began to fail again. Hospice helped make her more comfortable, and she died the following day. Her advance directive, well understood by her family, had been respected.

"It was a big relief to have a plan," said Rosella Lazarz, who is confident that she abided by her sister-in-law's last wishes.

Adapted from Partnership for Caring

? What proportion of the state's deaths occur at home?

About 50 percent of Americans 65 and older die in hospitals, often after stays in intensive care units, visits to multiple physicians in the months before death, and expensive life-prolonging treatments. Another 20 to 25 percent die in nursing homes, and this proportion is growing. Only 24.9 percent of Americans die at home, although more than 70 percent say that is their wish.[33]

Certainly, not all people with life-threatening illnesses can die at home. Sometimes a hospital or nursing home is the most appropriate place for people whose conditions require advanced medical technology or when home care is difficult or not desired. Still, most patients who die in hospitals and nursing homes would not require institutional care if support were available for them at home.[34] That, coupled with the large proportion of people who want to die at home, suggests that the 24.9 percent rate of home deaths easily could be higher.

Only 24.9 percent of Americans die at home, although more than 70 percent say that is their wish.

Where people die—and what kind of end-of-life care they receive—may be less a reflection of their wishes and more influenced by local doctors' practice habits, the availability of hospice services and the proportion of open hospital beds in the community.[35] People use hospice services earlier in their course of illness if they live in areas that have more hospital beds, more hospice services and more general practitioners.[36] They are less likely to die in hospitals if they live in areas where nursing homes and hospices are more available. Patients' preferences often are not the deciding factor in where they die.[37]

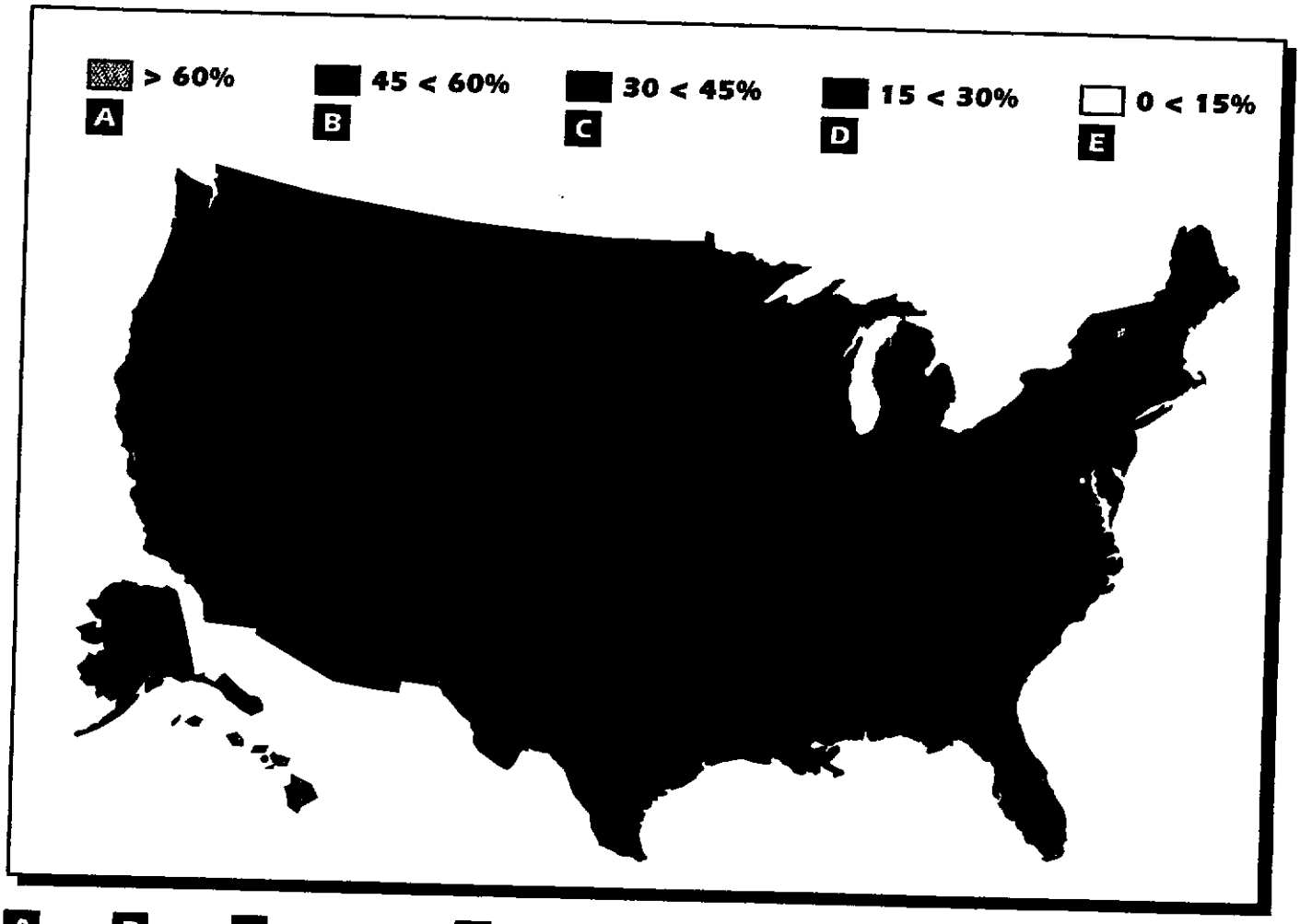
✔ How we rated the states regarding proportion of at-home deaths

We gave states one of five grades, with the top grade reserved for states where more than 60 percent of deaths occurred at home, a level below the expressed desire of more than 70 percent of Americans. No state receives an A on the map on page 14.

2

Deaths at home, 1997

Range 14.7% – 35.8% Mean 24.9%



A —

B —

C Alaska, Idaho, New Mexico, Nevada, Oregon, Utah, Washington

D Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia, West Virginia, Wisconsin, Wyoming

E District of Columbia

Source: Brown University Center for Gerontology and Health Care Research, *www.chcr.brown.edu/dying/forresearcherssod.htm.*

CASE STUDY

A family-centered death at home

For 11 years, Ruth Wolf waged a fierce battle against cancer. At the age of 58, she had gone through chemotherapy, attended cancer support groups, researched new cancer treatments, challenged her oncologist's decisions, and endured both a double mastectomy and a bone marrow transplant. When the cancer spread to her brain, she decided it was time to die.

Ruth wanted to exert as much control over the course of her death as she had over her disease, and dying at home was paramount to that wish. With the help of hospice, her two extremely supportive daughters and her husband, she was able to do just that. Ruth had her hospital bed and oxygen tank placed in her living room, so that her many friends would feel more comfortable visiting than if she were in her bedroom. "She wasn't hiding," recalled her daughter, Dagny. A multitude of friends came through—friends from childhood, from her college days, and from her cancer support group. "They had time to talk with her," Dagny said. "In fact, people would come and camp out in our house." For the two months before her death, the house was constantly filled with the sounds of laughter, talking and ringing phones, just as Ruth had wanted.

"Mom had collected dozens of scarves to cover her head while she was in chemotherapy," Dagny said. "She had us drape the scarves over the furniture, and asked each visitor to take a scarf to have something to remember her by. When they chose a scarf, she told a story that went along with how she had bought that particular one. It's tragic that she died so young, but if we could all die like she did, we'd be fortunate. I take great pride in the fact that we helped her have the death that she wanted, and that she was able to do it at home."

Adapted from an interview with Ruth Wolf's daughter, Dagny

? Is hospice care widely used in the state?

Hospice is a philosophy of care that considers the dying patient and family as one unit and focuses on relieving symptoms (palliation) rather than attempting to cure underlying disease. This kind of palliative care can be provided wherever the patient calls home—a private residence, a nursing home, assisted living or a hospice facility. The care is multifaceted, attending not only to physical symptoms, but also to psychological, emotional and spiritual needs. Support for family members continues after the patient's death—one-year bereavement services are a standard hospice benefit.

Over the years, Americans have increasingly turned to hospice. Enrollment has risen from about 1,000 per year in 1975, when hospice care was introduced in the United States, to 700,000 in 2000.[38] This increase in enrollment was made possible in large part by congressional approval of hospice care as a separate Medicare benefit in 1982. Since Medicare covers almost every American 65 and older, and since 75 percent of Americans who die are in that age group, hospice then became a covered benefit for the vast majority of dying Americans. To qualify, a patient must have a life expectancy of six months or less and must forgo curative treatments. Medicaid also pays for care near the end of life, largely through funding of long-term-care services for low-income people. Medicaid's role in paying for hospice is small and follows Medicare's rules.

Many end-of-life care experts, as well as patients and families, consider hospice to be the "gold standard" in end-of-life care—in terms of both quality and cost-effectiveness.[39] Most people equate end-of-life palliative care with hospice care, but it can also be effectively delivered in hospitals, nursing homes and other long-term-care facilities. Family members consistently report the quality of hospice care to be excellent.[40] Compared to traditional care for the terminally ill, hospice care and the use of advance directives such as living wills and medical powers of attorney could save up to 10 percent of the cost of care in a

ISLAND OF HOPE

Hospice of the Florida Suncoast ▪ Largo, Florida

This award-winning organization provides high-quality end-of-life care for 4,700 people each year, and in its Pinellas County region it is "the place to go" for support when death touches life. HFSC reaches out to many segments of the community—police officers, employers and doctors' office staff, as well as families—with bereavement counseling services. "They helped me get myself together and prepare for the future," said one widow whom HFSC aided.

patient's last year of life, 10 to 17 percent in the last six months, and 25 to 40 percent in the final month.[41] Traditional end-of-life care seriously affects family income and savings.[42]

The average length of stay in hospice has dropped . . . from 70 days in 1983 to 36 days more recently.

Experts agree that patients need to be enrolled in hospice for at least 60 days to maximize its benefits, in terms of pain and symptom management and psychological and spiritual support.[43] Unfortunately, the average length of stay in hospice has dropped over the years, from 70 days in 1983 to 36 days more recently. In 1998, 28 percent of hospice patients were enrolled for one week or less before dying.[44]

✔ How we rated the use of hospice care

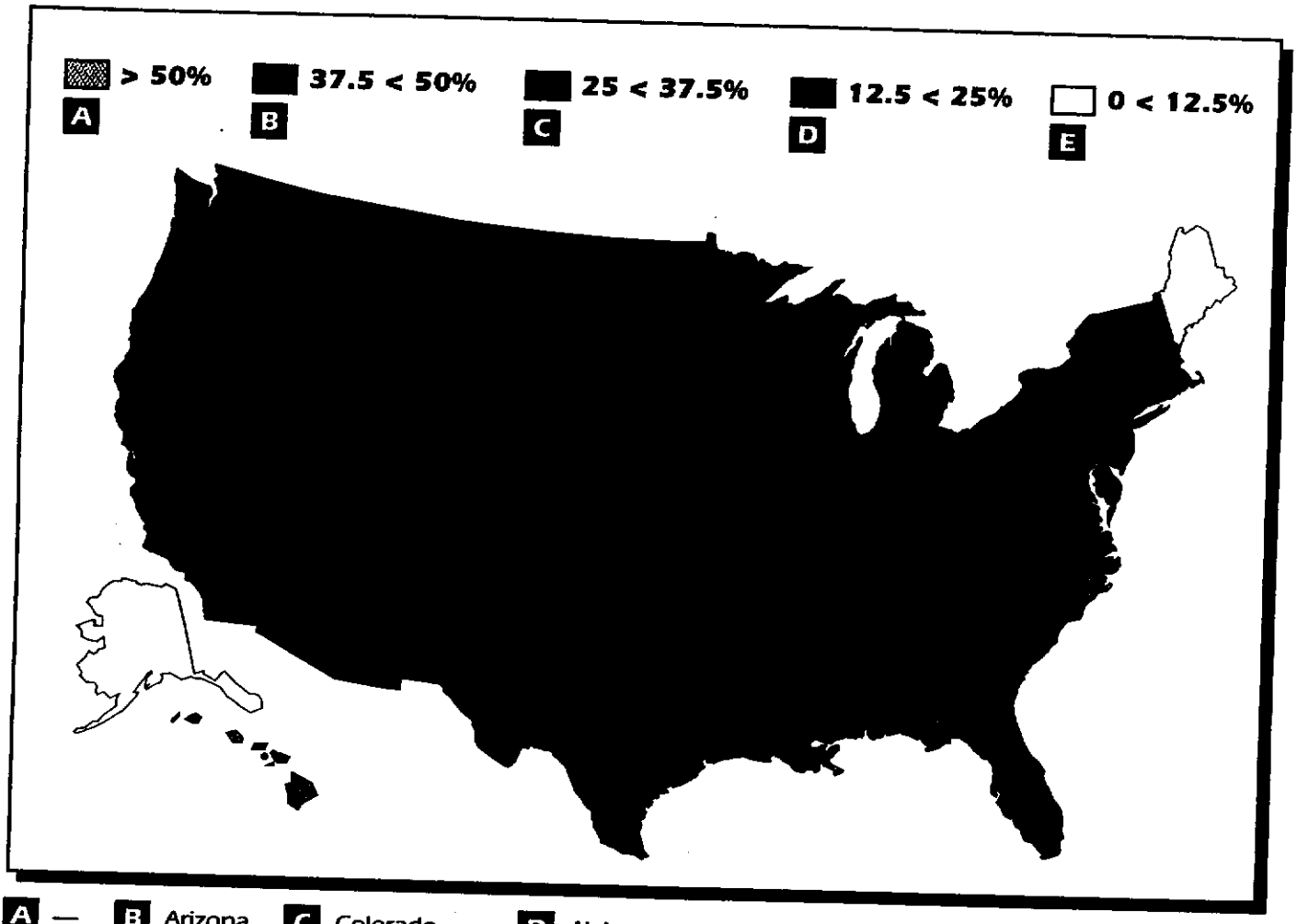
This report measures hospice use in two separate ways: How many state residents who die receive hospice care, and for how long? For each, we placed each state into one of five groups, A through E.

For the percentage of residents who obtain hospice care, states receiving an A would be those where more than 50 percent of people over 65 used hospice in their last year of life. For the length of hospice care, states in the A group would have median patient stays of at least the recommended 60 days. The remaining four grades were set at equal intervals. Data for the hospice care measure are from 2000; data for length of stay are from 2001. Note that no state gets an A, and only one achieves a B.

3

People over 65 who used hospice in the last year of life, 2000

Range 4.9 – 42.0% Mean 21.5%



A —

B Arizona

C Colorado, Florida, Illinois, Michigan, Nevada, New Mexico, Ohio, Oklahoma, Oregon, Texas

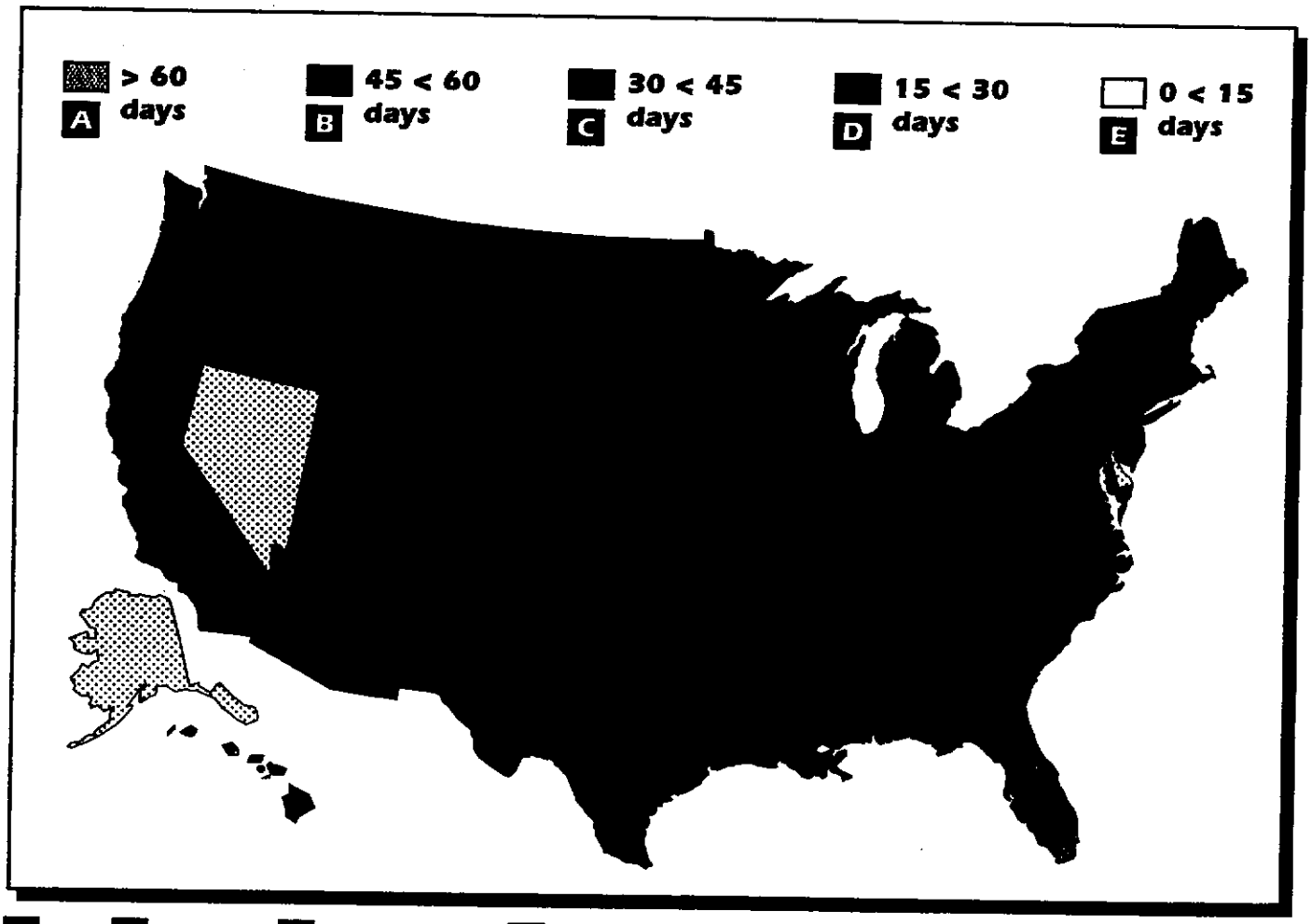
D Alabama, Arkansas, California, Connecticut, Delaware, District of Columbia, Georgia, Hawaii, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming

E Alaska, Maine

Source: Special analysis by the research team for the *Dartmouth Atlas of Health Care*, Web site *www.dartmouthatlas.org*.

Median number of days in hospice, 2001

Range 13.7 – 42.9 days Mean 25.3 days



A —

B —

C Alabama, Louisiana, Mississippi, New Mexico, North Carolina, South Carolina

D Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New York, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming

E Rhode Island

Data not available
Alaska
Delaware
District of Columbia
Nevada

Source: National Hospice and Palliative Care Organization.

CASE STUDY

Hospice care allows comfort and closure

A round of chemotherapy had produced less than promising results for Tom Bradshaw, 61. Doctors said that his esophageal cancer had grown, and new cancers had appeared in his liver and stomach. Tom decided that he did not want to spend his final days in a losing battle with a rapidly advancing and very painful disease. He preferred to be as comfortable as possible and at home.

Tom and his wife, Mimi, contacted a local Miami hospice organization that helped them set up the range of services Tom would need through what turned out to be his final two months of his life. The hospice assigned a nurse and a physician to Tom's case. Then hospice staff trained Mimi, their friends and family, in administering Tom's pain medications and using tiny ice chips to help him cope with an extremely dry throat and mouth. The hospice nurse also taught Mimi how to tell when Tom's pain was increasing, so that he could be given a higher dosage of morphine to bring him comfort.

In addition, Tom received visits from a family psychologist to discuss death, and how to make peace with his son, with whom he had a strained relationship. In his last meeting with the psychologist, Tom said, "I don't want to die, but it seems to be my time. It'll be okay."

When the hospice nurse estimated that Tom would probably die in about two days, she told Mimi to alert family and friends who lived at a distance, so that they would have time to visit with him and say goodbye. In those two days, Tom was surrounded by a round-the-clock vigil of those who loved him.

Later, many said they felt good about the way Tom died. They were grateful for the opportunity to be part of a courageous, peaceful and graceful death in the comfort and familiar surroundings of Tom's home. A social worker from the hospice kept in touch with Mimi for a year after Tom's death, helping her to cope with her feelings of loss.

Adapted from an interview with Tom Bradshaw's son, Keenan

? Do hospitals in the state offer pain and palliative care services?

Although the proportion of deaths occurring in hospitals is declining in America, about half of all deaths still take place there. All hospitals should offer critically ill and dying patients the palliative care services they need. A self-reported survey conducted by the American Hospital Association (AHA) in 2000 found that only 42 percent of U.S. hospitals reported offering a formal pain management program, and 23 percent and 14 percent offered formal hospice or palliative care programs, respectively. These services are defined by the AHA as follows:

Only 42 percent of U.S. hospitals offered a formal pain management program.

a) **Pain Management:** A formal program that educates staff about how to manage chronic and acute pain based on accepted academic guidelines.

b) **Hospice:** A program providing palliative care and supportive services that address the emotional, social, financial and legal needs of terminally ill patients and their families. This care can be provided in the hospital or at home under the auspices of the hospital.

c) **Palliative Care Program:** A program providing specialized medical care, drugs or therapies to manage acute or chronic pain and/or control other symptoms. The program, run by specially trained physicians and other clinicians, also provides services such as counseling about advance directives, spiritual care and social services to seriously ill patients and their families.

While the number of organized palliative care programs in hospitals is increasing, they are not yet the norm and do not easily fit into the coverage and payment policies of Medicare and other insurers. Funding for these programs often depends on cobbling together resources from different departments and funding streams, including short-term grants. Their continuation is jeopardized whenever any of these resources disappear.

✔ How we rated the availability of end-of-life care services in hospitals

As with any self-reported survey, the data depend on the accuracy of reporting by many individuals. While such a method is less reliable than a special study, the AHA has conducted this survey for many years, and it is a reasonably trustworthy snapshot of the nation's approximately 6,000 hospitals.

Each service was considered separately. States were placed into one of five equally distributed groups, with the better states having the most hospitals that offer formal end-of-life care services. No state would earn an A in any of the three services.

ISLAND OF HOPE

Beth Israel Medical Center ▪ Manhattan

"We create a system around the patient," says Russell K. Portenoy, M.D., describing the comprehensive services of Beth Israel's Department of Pain Management and Palliative Care. It offers patients and families—early in the trajectory of a serious illness—a broad range of services, including intensive pain and symptom management, but also inpatient consultations, case management and community-based services. This successful program is becoming integral to patient care, teaching and research programs throughout the institution.

Hospice of the North Country

7/25/05
Centers for Medicare and Medicaid Services
Dept. of Health and Human Services
Attn: CMS-3844-P
PO Box 8010
Baltimore, MD 21244-8010

Dear Sir or Madam,

Thank you for this opportunity to comment on the Medicare and Medicaid Programs: Conditions of Participation: Proposed Rule published on May 27, 2005 in the Federal Register. The following comments are derived from participation in the Hospice and Palliative Care Association of New York State audio conferences re the proposed changes as well as from personal observation of the effects these changes may have on our small, rural hospice in Upstate New York.

The work that has been done by CMS to modify the CoPs is to be commended. The shift in focus from a somewhat punitive stance, looking to discover flaws, to one of performance improvement focusing on clinical outcomes and real outcomes is welcome.

Following are comments and suggestions for changes to the proposed revisions. They are in bold type. Vignettes from our own hospice experience will follow certain recommendations and will be indented and in quotes.

Subpart A - Definitions

(a) (3) Attending physician, please add: (3) The hospice medical director, hospice physician or nurse practitioner may also act as the patient's attending physician.

Add "Counseling Services: counseling services are services that assist the patient/family to minimize the stress and problems that arise from the terminal illness or from the dying process.

Drug restraint: a medication used to control behavior or to restrict the patient's freedom of movement, *which is not a standard hospice treatment for a medical or psychiatric condition, or not requested by the patient of the patient's surrogate.*

130 Park Street
Malone New York 12953
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43 Durkee Street
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Plattsburgh New York 12901
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"Our hospice frequently uses Ativan or Haldol for terminal restlessness and anxiety. Terminal restlessness is a common occurrence in the dying person and is uncomfortable for both the patient and the family. Ativan and Haldol are very effective at calming the terminally restless, thus creating a much calmer atmosphere for the patient and family to experience the death. We believe it is within the patient's rights to have available to them the medications that can provide the greatest degree of symptom control. In addition, having to report the deaths of our patients who have been prescribed these medications would create unnecessary and onerous additional paperwork unless said death was unexpected."

Nursing Services: care provided by a licensed nurse or under the supervision of a licensed nurse as allowed by law.

Palliative Care: add interdisciplinary group to the definition: palliative care is patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care *uses an interdisciplinary team* to address physical, intellectual, emotional, social and spiritual needs and to facilitate patient autonomy, access to information and choice.

Patient's residence: patient's chosen setting in which he/she lives.

Section 418.52 Condition of Participation: Patient's Rights
Section (a) Standard: Notice of Rights
Section (a) (3) needs to be adjusted to assure patient and family comfort. Would prefer this section to read: "The Hospice must inform the patient and family of the hospice's drug policies and procedures re management and disposal of controlled substances during the comprehensive assessment." We would prefer to have this information included in the admission packet, introduced and then gone over at a later date. Patients and families are exhausted by the admission process and would not necessarily be able to take in extra information.

(a) (1) (v.) **Please add the "right of the patient to be involved in her or her plan of care."**

(a) (1) (vi.) **Please add the "right of the patient to refuse treatment"**

Section (e) Patient Liability
Please consider changing the Standard language to read:
"Before care is initiated, the patient must be informed, verbally and in writing, and in a language that he/she can understand, if payment may be expected from the patient as well as hospice's intention to bill Medicare, Medicaid or third party payers, or other resources of funding known to hospice..."

"As a small rural hospice, it is virtually impossible for us to identify insurance coverage during a weekend or after hours admission. Would it be acceptable that the patient and family be informed that coverage has not

been determined and, therefore, that they may be personally responsible for the cost of hospice services? In our world of declining length of stay, the imperative is that they get hospice care as soon as possible in order to reap the benefits of our services."

Section (a) Standard: Initial Assessment:

There is no "physician admission order for care". We recommend that this be changed to "physician's certification" to be consistent with the Hospice statute.

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

Please consider making this a 7 day time frame. Reducing this to 4 days would put undue pressure on the patient and family at a highly stressful time.

"At our hospice and I believe all hospices, our priority is symptom control. Having a four day restriction would place pressure on patients and families who may be dealing with any number of stressors, both physical and emotional. I believe strongly that our IDG members are qualified to make the decision on what disciplines have the imperative to get into a home quickly. If we have a patient dealing with intractable nausea who is reticent to have new folks in his home and we mandate that he also have to see the social worker to meet regulations, we are not keeping the patients rights in mind."

Please consider changing the language re the attending physician to read "... the attending physician, *if he/she is willing to participate...*" Attendings are invited to participate in IDG meetings, most do not, probably due to time constraints.

Section (d) Standard: Update of the comprehensive assessment.

Please consider changing this time frame from "every 14 days" to every two weeks or "15 days". This change would provide the flexibility to accommodate holidays, emergencies, staff schedules and would synchronize with the Hospice 90/90/60 certification periods with minimal impact on the CoPs.

418.56 Condition of Participation: interdisciplinary group care planning and coordination of services.
Section (a) Standard: Approach to Service Delivery

(1) (i) please change to "the hospice Medical Director or physician designee" to be consistent with the other section of the CoPs. This change will also alleviate a potential problem if the Medical Director or hospice physician is also the attending.

(2) This should be removed, or changed to read : if a hospice has more than one interdisciplinary group, there will be consistency across teams and an inclusive process for developing policies that represent all disciplines and teams, *with final authority resting with the governing body and senior management.*" It is the role of

the governing body to establish policy for an organization so the existing language is not only contrary to common practice, but also to corporate law.

Section (c) Standard: Content of Care Plan

(C)(6) Regarding family agreement, strongly recommend that "agreement" be deleted.

> " It is so common in hospice to have family members at odds with one another. To mandate family agreement could potentially stop a patient's hospice care in it's tracks. To be sure, we work with families to overcome disagreements, we mediate arguments and we work very diligently to try and bring families together, but families are dynamic entities and we are never fully assured of agreement. Ultimately it is the patient's or the patient's surrogate who get the final say."

Section (d) Standard: Review of Plan of Care:
Again, please consider changing "every 14 days" to every two weeks or "15 days". This accommodates for holidays, emergencies and staffing and synchronizes with the hospice 90/90/60 day certification periods.

Please do not separate the medical director or physician designee from the rest of the hospice interdisciplinary team at the beginning of this standard. The team is based on the philosophy that no one is more important than anyone else, that everyone's voice is heard equally because they represent the different and equally important parts of the whole patient. We have worked very hard to create this equality. Please reconsider taking it away.

418.58 Condition of Participation: Quality assessment and performance improvement.

Hospices across the country are acknowledging and acting upon the need to be more data driven. It will take time to fully develop QAPI protocols. As well it will take people power.

> " As a small rural hospice, it is very difficult and time consuming to put into place all the data collection and analysis that we would like to. I am of the belief that this is definitely the direction in which we need to grow, but I also have a hard time paying the salaries of my clinical staff, my compliance staff, my administrative and support staff. Tacking on more hours for collection and analysis adds up. Will CMS consider increasing hospice reimbursement to augment the added person power?"

418.64 Condition of Participation: Core Services
We recommend that hospices be allowed to contract for continuous care staff on a routine basis.

> "Again, as a small rural hospice serving 1700 square miles of upstate New York, it is nearly impossible for us to give continuous care. Our nurses are overworked and we have one LPN for 1700 square miles. If someone is in

need of continuous care, we are more likely to admit them to the hospital. Being able to contract for these services would alleviate a real staffing crunch."

418.76 Condition of Participation: Home health aide and homemaker services
Again, please consider changing "every 14 days" to "every two weeks" or "15 days" for the reasons stated prior.

418.102 Condition of Participation: Medical Director
Section (c)Standard: Coordination of Medical Care

We strongly recommend that the last sentence in this section be revised to read: "The Medical Director or physician designee is also responsible for *participating in* the hospice's QAPI program. The program *may be* directed by the medical director, physician designee or other qualified professional."

"In this small rural hospice, we have a very busy gastroenterologist as our volunteer medical director. On our QAPI committee we have a Director of Public Health Nursing, 2 local physician board members (one retired) and three nurses as well as our Medical Director. Our committee is led by the retired doc with an enormous amount of help and talent from the other local physician and the nurses. It would be poor form to belittle their input and commitment in order to have the one doc with the least amount of time hold the title in name only."

Section (b) Standard: Authentication
This section is doable in a hospital setting but not for home based hospice. Nursing facilities and Home Health agencies do not have this standard, why then should hospice? Hospices have no mechanism beyond the verbal order taken by the registered nurse to authenticate a covering physicians signature.

Section (e) Standard: Discharge or transfer of care.
There is really no need to do more than *offer* the full clinical record to the attending physician. If they desire it, it will be sent. HIPAA clearly states that only the minimum necessary information be exchanged. It would seem appropriate to leave the decision of what is necessary to the attending physician.

"Our hospice has always sent a discharge summary to the attending physician. We have never been asked to provide the full clinical record. If we had, we would have furnished it. It seems a waste of time and resources, both in short supply, to send a record for which we have never been asked."

Section (b) Standard: Controlled drugs in the patient's home.
We recommend the following change in language: "The hospice must have written policy for disposing of controlled drugs, in the hospice plan of care, that are maintained in the patient's home..." Hospices are not legally able to collect controlled substances in a patient's home. It is illegal to transport a controlled

substance without a prescription. When a patient dies, the prescription is no longer valid. The words "collecting" and "tracking" should be removed. We are working in homes, not in a hospital setting. We do not, for the most part, administer medications as is done in a hospital. We do count medications, watch for misuse and address issues as they arise. While we do have a policy for drug disposal, those drugs legally belong to the family. Families can refuse to have the medications disposed of. What is the liability of the hospice in that case?

Section 418.108 Condition of Participation: Short term inpatient care.

Please include "caregiver collapse" as an eligible need as is currently allowed in existing hospice regulations.
(a) Standard: Inpatient care for symptom management, pain Control and psychosocial issues.
It is of utmost importance that psychosocial issues/care giver collapse be covered under general inpatient care. Paragraph (a) should note that pain control and symptom management would be done on an inpatients basis either because of the specific need for the staff and equipment available there for because or the inability of the hospice and /or the patient's caregivers to assure that the services are properly provided in the home. We strongly advocate for the need for RN presence on a 24 hours basis for the general inpatient level of care. The critical issues encountered with the hospice patient in this setting facing end-stage changes call for the assessment and treatment skills of an RN. RN presence on a 24 hours basis respite care is not seen as presenting the equivalent need.

Please also replace the word "approved" with "certified" in item (a) (1).

418.110 Condition of Participation: Hospices that provide inpatient care directly
Item (o) Standard: Restraint and Seclusion.

"Restraint" and "seclusion" are perceived differently in hospice. Seclusion is often what a patient and family want as they near the end. As mentioned earlier, medications which are considered "restraints" in the hospital are considered comfort care in hospice, when a patient may choose comfort over alertness. Both of these words have the connotation of punishment for poor behavior. Nothing is farther from the case in hospice. Privacy and the patient's right to have their symptoms controlled are the imperatives.

Item (o)(7)
Request that the word "unpredicted" precede "death" in the sentence which refers to the reporting of any death while the patient is restrained.

418.12 Conditions of participation: Hospices which provide hospice care to residents of a SNF/ICF, MR or other facilities.

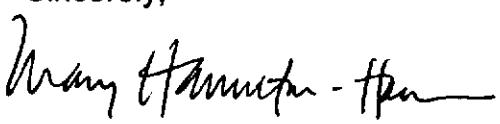
(d) Standard: Medical Director

Please re-title this standard to : Interdisciplinary Group
Please revise text to read: The hospice interdisciplinary group must provide overall coordination of the care of the hospice resident that resides in an SNF, NF or other facility. Members of the interdisciplinary group will regularly communicate and coordinate care with SNF/NF staff to ensure quality care for the patient and family. Th hospice Medical Director or physician designee will communicate with the Medical Director of the SNF/NF, the patient's attending physician, and other physicians participating in the provision of car for the terminal and related conditions *as necessary*.

> "We have a good relationship with the several nursing home facilities in our catchment area. This has been accomplished with a variety of communication routes, the majority of which involve nursing staff to nursing staff and administration to administration. When we have needed a physician to physician interaction, that has occurred but in no way has it held more sway than in the other instances. Mandating physician physician communication in nursing homes would put an undue and unnecessary burden on our part time, volunteer, very busy medical director. Again, I believe these sorts of judgment decisions should be left to the interdisciplinary team. Again, this will really impact the workings of small rural hospices on shoestring budgets. We may be small but we are doing the work for folks who have no other avenues."

In closing, thank you again for the opportunity to respond to the new revisions. I would ask that when finalizing the new CoPs, you remember us little guys out here. We do not have large censuses, we do not have any fat in our budgets. We do provide excellent end-of-life care for many rural, disenfranchised, isolated folks. We need CMS to understand our financial and service delivery issues when making these changes and to compromise where you see fit.

Sincerely,



Mary Hamilton-Homer, RN
Executive Director
Hospice of the North Country

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ASSURED
HOME HEALTH & HOSPICE

July 25, 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]:

As a Medicare and Medicaid-participating Hospice provider deeply concerned with the well-being of hospice patients, Assured Home Health and Hospice welcomes the opportunity to comment upon the Hospice COPs' revisions proposed in the Federal Register publication of May 27, 2005 [70 Fed. Reg. 30839-30891.]

By all appearances, CMS shares the views of virtually all providers and health care professionals in the hospice industry that quality of care is the prime component of this very important and compassionate benefit. CMS has also through the years championed the articulation and expansion of patients' rights in the election, exercise, care planning and end of life determinations which those facing terminal illnesses enjoy.

We therefore wish to bring to your attention a gap in the hospice regulations, which needs to be filled in the finalization of these hospice COPs. Specifically, language should be inserted in the hospice COPs to ensure that a patient's right to choice of his/her hospice provider is protected and enhanced.

Section 42 CFR 418.52 Condition of participation: Patient's rights

We propose that CMS add a subsection within this Condition, at 42 CFR 418.52(a) under "*Standard: Notice of Rights*" and/or at 42 CFR 418.52(b), "*Standard: exercise of rights and respect for property and person*", stating:

"Hospice shall ensure that the patient has been provided a choice of hospice providers and is aware of his/her right to change or transfer to another hospice of his/her choice."

Section 42 FR 418.113 Condition of Participation; Hospices that provide hospice care to residents of a SNF/NF, ICF/MR, or other facilities

Because the revised hospice COPs as proposed would include a new section, 42 CFR 418.112, regarding hospice services provided to residents of a "SNF/NF, ICF/MR, or other facilities", it is clear CMS recognizes that an important and exceedingly vulnerable group of persons at the end of life are Medicare beneficiaries, Medicaid recipients and others who have made their homes in

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nursing homes, homes for the aged, homes for the handicapped or impaired and other facilities serving those no longer able to reside in private homes.

Most of these individuals **do not come to reside in such facilities at the moment of determination of terminal status**, i.e. within six months of the time of death should their conditions deteriorate as would normally be expected. Nor do these individuals give up any legal rights under the Medicare or Medicaid programs as to the election of hospice care and the choice of providers. How could they be exercising such rights if they are not yet at the point where their conditions have identified that such rights are at stake? Their admission contracts to facilities do not identify that they are giving up a hospice provider right of choice. They are not electing a particular HMO or other managed care plan, which with their knowledge and election, limits the panel of available providers. Since the nursing facility or other residence will not have hospice as a vendor to the facility under consolidated billing by the facility, the resident is not waiving any rights to a future provider election regarding hospice.

We call on CMS to add to 42 CFR 418. 112 a subparagraph, which states that a hospice may not enter into arrangements to provide hospice services for residents in a nursing facility if that facility discriminates against residents in their choice of hospice provider. We believe that a patient's right to quality of care includes selecting a hospice whose care is, in that patient's opinion, superior. A nursing facility and a "captive" hospice should not be provided sanctuary under the Medicare program if they collaborate in depriving a patient of a reasonable choice of alternative hospices.

We believe it is incumbent of CMS to strengthen the statutory provisions that promote a patient's right to elect the provider of his or her choice. What more important time could there be than at the time of impending death? Why should a residential facility unreasonably restrict such an election, when the practical implications of having multiple hospice choices for their residents are inconsequential and the alternatives—forcing a hospice upon a resident or forcing a resident to move at the very end of life—are so contrary to the intentions of Congress in its recognition of patients' rights in receiving services they have earned through the contribution of tax dollars?

Thank you for this opportunity to participate in the comment period on this Hospice COP revision. While we recognize there will be additional revisions to the SNF/NF COPs in the future where parallel provisions should be added, we do not believe CMS should defer or waiver in its providing the hospice COPs with the strongest language possible in order to preserve and protect one of the most sacred provisions of Medicare law; the patient's right to choose their healthcare provider.

Respectfully submitted,
Wilma Wayson (signature on file)
Wilma Wayson, BSN
Vice President and Director of Hospice

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Michigan Home Health Association

July 22, 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: File Code CMS-3844-P

Dear Colleagues:

The Michigan Home Health Association (MHHA) welcomes the opportunity to comment on the proposed Hospice Conditions of Participation. While many of the proposed changes will improve care for our patients and their families, we are concerned that some changes reflect an increasing medical model of care. One of the basic tenets of hospice care is the team approach for care. This team approach recognizes that the spiritual and psycho-social concerns of a patient and family at the end of life are just as important as the physical/medical issues. It is only through the coordination of all the team members that quality hospice care can be delivered..

The attached issues and recommendations have been developed through the collaborative efforts of our hospice leaders. While many of the areas of comment call for further clarification, some comments indicate areas of concern that may actually become access to care issues.

In summary, we welcome this opportunity to assist in the development of Hospice COPs that will improve the care of our hospice clients. Thank you.

Chris Chesny
President

Harvey Zuckerberg
Executive Director

2140 University Park Drive, Suite 220, Okemos, Michigan 48864
Phone 517 349-8089 Fax 517 349-8090

Michigan Home Health Association

COMMENTS ON THE 2005 PROPOSED MEDICARE CONDITIONS OF PARTICIPATION FOR HOSPICE PROGRAMS

7/22/05

2005 CMS PROPOSED COPS Subpart C	*ISSUES*	*SUGGESTED REVISION*
§418.2 Scope of the Part		
§418.3 Definitions **Drug restraint** means a medication used to control behavior or to restrict the patient's freedom of movement which is not a standard treatment for a patient's medical or psychiatric condition.	**As hospice gives many meds for the purpose of sedation to promote the comfort and dignity of the dying patient it is important that CMS change this language.**	**§418.3 Definitions** **Drug restraint** means a medication used to control behavior or to restrict the patient's freedom of movement which is not a standard hospice treatment for a patient's medical or psychiatric condition and/or is against the patient/patient advocates desire for end of life care.
§ 418.52 Condition of participation: Patient's rights. The patient has the right to be informed of his or her rights, and the hospice must protect and promote the exercise of these rights.		
(a) Standard: Notice of rights. (1) The hospice must provide the patient or representative with written and verbal 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	**There are multiple dialects of the same language, and may be impossible to provide all with written materials** **Policies are written for professional users. Language may include information not appropriate for**	*(a) Standard: Notice of rights.* (1)The hospice must provide the patient or representative with verbal 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. Verbal notice may be made through an interpreter. Written notice must be provided when available. (2)… 3)The hospice must inform the patient and family of the hospice's drug practices, including those regarding the tracking and disposing of controlled

2005 CMS PROPOSED COPS Subpart C	*ISSUES*	*SUGGESTED REVISION*
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.	patient/family.	substances within 7days of hospice admission or at the time of death. (4)…
(b) *Standard: Exercise of rights and respect for property and person.* (1) The patient has the right— (i)To exercise his or her rights as a patient of the hospice; (ii)To have his or her property and person treated with respect; and (iii)To voice grievances regarding treatment or care that is (or fails to be) furnished and the lack of respect for property by anyone who is furnishing services on behalf of the hospice; and (iv)To not be subjected to discrimination or reprisal for exercising his or her rights. (2) If a patient has been adjudged incompetent under State law by a court of proper jurisdiction, the rights of the patient are exercised by the person appointed pursuant to State law to act on the patient's behalf. (3) If a State court has not adjudged a patient incompetent, any legal representative designated by the patient in accordance	**Need to include patients rights to refuse treatment**	(b) *Standard: Exercise of rights and respect for property and person.* (5) The patient has the right— (i))To exercise his or her rights as a patient of the hospice; (ii) To refuse care and treatment recommended by hospice (ii)To have his or her property and person treated with respect; and (iii)To voice grievances regarding treatment or care that is (or fails to be) furnished and the lack of respect for property by anyone who is furnishing services on behalf of the hospice; and (iv)To not be subjected to discrimination or reprisal for exercising his or her rights. (2) …

2005 CMS PROPOSED COPS Subpart C	*ISSUES*	*SUGGESTED REVISION*
with State law may exercise the patient's rights to the extent allowed by State law.		
(4) The hospice must—		(4)The hospice must—
(i.) Ensure that all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property are reported to State and local bodies having jurisdiction (including to the State survey and certification agency) within at least 5 working days of the incident, and immediately to the hospice administrator. Investigations and/or documentation of all alleged violations must be conducted in accordance with established procedures.	**Hospice needs to investigate complaints and allegations before acting on them. Some patients make allegations because they are upset with a family member etc**	(i)Investigate complaints made by a patient or the patient's family or representative regarding treatment or care that is (or fails to be) furnished, lack of respect for the patient or the patient's property by anyone furnishing services on behalf of the hospice, and document both the existence of the complaint and the steps taken to resolve the complaint. (ii) Investigate and document all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property in accordance with established procedures. (iii)Ensure that all violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property are reported immediately to the hospice administrator, and to State and local bodies having jurisdiction (including to the State survey and
(ii.) Immediately investigate all alleged violations and immediately take action to prevent further		

2005 CMS PROPOSED COPS *Subpart C*	*ISSUES*	*SUGGESTED REVISION*
potential abuse while the alleged violation is being verified; (iii.) Take appropriate corrective action in accordance with State law if the alleged violation is verified by the hospice administration or an outside body having jurisdiction, such as the State survey agency or local law enforcement agency; and (iv.) Investigate complaints made by a patient or the patient's family or representative regarding treatment or care that is (or fails to be) furnished, lack of respect for the patient or the patient's property by anyone furnishing services on behalf of the hospice, and document both the existence of the complaint and the steps taken to resolve the		certification agency) as required by law, within at least 5 working days of the incident (i.) Immediately investigate all alleged violations and immediately take action when violation involves the physical/emotional safety of the patient. (ii.) Take appropriate corrective action in accordance with State law if the alleged violation is verified by the hospice administration or an outside body having jurisdiction, such as the State survey agency or local law enforcement agency; and

2005 CMS PROPOSED COPS Subpart C	*ISSUES*	*SUGGESTED REVISION*
complaint.		
(c) *Standard: Pain management and symptom control.* The patient has a right to receive effective pain management and symptom control from the hospice.		
(d) *Standard: Confidentiality of clinical records.* The hospice must maintain the confidentiality of clinical records. Access to or release of patient information and clinical records is permitted in accordance with 45 CFR parts 160 and 164.		
(e) *Standard: Patient liability.* Before care is initiated, the patient must be informed, verbally and in writing, and in a language that he or she can understand, of the extent to which payment may be expected from the patient, Medicare or Medicaid, third-party payers, or other resources of funding known to the hospice.	**Hospice may not know patient pay amounts, spend downs, amount of cap or copay already spent.**	*(E) Standard: Patient liability.* Before care is initiated, the patient must be informed, verbally and in writing, and in a language that he or she can understand, of the extent to which hospice is aware, what may be expected from the patient, Medicare or Medicaid, third-party payers, or other resources for the coverage of hospice care.
§ 418.54 Condition of participation: Comprehensive assessment of the patient. The hospice must conduct and document in writing a patient-specific comprehensive assessment that identifies the patient's need for hospice care and services, and the patient's need for medical, nursing, psychosocial, emotional, and spiritual care. This care includes, but is not limited to, the palliation and management of the terminal illness and related medical conditions.	**Need clarification as to what this is**	**§ 418.54 Condition of participation: Comprehensive assessment of the patient.** The hospice must conduct and document in writing a patient-specific comprehensive assessment that identifies the patient's need for hospice care and services including physical status, coping, grief and bereavement, resources, and spiritual needs for the palliation and management of the terminal illness.
(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.	**During times of staffing shortages it may put an agency at risk to need to admit within 24 hours.** **Need consideration for patient and family wishes**	*(a) Standard: Initial assessment.* The hospice registered nurse must make an initial assessment visit within 48 hours after the hospice receives a physician's admission order for care (unless ordered otherwise by the physician) and the patient/family accept admission, to determine the patient's immediate care and support needs.

2005 CMS PROPOSED COPS Subpart C	***ISSUES***	***SUGGESTED REVISION***
(b) *Standard: Time frame for completion of the comprehensive assessment.* The hospice interdisciplinary group in consultation with the individual's attending physician must complete the comprehensive assessment no later than 4 calendar days after the patient elects the hospice benefit.	**Again consideration for patient/family wishes needed. They are often overwhelmed at start of care and want to space visits out.**	(b)*Standard: Time frame for completion of the comprehensive assessment.* The hospice interdisciplinary group in consultation with the individual's attending physician must complete the comprehensive assessment no later than 7 calendar days after the patient elects the hospice benefit, as allowed by the patient/family.
(c) *Standard: Content of the comprehensive assessment.* The comprehensive assessment must identify the physical, psychosocial, emotional, and spiritual needs related to the terminal illness that must be addressed in order to promote the hospice patient's well-being, comfort, and dignity throughout the dying process. The comprehensive assessment describes— (1) The nature and condition causing admission (including the presence or lack of objective data and subjective complaints); (2) Complications and risk factors that affect care planning; (3) Factors that must be considered in developing individualized care plan interventions, including— *(i.)* *Bereavement.* An initial bereavement assessment of the needs of the patient's family and other individuals focusing on the social, spiritual, and cultural factors that may impact their ability to cope with the patient's death.	**Need to address current medications**	(c) *Standard: Content of the comprehensive assessment* The comprehensive assessment must identify the physical, psychosocial, emotional, and spiritual needs related to the terminal illness and an assessment of current medication must be addressed in order to promote the hospice patient's well-being, …

2005 CMS PROPOSED COPS Subpart C	*ISSUES*	*SUGGESTED REVISION*
Information gathered from the initial bereavement assessment must be incorporated into the bereavement plan of care. *(ii.)* *Drug therapy.* A review of the patient's prescription and over-the-counter drug profile, including but not limited to identification of the following— (i.) Ineffective drug therapy; (ii) Unwanted drug side and toxic effects; and (iii) Drug interactions. (4) The need for referrals and further evaluation by appropriate health professionals.		
(d) *Standard: Update of the comprehensive assessment.* The update of the comprehensive assessment must be accomplished by the hospice interdisciplinary group and must consider changes that have taken place since the initial assessment. It must include information on the patient's progress toward desired outcomes, as well as a reassessment of the patient's response to care. The assessment update must be accomplished— (1) As frequently as the condition of the patient requires, but no less frequently than every	**Usually comprehensive assessment is done only as a baseline and then ongoing assessments are based on patient need.** **Frequency should be based on patient need not dates**	*(d) Standard: Update of the comprehensive assessment.* An updated assessment must be accomplished by the hospice interdisciplinary group and must consider changes that have taken place since the initial assessment. It must include information on the patient's progress toward desired outcomes, as well as a reassessment of the patient's response to care. The assessment update must be accomplished— (1) As frequently as the condition of the patient requires, but no less frequently than the beginning of every certification period

2005 CMS PROPOSED COPS Subpart C	*ISSUES*	*SUGGESTED REVISION*
14 days; and (2) At the time of each recertification.		
(e) *Standard: Patient outcome measures.* (1) The comprehensive assessment must include data elements .that allow for measurement of outcomes. The hospice must measure and document data in the same way for each patient. The data elements must take into consideration aspects of care related to hospice and palliation. (2) The data elements must be an integral part of the comprehensive assessment and must be documented in a systematic and retrievable way for each patient. The data elements for each patient must be used in individual patient care planning and in the coordination of services, and must be used in the aggregate for the hospice's quality assessment and performance improvement program.	Data elements need to be specific to patients needs. Not all patients need the same data elements measured. Should not waste time assessing what does not impact this patient's outcome	(e) *Standard: Patient outcome measures.* (1) The comprehensive assessment must include data elements .that allow for measurement of outcomes. The hospice must measure and document data in the same way for all patients to which the data element applies. The data elements must take into consideration aspects of care related to hospice and palliation. (2) The data elements must be an integral part of the comprehensive assessment and must be documented in a systematic and retrievable way. The data elements for each patient must be used in individual patient care planning and in the coordination of services, and must be used in the aggregate for the hospice's quality assessment and performance improvement program.
§ 418.56 Condition of participation: Interdisciplinary group care planning and coordination of services. The hospice must designate an interdisciplinary group or groups as specified in paragraph (a) of this section which, in consultation with the patient's attending physician, must prepare a written plan of care for each patient. The plan of care must specify the hospice care and services necessary to meet the patient and family-specific needs identified in the comprehensive		

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assessment and as it relates to the terminal illness and related conditions.		
(a) *Standard: Approach to service delivery.* (1) The hospice must designate an interdisciplinary group or groups composed of individuals who work together to meet the physical, medical, social, emotional, and spiritual needs of the hospice patients and families facing terminal illness and bereavement. Interdisciplinary group members must provide the care and services offered by the hospice, and the group in its entirety must supervise the care and services. The hospice must designate a qualified health care professional that is a member of the interdisciplinary group to provide coordination of care and to ensure continuous assessment of each patient's and family's needs and implementation of the interdisciplinary plan of care. The interdisciplinary group must include, but is not limited to, individuals who are qualified and competent to practice in the following professional roles: (i) A doctor of medicine or osteopathy (who is not the patient's attending physician). (ii) A registered nurse. (iii) A social	**Medical is physical** **Needs to be RN who coordinates care, other members of IDT would have a hard time based on the acuity of the dying patient.**	(a) *Standard: Approach to service delivery.* (1)The hospice must designate an interdisciplinary group or groups composed of individuals who work together to meet the physical, social, emotional, and spiritual needs of the hospice patients and families facing terminal illness and bereavement. Interdisciplinary group members must provide the care and services offered by the hospice, and the group in its entirety must supervise the care and services. … The hospice must designate a RN member of the interdisciplinary group to provide coordination of care and to ensure continuous assessment of each patient's and family's needs and implementation of the interdisciplinary plan of care…

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worker. (iv) A pastoral, clergy, or other spiritual counselor. (2) If the hospice has more than one interdisciplinary group, it must designate in advance only one of those groups to establish policies governing the day-to-day provision of hospice care and services.		
(b) *Standard: Plan of care.* All hospice care and services furnished to patients and their families must follow a written plan of care established by the hospice interdisciplinary group in collaboration with the attending physician. The hospice must ensure that each patient and family and primary caregiver(s) receive education and training provided by the hospice as appropriate to the care and services identified in the plan of care.		

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(c) *Standard: Content of the plan of care.* The hospice must develop a written plan of care for each patient that reflects prescribed interventions based on the problems identified in the initial comprehensive and updated comprehensive assessments, and other assessments. The plan of care must include but not be limited to— (1) Interventions to facilitate the management of pain and symptoms; (2) A detailed statement of the scope and frequency of services necessary to meet the specific patient and family needs; (3) Measurable targeted		

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outcomes anticipated from implementing and coordinating the plan of care; (4) Drugs and treatment necessary to meet the needs of the patient; (5) Medical supplies and appliances necessary to meet the needs of the patient; and (6) The interdisciplinary group's documentation of patient and family understanding, involvement, and agreement with the plan of care, in accordance with the hospice's own policies, in the clinical record.	Patients and families do not always agree with the POC, which family members, what about the one family member who disagrees	(6)The interdisciplinary group's documentation of patient and family understanding, involvement, and agreement with the plan of care, in accordance with the hospice's own policies, in the clinical record.
(d) *Standard: Review of the plan of care.* The medical director or physician designee, and the hospice interdisciplinary team (in collaboration with the individual's attending physician to the extent possible) must review, revise and document the plan as necessary at intervals specified in the plan but no less than every 14 calendar days. A revised plan of care must include information from the patient's updated comprehensive assessment and the patient's progress toward outcomes specified in the plan of care.	**Medical director/physician is a member of IDT** **What does to extent possible mean** **14 days is too prescriptive, needs to be based on patient need**	(d) *Standard: Review of the plan of care.* The hospice interdisciplinary team must review, revise and document the plan as necessary at intervals specified in the plan but no less than every certification period. A revised plan of care must include information from the patient's updated comprehensive assessment and the patient's progress toward outcomes specified in the plan of care.
(e) *Standard: Coordination of services.* The hospice must develop and maintain a system of communication and integration, in accordance with the hospice's own policies and procedures, to— (1) Ensure the interdisciplinary group, through its designated professionals, maintains responsibility for directing, coordinating, and supervising the care and services provided; (2) Ensure that care and services are provided in accordance with the		

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plan of care; (3) Ensure that the care and services provided are based on all assessments of the patient and family needs; and (4) Provide for and ensure the ongoing sharing of information between all disciplines providing care and services in the home, in outpatient settings, and in inpatient settings, irrespective whether the care and services are provided directly or under arrangement.	**This would mean that we need to coordinate with all health care persons involved in care.**	(4)Provide for and ensure the ongoing sharing of information between all disciplines providing hospice care and services in the home, in outpatient settings, and in inpatient settings, irrespective whether the care and services are provided directly.
§ 418.58 Condition of participation: Quality assessment and performance improvement. The hospice must develop, implement, and maintain an effective, ongoing, hospice-wide data-driven quality assessment and performance improvement program. The hospice's governing body must ensure that the program: Reflects the complexity of its organization and services; involves all hospice services (including those services furnished under contract or arrangement); focuses on indicators related to improved palliative outcomes; focuses on the end-of-life support services provided; and takes actions to demonstrate improvement in hospice performance. The hospice must maintain documentary evidence of its quality assessment and performance improvement program and be able to demonstrate its operation to CMS.		
(a) *Standard: Program scope.* (1) The program must at least be capable of showing measurable improvement in indicators for which there is evidence that		

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improvement in those indicators will improve palliative outcomes and end-of-life support services. (2) The hospice must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that enable the hospice to assess processes of care, hospice services, and operations.	**Define.** **Is this a sentinel event as defined by JCAHO**	
(b) *Standard: Program data.* (1) The program must utilize quality indicator data, including patient care, and other relevant data, in the design of its program. (2) The hospice must use the data collected to— (i) Monitor the effectiveness and safety of services and quality of care; and (ii) Identify opportunities for improvement. (3) The frequency and detail of the data collection must be specified by the hospice's governing body.		
(c) *Standard: Program activities.* (1) The hospice's performance improvement activities must— (i) Focus on high risk, high volume, or problem-prone areas; (ii) Consider incidence, prevalence, and severity of problems in those areas; and		

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(iii) Affect palliative outcomes, patient safety, and quality of care. (2) Performance improvement activities must track adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospice. (3) The hospice must take actions aimed at performance improvement and, after implementing those actions; the hospice must measure its success and track performance to ensure that improvements are sustained.		
(d) *Standard: Performance improvement projects.* (1) The number and scope of distinct improvement projects conducted annually must reflect the scope, complexity, and past performance of the hospice's services and operations. (2) The hospice must document what quality improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.		
(e) *Standard: Executive responsibilities.* The hospice's governing body is responsible for ensuring the following: (1) That an ongoing program for quality	**Governing bodies do not usually want the level of detail of ensuring**	(e) *Standard: Executive responsibilities.* The hospice's governing body is responsible for oversight of the following: (1),,,

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improvement and patient safety is defined, implemented and maintained; (2) That the hospice-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety, and that all improvement actions are evaluated for effectiveness; and (3) That clear expectations for patient safety are established.		
§418.60 Condition of participation: Infection control. The hospice must maintain and document an effective infection control program that protects patients, families and hospice personnel by preventing and controlling infection and communicable diseases.		
(a) *Standard: Prevention.* The hospice must follow accepted standards of practice to prevent the transmission of infections and communicable diseases, including the use of standard precautions. (b) *Standard: Control.* The hospice must maintain a coordinated agency-wide program for the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases that— (1) Is an integral part of the hospice's quality assessment and performance improvement program; and (2) Includes: (i.) A method of identifying infectious; and communicable disease problems; and (ii.) A plan for the		

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appropriate actions that are expected to result in improvement and disease prevention.		
(c) *Standard: Education.* The hospice must provide infection control education to staff, patients, and family members or other caregivers.		
§ 418.62 Condition of participation: Licensed professional services. (a) Licensed professional services provided directly or under arrangement must be authorized, delivered, and supervised only by health care professionals who meet the appropriate qualifications specified under 418.114 and who practice under the hospice's policies and procedures. (b) Licensed professionals must actively participate in the coordination of all aspects of the patient's care, in accordance with current professional standards and practice, including participating in ongoing interdisciplinary comprehensive assessments, developing and evaluating the plan of care, and contributing to patient and family counseling and education; and (c) Licensed professionals must participate in the hospice's quality assessment and performance improvement program and hospice sponsored in-service training.		(b)Licensed professionals must actively participate in the coordination of all aspects of the patient's hospice care, in accordance with current professional standards and practice, including participating in ongoing interdisciplinary comprehensive assessments, developing and evaluating the plan of care, and contributing to patient and family counseling and education; and
§ 418.64 Condition of participation: Core services. A hospice must routinely provide substantially all core services directly by hospice employees. These services must be provided in a manner consistent with acceptable standards of practice. These services		

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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		

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physician employee is responsible for meeting the medical needs of the patient.		
(b) *Standard: Nursing services.* (1) The hospice must provide nursing care and services by or under the supervision of a registered nurse. Nursing services must ensure that the nursing needs of the patient are met as identified in the patient's initial comprehensive assessment and updated assessments. (2) If State law permits nurse practitioners (NPs) to see, treat and write orders for patients, then NPs may provide services to beneficiaries receiving hospice care. The role and scope of the services provided by a NP that is not the individual's attending physician must be specified in the individual's plan of care. (3) Highly specialized nursing services that are provided so infrequently that the provision of such services by direct hospice employees would be impracticable and prohibitively expensive, may be provided under contract.		
(c) *Standard: Medical social services.* Medical social services must be provided by a qualified social worker, under the direction of a physician. Social work services must be based on the patient's psychosocial assessment and the		

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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		

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provided and the frequency of service delivery. A special coverage provision for bereavement counseling is specified in § 418.204(c). (2) *Nutritional counseling.* Nutritional counseling, when identified in the plan of care, must be performed by a qualified individual, which include dietitians as well as nurses and other individuals who are able to address and assure that the dietary needs of the patient are met. (3) *Spiritual counseling.* The hospice must: (i) Provide an assessment of the patient's and family's spiritual needs; (ii) Provide spiritual counseling to meet these needs in accordance with the patient's and family's acceptance of this service, and in a manner consistent with patient and family beliefs and desires; (iii) Facilitate visits by local clergy, pastoral counselors, or other individuals who can	**In some situations local clergy do not want to be involved**	iii)Provide reasonable facilitation of visits by local clergy, pastoral counselors, or other individuals who can support the patient's spiritual needs to the best of its ability.

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support the patient's spiritual needs to the best of its ability. The hospice is not required to go to extraordinary lengths to do so; and (iv) Advise the patient and family of this service.		
§ 418.66 Condition of participation: Nursing services—Waiver of requirement that substantially all nursing services be routinely provided directly by a hospice. (a) CMS may waive the requirement in § 418.64(b) that a hospice provide nursing services directly, if the hospice is located in a nonurbanized area. The location of a hospice that operates in several areas is considered to be the location of its central office. The hospice must provide evidence to CMS that it has made a good faith effort to hire a sufficient number of nurses to provide services. CMS may waive the requirement that nursing services be furnished by employees based on the following criteria: (1) The location of the hospice's central office is in a nonurbanized area as determined by the Bureau of the Census. (2) There is evidence that a hospice was operational on or before January 1, 1983 including— (1) Proof that the organization was established to provide hospice	**Need to provide waivers for urban areas as well. Nurses, are hard to recruit and retain in all areas of the state.** **Suggest allowing to contract for continuous care. This will increase access to this benefit.**	

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services on or before January 1, 1983; (2) Evidence that hospice-type services were furnished to patients on or before January 1, 1983; and (3) Evidence that hospice care was a discrete activity rather than an aspect of another type of provider's patient care program on or before January 1, 1983. (3) By virtue of the following evidence that a hospice made a good faith effort to hire nurses: (i) Copies of advertisements in local newspapers that demonstrate recruitment efforts; (ii) Job descriptions for nurse employees; (iii) Evidence that salary and benefits are competitive for the area; and (iv) Evidence of any other recruiting activities (for example, recruiting efforts at health fairs and contacts with nurses at other providers in the area). (b) Any waiver request is deemed to be granted unless it is denied within 60 days after it is received.		

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(c) Waivers will remain effective for 1 year at a time from the date of the request. (d) CMS may approve a maximum of two 1-year extensions for each initial waiver. If a hospice wishes to receive a 1-year extension, it must submit a request to CMS before the expiration of the waiver period, and certify that the conditions under which it originally requested the initial waiver have not changed since the initial waiver was granted.		
Non-Core Services **§ 418.70 Condition of participation: Furnishing of non-core services.** A hospice must ensure that the services described in § 418.72 through § 418.78 are provided directly by the hospice or under arrangements made by the hospice as specified in § 418.100. These services must be provided in a manner consistent with current standards of practice.		
§ 418.72 Condition of participation: Physical therapy, occupational therapy, and speech-language pathology. Physical therapy services, occupational therapy services, and speech-language pathology services must be available, and when provided, offered in a manner consistent with accepted standards of practice.		**§ 418.72 Condition of participation: Dietary counseling, Physical therapy, occupational therapy, and speech-language pathology.**
§ 418.74 Waiver of requirement—Physical therapy, occupational therapy, speech-language pathology, and dietary counseling. (a) A hospice located in a non-urbanized area may submit a written request for a waiver of the requirement for providing physical therapy, occupational therapy, speech-language pathology, and dietary counseling services. The hospice may seek a waiver of the requirement that it make physical		

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therapy, occupational therapy, speech-language pathology, and dietary counseling services (as needed) available on a 24-hour basis. The hospice may also seek a waiver of the requirement that it provide dietary counseling directly. The hospice must provide evidence that it has made a good faith effort to meet the requirements for these services before it seeks a waiver. CMS may approve a waiver application on the basis of the following criteria: (1) The hospice is located in a non-urbanized area as determined by the Bureau of the Census. (2) The hospice provides evidence that it had made a good faith effort to make available physical therapy, occupational therapy, speech-language pathology, and dietary counseling services on a 24-hour basis and/or to hire a dietary counselor to furnish services directly. This evidence must include— (i) Copies of advertisements in local newspapers that demonstrate recruitment efforts; (ii) Physical therapy, occupational therapy, speech-language pathology, and dietary counselor job descriptions; (iii) Evidence that salary and benefits are competitive for the area;		

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and (iv) Evidence of any other recruiting activities (for example, recruiting efforts at health fairs and contact discussions with physical therapy, occupational therapy, speech-language pathology, and dietary counseling service providers in the area). (b) Any waiver request is deemed to be granted unless it is denied within 60 days after it is received. (c) An initial waiver will remain effective for 1 year at a time from the date of the request. (d) CMS may approve a maximum of two 1-year extensions for each initial waiver. If a hospice wishes to receive a 1-year extension, it must submit a request to CMS prior to the expiration of the waiver period and certify that conditions under which it originally requested the waiver have not changed since the initial waiver was granted.		
§ 418.76 Condition of participation: Home health aide and homemaker services. All home health aide services must be provided by individuals who meet the personnel requirements specified in paragraph (a) of this section. Homemaker services must be provided by individuals who meet the personnel requirements specified in paragraph (j) of this section.		

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(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.		
(b) *Standard: Content and duration of home health aide classroom and supervised practical training.* (1) Home health aide		

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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;		

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(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		

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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 eliminati on; (x) Safe transfer techniques and ambulation. (xi) Normal range of motion and positioning. (xii) Adequate		

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(xiii) Any other task that the hospice may choose to have an aide perform. The hospice is responsible for training home health aides, as needed, for skills not covered in the basic checklist, as described in paragraph (b)(3)(ix) of this section. (4) The hospice must maintain documentation that demonstrates that the requirements of this standard are met.		
(c) *Standard: Competency evaluation*. An individual may furnish home health services on behalf of a hospice only after that individual has successfully completed a competency evaluation program as described in this section. (1) The competency evaluation must address each of the subjects listed in paragraphs (b)(1) through (b)(3) of this section. Subject areas specified under paragraphs (b)(3)(i), (b)(3)(iii), (b)(3)(ix), (b)(3)(x) and (b)(3)(xi) of this section must be evaluated by observing an aide's performance of the task with a patient. The remaining		

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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.		
(d) *Standard: In-service training.* A home health aide must receive at least 12 hours of in-service training during each 12-month period. In-service training may occur while an aide is furnishing care to a patient. (1) In-service training may be offered by any organization except one		

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

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found to have furnished substandard care (or for other reasons at the discretion of CMS or the State); (4) Was assessed a civil monetary penalty of $5,000 or more as an intermediate sanction; (5) Was found by CMS to have compliance deficiencies that endangered the health and safety of the home health agency's patients and had temporary management appointed to oversee the management of the home health agency; (6) Had all or part of its Medicare payments suspended; or (7) Was found by CMS or the State under any Federal or State law to have: (i) Had its participation in the Medicare program terminated; (ii) Been assessed a penalty of $5,000 or more for deficiencies in Federal or State standards for home health agencies; (iii) Been subjected to a suspension of Medicare payments to which it otherwise would have been entitled; (iv) Operated under temporary managemen		

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July 26, 2005

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

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

Dear Administrator McClellan:

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

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

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

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

Sincerely,

Val J. Halamandaris
President, NAHC

Janet E. Neigh
Director, HAA

418.3 - Definitions

Attending physician

(1) (i) Doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she performs that function or action; or
(ii) Nurse practitioner who meets the training, education and experience requirements as the Secretary may prescribe; and

(2) Is identified by the individual, at the time he or she elects to receive hospice care, as having the most significant role in the determination and delivery of the individual's medical care.

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

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

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

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

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

Subpart C – Patient Care

418.52 Condition – Patient's rights –

(a) Standard: Notice of rights.

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

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

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

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

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

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

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

(4) The hospice must maintain documentation showing that it has complied with the requirements of this section and that the patient or representative has demonstrated an understanding of these rights.

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

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

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

(1) The patient has the right—

(i.) To exercise his or her rights as a patient of the hospice;
(ii.)To have his or her property and person treated with respect; and
(iii.)To voice grievances regarding treatment or care that is (or fails to be) furnished and the lack of respect for property by anyone who is furnishing services on behalf of the hospice; and
(iv.)To not be subjected to discrimination or reprisal for exercising his or her rights.

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

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

Standard (e) Patient liability – Before care is initiated, patient must be informed, verbally and in writing, and in a language they can understand, of the extent to which payment may be expected from the patient, Medicare or Medicaid, third-party payers, or other resources of funding known to the hospice.

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

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

418.54 Condition – Comprehensive assessment of patient
The hospice must conduct and document in writing a patient-specific comprehensive assessment that identifies the patient's need for hospice care and services, and the patient's need for medical, nursing, psychosocial, emotional, and spiritual care. This care includes, but is not limited to, the palliation and management of the terminal illness and related medical conditions.

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

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

Standard (a) Initial assessment –
The hospice registered nurse must make an initial assessment visit within 24 hours after the hospice receives a physician's admission order for care (unless ordered otherwise by the physician), to determine the patient's immediate care and support needs.

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

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

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

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

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

Standard (c) Content of the comprehensive assessment – The comprehensive assessment must identify the physical, psychosocial, emotional, and spiritual needs related to the terminal illness that must be addressed in order to promote the hospice patient's well-being, comfort, and dignity throughout the dying process. The comprehensive assessment describes—

(1) The nature and condition causing admission (including the presence or lack of objective data and subjective complaints);
(2) Complications and risk factors that affect care planning;
(3) Factors that must be considered in developing individualized care plan interventions, including—
  (i.) Bereavement. An initial bereavement assessment of the needs of the patient's family and other individuals focusing on the social, spiritual, and cultural factors that may impact their ability to cope with the patient's death. Information gathered from the initial bereavement assessment must be incorporated into the bereavement plan of care.
  (ii.) Drug therapy. A review of the patient's prescription and over-the-counter drug profile, including but not limited to identification of the following—
    (i.) Ineffective drug therapy;
    (ii) Unwanted drug side and toxic effects; and
    (iii) Drug interactions.
(4) The need for referrals and further evaluation by appropriate health professionals.

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

The revised Standard (c) would now read (additions underlined): The comprehensive assessment must identify the physical, psychosocial, emotional, and spiritual needs related to the terminal illness that must be addressed in order to promote the hospice patient's well-being, comfort, and dignity throughout the dying process.

> **Factors that must be considered in developing individualized care plan interventions, include—**
>
> (1) **The nature and condition causing admission (including the presence or lack of objective data and subjective complaints);**
>
> (2) **Complications and risk factors that affect care planning, <u>e.g. individual's functional status and ability to understand and participate in the plan of care;</u>**
>
> (3) **<u>Imminence of death;</u>**
>
> (4) **<u>Severity of symptoms;</u>**
>
> (5) **Bereavement. An initial bereavement assessment of the needs of the patient's family and other individuals focusing on the social, spiritual, and cultural factors that may impact their ability to cope with the patient's death. Information gathered from the initial bereavement assessment must be incorporated into the bereavement plan of care.**
>
> (6) **Drug therapy. A review of the patient's prescription and over-the-counter drug profile, including but not limited to identification of the following—**
>
> **(i) Effective drug therapy;**
>
> **(ii) Drug side effects; and**
>
> **(iii) <u>Potential</u> Drug interactions.**
>
> (7) **The need for referrals and further evaluation by appropriate health professionals.**

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

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

Standard (d) Update of the comprehensive assessment -. The assessment update must be accomplished—

(1) As frequently as the condition of the patient requires, but no less frequently than every 14 days; and
(2) At the time of each recertification.

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

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

Standard (e) Patient outcome measures –

(1) The comprehensive assessment must include data elements that allow for measurement of outcomes. The hospice must measure and document data in the same way for all patients. The data elements must take into consideration aspects of care related to hospice and palliation.
(2) The data elements must be an integral part of the comprehensive assessment and must be documented in a systematic and retrievable way for each patient. The data elements for each patient must be used in individual patient care planning and in the coordination of services, and must be used in the aggregate for the hospice's quality assessment and performance improvement program.

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

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

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

(1) **Standard (a) Approach to service delivery** - The hospice must designate an interdisciplinary group or groups composed of individuals who work together to meet the physical, medical, social, emotional, and spiritual needs

of the hospice patients and families facing terminal illness and bereavement. Interdisciplinary group members must provide the care and services offered by the hospice, and the group in its entirety must supervise the care and services. The hospice must designate a qualified health care professional that is a member of the interdisciplinary group to provide coordination of care and to ensure continuous assessment of each patient's and family's needs and implementation of the interdisciplinary plan of care. The interdisciplinary group must include, but is not limited to, individuals who are qualified and competent to practice in the following professional roles:

(i) A doctor of medicine or osteopathy (who is not the patient's attending physician).
(ii) A registered nurse.
(iii) A social worker.
(iv) A pastoral, clergy, or other spiritual counselor.

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

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

Standard (c) Content of the plan of care -

(6)The interdisciplinary group's documentation of patient and family understanding, involvement, and agreement with the plan of care, in accordance with the hospice's own policies, in the clinical record.

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

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

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

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

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

418.58 Condition – Quality assessment and performance improvement –

Standard (a) – Program scope –

Standard (b) – Program data –

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

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

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

Standard (c) - Program activities –

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

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

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

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

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

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

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

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

Standard (d) – Performance improvement projects -

(1) The number and scope of distinct improvement projects conducted annually must reflect the scope, complexity, and past performance of the hospice's services and operations.

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

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

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

418.64 Condition – Core services – Standard (d) (1) Counseling services –. Bereavement counseling. The hospice must:

(i) Have an organized program for the provision of bereavement services furnished under the supervision of a qualified professional with experience in grief/loss counseling.

(ii) Make bereavement services available to the family and other individuals in the bereavement plan of care up to one year following the death of the patient. Bereavement counseling also extends to residents and employees of a SNF/NF, ICF/MR, or other facility when appropriate and identified in the bereavement plan of care.

(iii) Ensure that bereavement services reflect the needs of the bereaved.

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

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

(2) Nutritional counseling . Nutritional counseling, when identified in the plan of care, must be performed by a qualified individual, which include dietitians as well as nurses and other individuals who are able to address and assure that the dietary needs of the patient are met.

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

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

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

(i) Ordered by the physician or nurse practitioner;

(ii) Included in the plan of care;

(iii) Permitted to be performed under State law by such home health aide; and

(iv) Consistent with the home health aide training.

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

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

Standard (d) In-service training. A home health aide must receive at least 12 hours of in-service training during each 12-month period. In-service training may occur when an aide is furnishing care to a patient.

(1) In-service training may be offered by any organization except one that is excluded by paragraph (f) of this section, and must be supervised by a registered nurse.

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

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

Standard (h) - Supervision of home health aides –

i. A registered nurse or qualified therapist must make an onsite visit to the patient's home no less frequently than every 14 days to assess the home health aide's services. The home health aide does not have to be present during this visit. A registered nurse or qualified therapist must make an onsite visit to the location where the patient is receiving care in order to observe and assess each aide while he or she is performing care no less frequently than every 28 days.

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

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

Subpart D – Organizational Environment

418.100 Condition – Organization and administration of services. Standard (a) – . The hospice must ensure—

(1) That each patient receives and experiences hospice care that optimizes comfort and dignity; and

(2) That each patient experience hospice care that is consistent with patient and family needs and desires.

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

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

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

(1) Authorized by the hospice;

(2) Furnished in a safe and effective manner by personnel having at least the same qualifications as hospice employees; and

(3) Delivered in accordance with the patient's plan of care.

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

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

qualifications as hospice employees."

Standard (f) – Hospice satellite locations –

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

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

418.102 Condition – Medical director – The hospice must designate a physician to serve as medical director. The medical director must be a doctor of medicine or osteopathy who is either employed by, or under contract with, the hospice. When the medical director is not available, a physician designated by the medical director assumes the same responsibilities and obligations as the medical director. The medical director and physician designee coordinate with other physicians and health care professionals to ensure that each patient experiences medical care that reflects hospice policy.

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

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

Standard (b) Recertification – Before the recertification period for each patient, as described in § 418.21(a), the medical director or physician designee must review:

(1) The patient's clinical information; and
(2) The patient's and family's expectations and wishes for the continuation of hospice care.

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

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

Standard (c) Coordination of medical care – The medical director or physician designee, and the other members of the interdisciplinary group are jointly responsible for the coordination of the patient's medical care in its entirety. The medical director or physician designee is also responsible for directing the hospice's quality assessment and performance improvement program.

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

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

Standard (b) – Authentication – All entries must be legible, clear, complete, and appropriately authenticated and dated. All entries must be signed, and the hospice must be able to authenticate each handwritten and electronic signature of a primary author who has reviewed and approved the entry.

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

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

Standard (d) – Retention of records – Patient clinical records must be retained for 5 years after the death or discharge of the patient, unless State law stipulates a longer period of time.

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

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

Standard (e) – Discharge or transfer of care –

(1) If the care of a patient is transferred to another Medicare/ Medicaid-approved facility, the hospice must forward a copy of the patient's clinical record and the hospice discharge summary to that facility.

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

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

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

418.106 Condition – Drugs, controlled drugs and biologicals, medical supplies, and durable medical equipment – Standard (b) The hospice must have a written policy for tracking, collecting, and disposing of controlled drugs maintained in the patient's home. During the initial hospice assessment, the use and disposal of controlled substances must be discussed with the patient and family to ensure the patient and family are educated regarding the uses and potential dangers of controlled substances. The hospice nurse must document that the policy was discussed with the patient and family.

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

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

Standard (c) – Use and maintenance of equipment and supplies – (1) The hospice must follow manufacturer recommendations for performing routine and preventive maintenance on durable medical equipment. The equipment must be safe and work as intended for use in the patient's environment. Where there is no manufacturer recommendation for a piece of equipment, the hospice must develop in writing its own repair and routine maintenance policy. The hospice may use persons under contract to ensure the maintenance and repair of durable medical equipment.

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

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

418.108 Condition –Short-term inpatient care – Inpatient care must be available for pain control, symptom management, and respite purposes, and must be provided in a

participating Medicare or Medicaid facility.

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

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

Standard (a) – Inpatient care for symptom management and pain control – . Inpatient care for pain control and symptom management must be provided in one of the following:

(1) A Medicare-approved hospice that meets the conditions of participation for providing inpatient care directly as specified in § 418.110.
(2) A Medicare-participating hospital or a skilled nursing facility that also meets the standards specified in § 418.110(b) and (f) regarding 24-hour nursing services and patient areas.

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

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

418.110 Condition – Hospices that provide inpatient care directly – Standard (b) – Twenty-four hour nursing services – The hospice facility must provide 24-hour nursing services that meet the nursing needs of all patients and are furnished in accordance with each patient's plan of care.

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

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

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

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

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

Standard (o) – Seclusion and restraint – (1) The patient has the right to be free from seclusion and restraint, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. The term restraint includes either a physical restraint or a drug that is being used as a restraint. A physical restraint is any manual method or physical or mechanical device, material or equipment attached or adjacent to the patient's body that he or she cannot easily remove, that restricts free movement of, normal function of, or normal access to one's body. *A drug used, as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard treatment for a patient's medical or psychiatric condition.

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

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

418.112 Condition – Hospices that provide hospice care to residents of a SNF/NF, ICF/MR, or other facilities – Standard (b) Professional management. The hospice must assume full responsibility for professional management of the resident's hospice care, in accordance with the hospice conditions of participation and make any arrangements necessary for inpatient care in a participating Medicare/Medicaid facility according to Section 418.100.

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

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

Standard (d) – Medical director – The medical director and physician designee of the hospice must provide overall coordination of the medical care of the hospice resident that resides in an SNF, NF, or other facility. The medical director and physician designee must communicate with the medical director of the SNF/NF, the patient's attending physician, and other physicians participating in the provision of care for the terminal and related conditions to ensure quality care for the patient and family.

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

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

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

Standard (e) Written agreement.

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

(i) A significant change in the patient's physical, mental, social, or emotional status occurs;

(ii) Clinical complications appear that suggest a need to alter the plan of care;

(iii) A life threatening condition appears;

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

(v) The patient dies.

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

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

Standard (f) Hospice plan of care

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

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

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

Standard (g) Coordination of services. The hospice must provide the facility with the following information:

(1) Plan of care.

(2) Patient or patient's representative hospice consent form and advance directives.

(3) Names and contact information for hospice personnel involved in hospice care of the patient.
(4) Instructions on how to access the hospice's 24-hour on-call system.
(5) Medication information specific to the patient
(6) Physician orders.

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

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

Standard (h) Transfer, revocation or discharge from hospice care. Requirements for discharge or revocation from hospice care, § 418.104(e), apply. Discharge from or revocation of hospice care does not directly impact the eligibility to continue to reside in an SNF, NF, ICF/ MR, or other facility.

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

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

Standard (i) Orientation and training of staff – Hospice staff must orient facility staff furnishing care to hospice patients in the hospice philosophy, including hospice policies and procedures regarding methods of comfort, pain control, symptom management, as well as principles about death and dying, individual responses to death, patient rights, appropriate forms, and record keeping requirements.

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

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

418.114 Condition – Personnel qualifications for licensed professionals – Standard (b) Personnel qualifications for physicians, speech-language pathologists,

and home health aides.

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

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

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

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

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

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

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

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

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

HOMECARE & HOSPICE

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July 26, 2005

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

Attention: CMS-3844-P

Dear Dr. McClellan:

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

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

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

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

Following are AAHSA's comments:

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RESIDENTS RESIDING IN A FACILITY

Page 30858 / 30891

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

GENERAL COMMENTS:

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

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

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

RECOMMENDATION(S):

- This CoP cannot be successfully implemented absent conforming changes to the Requirements of Participation for Long Term Care Facilities.

- Changes to the RoPs and Interpretive Guidance must incorporate not only facility obligations, but also recognition and integration of the philosophy of hospice care for those residents electing these services.

- The effective date of this provision should be deferred pending completion of conforming amendments to the Requirements of Participation for Long Term Care Facilities and the Interpretive Guidance for Surveyors.

- In the interim, and at minimum, the [final] hospice CoP-418.112 should be incorporated by reference into the SNF/NF requirements, with implementation deferred until incorporation is effected.

- Clarification must be provided on how accountability will be determined if a negative [or potentially negative] outcome is identified under survey.

RECOMMENDATION(S):

- Coordination between nursing home and hospice oversight authorities at the Federal and State level is essential to ensure uniform understanding and consistent application of the requirements and related expectations at 418.112.

- Adequate notice and surveyor and provider training, i.e., for both hospice and nursing facilities, must be provided prior to implementation of this proposed standard and when changes to the RoPs are effected.

SPECIFIC COMMENTS

Page 30891

418.112 – Hospices that Provide Hospice Care to Residents of a SNF/NF, ICF/MR or Other Facilities. AAHSA questions the applicability of these

standards to "other facilities" or entities beyond SNF/NFs and ICFs/MR. For facilities where there is no federal oversight authority or jurisdiction, there is also no federal capability to distinguish and/or implement appropriate conforming or parallel regulatory standards (for example, all "other facilities" may not be required to have a medical director).

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

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

RECOMMENDATION(S):

- See AAHSA's recommendations under General Comments regarding needed amendment to the RoPs and Interpretive Guidance, deferred implementation pending incorporation of these changes.
- The RoPs and Interpretive Guidance must clearly allow nursing facilities to relinquish and/or assume secondary professional management responsibility for those residents electing the hospice benefit.
- Clarify how accountability with be determined if a negative [or potentially negative] outcome is identified under survey.

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

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

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

RECOMMENDATION(S):

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

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

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

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

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

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

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

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

RECOMMENDATION(S):

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

- The RoPs and Interpretive Guidance must clearly allow the nursing facility medical director to relinquish and/or assume secondary professional responsibility for the coordination of medical care for those residents electing the hospice benefit.

- Define "physician designee"

- Amend to clarify the distinction between coordination of care and primary responsibility for the provision of medical care for those residents electing hospice services.

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

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

RECOMMENDATION(S):

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

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

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

RECOMMENDATION(S):

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

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

RECOMMENDATION:

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

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

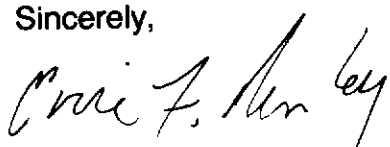
RECOMMENDATION(S):

- Amend proposed 418.112(i) and the RoPs for Long Term Care facilities to include that both administrative and direct care SNF/NF / ICF/MR staff must be oriented to the hospice philosophy and procedures.

- Corresponding language should mandate that hospice administrative and direct care staff must also be oriented to the governing practices and procedures of the SNF/NF or ICF/MR.

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

Sincerely,



Evvie F. Munley
Sr. Health Policy Analyst

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American Academy of Hospice and Palliative Medicine

Advancing the Science of Comfort ~ Affirming the Art of Caring

July 25, 2005

BY HAND DELIVERY

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Ave., S.W.
Washington, D.C. 20201

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

Dear Administrator McClellan:
We at the American Academy of Hospice and Palliative Medicine (AAHPM) appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS'") proposed changes to the Medicare and Medicaid Program proposed rule regarding Hospice Conditions of Participation. The AAHPM consists of nearly 2000 physicians who work in hospice and palliative medicine every day. As such, these rules are of vital importance to our members and to the patients they serve.

II. DEFINITIONS (PROPOSED §418.3)

We believe the **attending physician** should be the physician or nurse-practitioner **designated by the patient**, whether this physician is employed by the hospice or not. Clarification of this point would be helpful.

We are also very concerned about the definition of **drug restraint** as we will discuss below.

VIII. LICENSED PROFESSIONAL SERVICES (PROPOSED §418.62)

And
Proposed §418.100(e) *Standard: Professional management responsibility*

Licensed professionals should certainly **oversee the patient's hospice care**, but there may be other aspects of the patient's care such as dialysis unrelated to the terminal illness, that should remain under the control of others.

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XIV. MEDICAL DIRECTOR (PROPOSED §418.102)

The hospice should have the responsibility of designating another physician if the medical director is not available. This would be particularly important if the medical director suddenly became ill or for some other reason was not be able to arrange coverage.

Proposed §418.102(c) Standard: Coordination of medical care.

As stated above, we believe the medical director should be **responsible for overseeing the patient's hospice care.** As hospice extends to care for more patients with non-cancer illnesses that often have other medical problems, it will be even more important to involve other providers in the patient's care.
Likewise, we suggest that the **medical director participate in the quality improvement** efforts but not be held solely responsible this complex new process. Others will need to help to insure the best QA program.

XIX. SECLUSION AND RESTRAINT (PROPOSED §418.110(o))

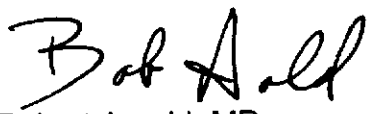
In some series, over 80% of hospice patients were found to develop delirium in their final days. Expert medical management can reverse some of these episodes of confusion and agitation, but the majority will require sedative medications to reduce the patient's distress. The medications most often used are the major (e.g. chlorpromazine, haloperidol) and minor (e.g. lorazepam, midazolam) tranquilizers. Rarely the barbiturates (e.g. phenobarbital) must be utilized. **The use of these medications for relief of the patient's distress is good medical practice, not drug or chemical restraint**. Clarification of this important point will prevent under treatment of these important symptoms.

Proposed §418.112(d) *Standard: Medical director*

We agree that the medical director or the physician designee should be charged with giving clinical guidance to the development of policies and procedures for nursing home residents, but the **overall responsibility for the patient's medical care should remain with the attending physician.**

We appreciate the opportunity to comment on these important regulations and would be happy to discuss these issues further.

Respectfully submitted,



Robert Arnold, MD
President

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JULY 26, 2005

BY HAND DELIVERY

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Ave., S.W.
Washington, D.C. 20201

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

Dear Administrator McClellan:

On behalf of VistaCare, a national hospice organization operating with 37 provider numbers in 14 states, I am pleased to provide you with our organization's comments on the Centers for Medicare and Medicaid Services' ("CMS'") proposed changes to the Medicare and Medicaid Program proposed rule regarding Hospice Conditions of Participation.

As the nation's third largest hospice provider and an organization dedicated to service excellence and regulatory compliance, VistaCare has greatly appreciated the opportunity to work with our colleagues at the National Hospice and Palliative Care Organization as we reviewed this long-awaited update. We have been actively involved with the NHPCO and our fellow providers throughout this process and fully support the recommendations advanced by the organization.

However, we do have a few additional comments and observations to share and have included those as part of this correspondence. I hope you'll find value in these comments and that you'll consider both these recommendations and the ones advanced by the NHPCO as you finalize the updates to the Hospice Conditions of Participation.

Proposed §418.54(a) *Standard: Initial Assessment*
VistaCare is in agreement with the NHPCO comments and requests for revisions to this proposed standard with one additional comment. We support the intent of this standard

in assuring a quick assessment and initiation of care, especially in light of the high number of short length of stay patients. The proposed language appears to require a physician's order for hospice. The hospice must obtain a physician's certification of the terminal illness (418.22), which is not the same as a physician's order for hospice care. Patients have the right to elect their hospice benefit which does not require a physician order for hospice. We do, however, recognize that there must be physician orders for care. As noted in the preamble of the proposed Hospice Conditions of Participation, hospices do meet with patients and families before the actual hospice care orders are received, and this standard would not prevent this practice. VistaCare requests that CMS clarify in the preamble that this practice would continue to be acceptable. We would also request clarification that a physician's order for care is required but that a physician's admission order to hospice is not.

If you have any questions about these recommendations or if there's anything further that I can do to support this important initiative, please don't hesitate to contact me at (480) 648-4530.

Thanks again for your time and for your valuable work within the hospice industry.

Respectfully submitted,

Richard R. Slager, Chairman and CEO

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VITAS®

INNOVATIVE HOSPICE CARE®

VITAS Healthcare Corporation
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Miami, FL 33131

July 26, 2005

Via Electronic Mail And Hand Delivery

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

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

Dear Dr. McClellan:

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

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

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

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

CMS Proposal: Section 418.52 – Patient's Rights

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

VITAS Comment

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

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

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

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

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

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

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

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

VITAS Comment

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

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

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

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

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

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

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

VITAS Comment

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

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

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

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

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

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

VITAS Comment

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

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

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

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

CMS Proposal: Section 418.60 – Infection Control

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

VITAS Comment

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

CMS Proposal: Section 418.64 – Core Services

The proposed rule would require a hospice routinely to provide substantially all core services directly by hospice employees. The rule would only allow a hospice to contract with another Medicare certified hospice under "extraordinary or non-routine circumstances," or with "highly specialized nursing services" that are "provided so infrequently that...[their] provision ...by direct hospice employees would be impracticable and prohibitively expensive...." The rule would provide that such emergency circumstances include: unanticipated periods of high patient loads, staffing shortages due to illness or other short-term temporary situations that interrupt patient care, and temporary travel of a patient outside of the hospice's service area. Outside contracting for continuous care would be prohibited. The proposed rule also would require that a social worker providing medical social services complete a psychological assessment of the patient.

VITAS Comment

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

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

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

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

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

CMS Proposal: Section 418.66 – Statutory Nursing Waiver

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

VITAS Comment

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

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

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

VITAS Comment

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

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

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

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

CMS Proposal: Section 418.78(e)

The proposed rule states at subsection (e) that "[v]olunteers must provide day-to-day administrative and/or direct patient care services in an amount that, at a minimum, equals 5 percent of the total patient care hours of all paid hospice employees and contract staff."

VITAS Comment:

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

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

We recommend amending this section as follows:

> (e) *Standard: Level of activity.* Volunteers must provide day-to-day administrative and/or direct patient care services in an amount that, at a minimum, equals 5 percent of the total ~~patient~~ routine home care patient care hours of all paid hospice employees and contract staff. The hospice must maintain records on the use of volunteers for patient care and administrative services, including the type of services and time worked. The volunteer hours that may be used in the calculation of the 5 percent rule may include volunteer travel time, actual time worked as a volunteer, and time spent documenting services provided; however, volunteer training and orientation time may not be included in the calculation.(suggested new language underscored)

CMS Proposal: Section 418.100 – Organization and Administration of Services

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

VITAS Comment

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

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

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

CMS Proposal: Section 418.102 – Medical Director

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

VITAS Comment

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

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

CMS Proposal: Section 418.104 – Clinical Records

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

VITAS Comment

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

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

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

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

VITAS Comment

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

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

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

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

CMS Proposal – 418.108 – Short-term Inpatient Care

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

VITAS Comment

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

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

CMS Proposal – 418.110 – Hospices That Provide Inpatient Care Directly

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

VITAS Comment

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

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

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

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

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

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

CMS Proposal: Section 418.112 – Residents Residing in a Facility

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

VITAS Comment

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our suggestions on revising this subsection are set forth below:

(e) *Standard: Written agreement.* The hospice and the facility must have a

written agreement that specifies the provision of hospice services in the facility. The agreement must be signed by authorized representatives of the hospice and the facility before the provision of hospice services. The written agreement must include at least the following:

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

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

(2)) Services to be provided by the hospice

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

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

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

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

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

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

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

(i) A significant change in the patient's physical, mental, social, or emotional status occurs;

(ii) Clinical complications appear that suggest a need to alter the plan of care;

~~(iii) A life threatening condition appears;~~

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

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

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

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

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

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

CMS Proposal: Section 418.114 – Personnel Qualifications for Licensed Professionals

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

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

VITAS Comment

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

CMS Impact Analysis

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

VITAS Comment

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

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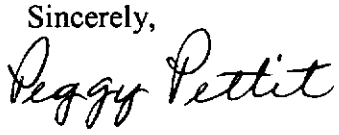
We appreciate the opportunity to submit comments, and would be pleased to answer questions or provide additional background, operational, or other information.

Sincerely,



Peggy Pettit
Executive Vice President
Chief Operating Officer

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National Hospice and Palliative Care Organization

July 26, 2005

BY HAND DELIVERY

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Ave., S.W.
Washington, D.C. 20201

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

Dear Administrator McClellan:

The National Hospice and Palliative Care Organization ("NHPCO") appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS'") proposed changes to the Medicare and Medicaid Program proposed rule regarding Hospice Conditions of Participation. NHPCO is the largest nonprofit membership organization representing hospice and palliative care programs and professionals in the United States. The organization is committed to improving end of life care and expanding access to hospice care with the goal of profoundly enhancing quality of life for people dying in America and their loved ones. NHPCO represents 80 percent of the hospices in the United States, and our members care for over 90 percent of the nation's hospice patients.

NHPCO welcomes this long-awaited update of the hospice conditions of participation and has appreciated the opportunity to work with CMS on a number of initiatives that contributed to the development of these proposed rules. We have reviewed these proposed rules carefully and have sought significant input from hospice providers throughout the country. NHPCO is pleased to submit these comments for your consideration.

I. OUTCOME-BASED PERFORMANCE MEASURES

CMS has requested comments on its proposal to require that hospices implement an outcome based internal performance improvement program, and has specifically asked for

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examples regarding clinical measures, patient experience of care measures, and systems measures specific to hospice care, including measures in development.

Currently, the Family Evaluation of Hospice Care (FEHC) and the End Result Outcome measures are the NHPCO tools used by many hospices to evaluate outcomes of clinical care. Further, member hospices collect data elements for the National Data Set that is comprised of data on structure and process such as employee retention, average length of stay, and average number of patient visits by discipline. NHPCO has developed a web-based system for submission of data for the NHPCO National Data Set and the FEHC, with an ability to aggregate and provide feedback information to participating hospices. These reports provide participating hospices with national level data to facilitate each program comparing their performance to an industry norm. The End Result Outcome Measures are also web-based; however, NHPCO is currently in the process of recruiting more hospices to collect data for these measures in order to develop a useful report.

Outcome measures regarding patient perception of care and bereavement services are currently in development by NHPCO and its research team. Survey tools should be available in the next two years. NHPCO will continue to identify and develop other outcome measures, and work with other vendors to develop hospice performance measures.

NHPCO is also a member of the National Quality Forum and is represented on the review committee for the Palliative and Hospice Care Quality project. While the first part of this project is to develop a framework and identify best practices in hospice and palliative care, it is anticipated that a second part of the project will focus on performance measures for endorsement. The NHPCO measures that include the FEHC, the End Result Outcome measures and the National Data Set, will be submitted for review and endorsement at that time. Any recommendations for research that result from this project will be explored by NHPCO.

Additional measures need to be identified, as NHPCO is committed to helping its members identify a core set of measures that address the six aims of the Institute of Medicine.[1] We are currently analyzing data from the National Data Set and the FEHC to develop measures of efficiency and equity, the two areas for which NHPCO does not have direct measures. As hospice and palliative care moves forward, adopting new technologies and developing new strategies for caring for people at the end of life, health services researchers in this field will continue to identify areas in practice that will benefit from evaluation with well-specified performance measures.

Like many others providing health care, many hospices find that performance measurement and reporting does pose challenges to organizations that are resource limited and/or are in rural areas where the challenges differ from their urban counterparts. It is not feasible to expect all hospices to be able to collect or submit performance measurement data within the next year (2006). Therefore, a reasonable timeframe for assisting those with the greatest needs is important. The measures currently available from NHPCO have been field tested for reliability,

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1 Institute of Medicine, *Crossing the Quality Chasm.* (Washington D.C., National Academy of Sciences, 2001)

feasibility and validity. However, not all NHPCO members currently have the infrastructure for collecting all of these measures or the capability of fully analyzing performance measurement data.

II. DEFINITIONS (PROPOSED §418.3)

NHPCO has the following comments and request for changes to the proposed definitions:

Attending Physician – We request that CMS clarify that the hospice medical director or hospice physician, or a nurse practitioner employed by the hospice, may function as a patient's attending physician if so designated by the patient. CMS has stated this in the Medicare Benefit Policy Manual, Chapter 9, section 40.1.3b, but there continues to be confusion around this issue and it would be helpful to have it clarified in the final rule. There is currently no language in this definition that would indicate that option.

Bereavement Counseling – Although hospices typically make bereavement counseling and/or bereavement services available to a broad range of individuals, and certainly to the patient's primary caregiver(s) and those the patient considers to be their "family" (whether or not such individuals are legally so designated), the statutory obligation is limited to the patient's immediate family. The requested change to this definition is consistent with the statutory requirement in Section 1861(dd)(2)(A)(i) of the Social Security Act.

As specified above, we request that this definition be changed to read as follows:

> *Bereavement counseling* means emotional, psychosocial, and spiritual support and services provided to the patient's immediate family after the death of the patient to assist with issues related to grief, loss, and adjusting.

Clinical Note – Hospice care focuses on the patient's psychosocial as well as physical needs, and a change in a patient's spiritual condition is significant and may necessitate a change in a patient's plan of care.

As specified above, we request that this definition be changed to read as follows:

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

Drug Restraint – NHPCO requests that this definition be changed to "Chemical Restraint", which is the more commonly used and accepted term. We are requesting that this change be made throughout the proposed rules. In addition, NHPCO is concerned that confusion may arise

from this proposed definition. In the management and palliation of symptoms related to a patient's terminal illness it is accepted protocol to prescribe medications that, in other settings, might be considered a chemical restraint. This concern is addressed more fully in proposed 418.110(o).

As specified above, we request that the wording of this definition be revised as follows:

> ~~*Drug*~~*Chemical restraint* means a medication used to control behavior or to restrict the patient's freedom of movement, which is not ~~standard~~ an accepted treatment for a hospice patient's medical or psychiatric condition.

Representative – Increasingly patients designate someone to have a "health care power of attorney" to make health-related decisions on behalf of the patient when the patient is unable to do so, or when they are capacitated but choose to have their health care power attorney make those decisions on their behalf. NHPCO feels it is important to recognize this mechanism.

As specified above, we request that the definition be changed to read as follows:

> *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, or designated under a health care power of attorney) to authorize or terminate medical care or to elect or revoke the election of hospice care on behalf of a terminally ill patient. ~~who is mentally or physically incapacitated~~. This may include a legal guardian.

In addition to the requested revisions listed above, NHPCO requests that the following additional definitions be considered for inclusion in the final rule:

Patient's Home – Hospices continue to face confusion among regulators and payers regarding whether various settings can be considered a hospice patient's home. NHPCO requests that CMS clarify that a patient's home is wherever the patient happens to reside, including skilled nursing facilities and a variety of other settings.

As specified above, we request that the following definition be added:

> *Patient's home* means wherever the patient resides, which may include a house, apartment, SNF/NF, ICF/MR, assisted living facility, adult home, shelter, or foster home.

Dietary Counseling – NHPCO requests that a definition of dietary counseling be added. The most common nutritional need is for education of the patient and family regarding patient nutrition expectations as the disease progresses. Alteration in nutritional status is an expected component of the hospice patient's illness course, and related education needs typically can be met by the hospice nurse with support from other team members. In the unusual situation in which a hospice patient requires complex medical nutritional services that are beyond the normal disease process (e.g. complicated feeding tube calculations or mechanical esophageal obstruction), services necessary to meet these needs should not be considered "dietary

counseling" and the hospice should be able to contract with a registered dietitian or other appropriate professional to provide these services.

As specified above, we request that the following definition be added:

> *Dietary counseling* means education and interventions provided to the patient and family regarding appropriate nutritional intake as the patient's condition progresses. Dietary counseling is provided by qualified individuals, which may include registered nurses, dietitians and nutritionists, when identified in the patient's plan of care.

III. PATIENT'S RIGHTS (PROPOSED §418.52)

NHPCO welcomes the addition of a provision specifically addressing patients' rights. The hospice philosophy of care is based on the concept of promoting an individual's right to make decisions about how they want to spend their final days, living and dying in comfort and with dignity. However, we do have concerns about some of the language in the proposed regulation, and also have suggestions for additions.

Proposed §418.52(a) ***Standard: Notice of rights***

Proposed §418.52(a)(1), requires that hospices provide patients and their representatives with verbal and written notice of the patient's rights and responsibilities in a language and manner the patient understands. NHPCO is concerned that if this requirement is interpreted literally it could be extremely burdensome for many hospice programs in ethnically diverse areas. In some hospice service areas, there may be patients that speak hundreds of different languages and dialects, and hospices do not have the resources to translate their materials into every language they may encounter. Hospices use a variety of methods to communicate with patients, ensuring that they understand their rights and responsibilities.

Hospices need the flexibility to address this requirement in a way that takes into account the prevalence of a particular language in the hospice's service area, the size of the hospice program and its policies and procedures for addressing communication barriers. We would ask CMS to specify that hospices should develop and adhere to their own policies regarding how they will address the communication needs of patients, and to clarify in the preamble to the final rule or the interpretive guidelines that it may be permissible to ensure that patients understand their rights via an interpreter, family member, or someone else who understands and can communicate these rights to the patient.

As specified above, we request that proposed §418.52(a)(1) be revised as follows:

(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 addresses the communication needs of the patient ~~understands~~ during the initial evaluation visit in advance of furnishing care.

Proposed §418.52(a)(3), requires informing the patient and family of the hospice's drug policies and procedures regarding the tracking and disposal of controlled substances. NHPCO is concerned about the use of the term "tracking" in this standard. As we understand it, the tracking procedure would require that the hospice nurse account for every dosage at every visit and make a record of the count, which would be extremely onerous and likely not well received by patients. NHPCO proposes the use of the term "monitoring," which would allow the hospice to have a policy that is flexible and can be implemented in a way to take into account the particular patient and family circumstances.

There also is confusion regarding the expected time frame for meeting this requirement, since in this section of the proposed regulations the implication is that patients and families would be informed of the hospice's drug policies "during the initial evaluation visit in advance of furnishing care" (consistent with the standard where this provision is placed). However, proposed §418.106(b), requires that the use and disposal of controlled substances must be discussed with the patient and family during the initial hospice assessment. In light of the similar intents of proposed §418.52(a)(3) and §418.106(b), and that the need to inform patients regarding a hospice's drug policies is not something one would typically think of as a "right", NHPCO requests that CMS delete proposed §418.52(a)(3). It is more appropriately placed under the proposed §418.106 condition of participation related to drugs.

While our preference would be to have 418.52(a)(3) deleted to avoid redundancy and potential confusion with 418.106(b), we request, at a minimum, that CMS consider the fragility of patients and their families at the time of admission to hospice care. The admission process includes, by necessity, an overwhelming amount of information that must be conveyed to and understood by patients and their families. Including additional information related to the hospice's drug policies and procedures in this early stage of hospice care (when it may not be immediately relevant) poses an unnecessary burden during an already difficult time. If CMS is unwilling to delete proposed §418.52(a)(3), we request that the language of this provision be revised.

As specified above, we request that proposed §418.52(a)(3) be deleted or, at a minimum, revised as follows:

(a) Standard: Notice of rights.

(3) The hospice must ~~inform~~ provide the patient and family with written information ~~of~~ regarding the hospice's drug policies and procedures, including the

policies and procedures regarding the ~~tracking~~ monitoring and disposing of controlled substances, that can be reviewed with the patient and family during the comprehensive assessment.

Proposed §418.52(a)(4) requires the hospice to maintain documentation that the patient or representative has demonstrated an understanding of their rights. NHPCO requests that CMS change "demonstrated an understanding" to "been informed of". If this change cannot be made, we request that CMS provide guidance on how a hospice would document that a patient or representative has "demonstrated" that they understand the rights addressed in this standard. We would recommend that a patient or representative's signature indicating that they have received their admission packet which includes information about these rights should be sufficient, and we request that the preamble to the final rule and/or the interpretive guidelines address this recommendation.

As specified above, we request that proposed §418.52(a)(4) be revised as follows:

(a) Standard: Notice of rights.

(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~~ been informed of these rights.

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

In proposed §418.52(b)(1), regarding the exercise of rights and respect for property and person, we would ask CMS to include the following additional rights:

- the right to receive information about the services covered under the Medicare Hospice Benefit
- the right to be involved in developing their plan of care, and
- the right to refuse treatment.

In proposed §418.52(b)(3), we would ask that the phrase "and practice" be added after "in accordance with State law", because it is our understanding that there are states in which the law itself may not specify who should be the patient's representative under certain circumstances, but standards or procedures have been developed and/or accepted by the State's courts.

In proposed § 418.52(b)(4), NHPCO is concerned about how this provision may be interpreted and the burdens it may place on hospices. For example, we are concerned about the requirement that hospices report all "alleged" violations involving "mistreatment", and ask that the term "mistreatment" be deleted because it is too vague and subject to varied

interpretation. It is not unusual for patients to feel that a family member or other person is not paying enough attention to them or not treating them as they would like, and they may even complain that they are being "mistreated", but this typically does not involve circumstances that would warrant reporting to state and local authorities.

NHPCO is also concerned about the requirement that all "alleged" violations be reported to state and local bodies, including the state survey and certification agency, even before the hospice has had an opportunity to investigate and determine whether the allegations are substantiated. We are requesting that this be revised to defer to state law. In this same provision we also request that the time frame for reporting be changed to within 5 working days of *becoming aware of* the incident. Hospice personnel are not necessarily in a patient's home every day, and cannot be expected to report an incident until after they have become aware of it.

As specified above, we request that proposed §418.52(b) be revised as follows:

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

(1) The patient has the right—

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

(ii.) To have his or her property and person treated with respect; ~~and~~

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

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

(v.) To be informed of the full range of services available under the Medicare hospice benefit;

(vi.) To be involved in developing his or her plan of care; and

(vii.) To refuse treatment.

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

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

(4) The hospice must—

(i.) Ensure that all alleged violations involving ~~mistreatment~~, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property are reported to State and local bodies having jurisdiction (including to the State survey and certification agency), to the extent required by State law, within at least 5 working days of becoming aware of the incident, and immediately to the hospice administrator. Investigations and/or documentation of all alleged violations must be conducted in accordance with established procedures.

(ii.) Immediately investigate all alleged violations and immediately

take action to prevent further potential abuse while the alleged violation is being verified;

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

(iv.) Investigate complaints made by a patient or the patient's family or representative regarding treatment or care that is (or fails to be) furnished, lack of respect for the patient or the patient's property by anyone furnishing services on behalf of the hospice, and document both the existence of the complaint and the steps taken to resolve the complaint.

Proposed §418.52(e) *Standard: Patient liability*

Providers have commented that it would be very difficult to determine the patient's liability at the time of admission. For patients who reside in skilled nursing facilities, the determination of patient liability and responsibility as it relates to Medicaid room and board and the collection of the patient's share of cost is becoming increasingly problematic across the country, as Medicaid programs utilize provider tax programs, various reimbursement mechanisms and managed care. NHPCO recommends that when the patient is in a nursing facility and their room and board is paid by Medicaid, the responsibility for informing the patient of his or her liability should remain with the nursing facility since the facility is directly involved with the Medicaid program and is therefore better able to address payment problems with the patient or responsible party. This could be clarified in the preamble to the final rule.

As for patient liability for services not covered by the hospice, information on what Medicare and Medicaid will cover for hospice services is usually included in the hospice's admission packet. Since it is difficult to anticipate all of the individual's care needs, a hospice program would have difficulty informing the patient of his or her liability "before care is initiated."

Consistent with the concerns outlined above in reference to 418.52(a)(1), NHPCO also requests that in this standard, consideration be given to the difficulty many hospice programs would have meeting the requirement "and in a language that he or she can understand."

As specified above, we request that proposed §418.52(e) be revised as follows:

> (e) *Standard: Patient liability.* ~~Before care is initiated, t~~The patient must be informed, ~~verbally and in writing, and in a language~~ in a manner that he or she can understand, of the extent to which payment may be expected from the patient, Medicare or Medicaid, third-party payers, or other resources of funding known to the hospice.

IV. COMPREHENSIVE ASSESSMENT AND TIME FRAMES (PROPOSED §418.54)

NHPCO welcomes the addition of provisions regarding assessment of the patient, because this is essential to identifying and addressing each patient's specific needs and goals. We agree with the value and importance of completing a comprehensive, interdisciplinary, patient-specific assessment, and we understand the role of this assessment in the development of the patient's plan of care. The observations and recommendations of members of the IDG constitute the comprehensive assessment, and are the basis upon which the plan of care is developed. However, NHPCO and its provider members have major concerns about certain aspects of the proposed requirements.

The introductory provision of proposed §418.54, states that the hospice's assessment of the patient's care needs "includes, but is not limited to, the palliation and management of the terminal illness and related conditions." NHPCO is concerned that hospices would be held responsible for assessing care needs beyond their expertise, which is in the palliation and management of terminal conditions and related illnesses. NHPCO requests that CMS revise this provision to clarify that the hospice's obligation is to identify the patient's care needs as they relate to the patient's terminal illness.

Also in this section, we request that CMS change "terminal illness and related medical conditions" to "terminal condition and related illnesses" since a patient's terminal diagnosis may not be based on a single illness but rather on a combination of factors.

As specified above, we request that the introductory provision of proposed §418.54 be revised as follows:

> *§ 418.54 Condition of participation: Comprehensive assessment of the patient.* The hospice must conduct and document in writing a patient-specific comprehensive assessment that identifies the patient's need for hospice care and services, and the patient's need for medical, nursing, psychosocial, emotional, and spiritual care. This identification of care needs includes, ~~but is not limited to~~, the palliation and management of the terminal ~~illness~~ condition and related illnesses ~~medical conditions~~.

Proposed §418.54(a) *Standard: Initial Assessment*

NHPCO has several comments and requests for revisions to this proposed standard. We request that the standard specify that the initial assessment may be done by a hospice physician as well as a hospice registered nurse. We also request that CMS expand the exception to the 24 hour time frame to include situations when the patient or representative request a longer period before the initial assessment visit is made. Patients sometimes request that the assessment visit be scheduled to accommodate their particular situations or needs. For example, a patient may be waiting for family members to arrive from out of state, and may want them to be present during the assessment visit.

NHPCO also requests that CMS clarify in the preamble that the requirement of this standard is met so long as a hospice registered nurse makes the initial assessment visit within the 24 hour timeframe, but that other members of the interdisciplinary group also may visit the patient, either with the registered nurse or prior to the nurse's visit.

Although we agree that the initial assessment visit should be completed by a registered nurse or physician, we have concerns about the severe nursing shortage in the United States and the impact this requirement could have on hospices. We request that CMS be sensitive to this issue and consider some flexibility in revising the 24 hour time frame should the nursing shortage persist.

As specified above, we request that proposed §418.54(a) be revised as follows:

> (a) *Standard: Initial assessment.* The hospice registered nurse or hospice physician 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 or as requested by the patient or representative), to determine the patient's immediate care and support needs.

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

NHPCO has serious concerns about the proposed requirement that the comprehensive assessment be completed within 4 calendar days after the patient elects the hospice benefit. While a patient's immediate care and support needs would be identified during the initial assessment visit, and the hospice would begin addressing them before the comprehensive assessment is done, completion of a comprehensive assessment can take up to 7 days, for a variety of reasons. For example, patients electing hospice are often in crisis with severe pain. They do not want and/or are unable to participate in having other needs assessed until their pain is under control, which can take up to several days.

Also, when patients have complicated medical needs and/or multiple caregivers, it can require more than 4 days to gather information and make contact with all of the individuals necessary for the completion of a comprehensive assessment. A longer time frame will help ensure that the vast majority of patients and families receive the benefit of all disciplines, including social work and spiritual care. In rural areas, hospices utilize part time social workers and chaplains, making the completion of an assessment within 4 days not feasible, especially with weekend admissions. Allowing 7 calendar days for completion of the comprehensive assessment is also more manageable for patients and families given the activity attendant to the admission of a patient to hospice. We strongly urge CMS to allow hospices up to 7 days to complete the comprehensive assessment, but certainly no fewer than 5 days. Providers acknowledge that comprehensive assessments should be completed as soon as feasible for patients who are in crisis and/or whose death is imminent, but for most patients, a better comprehensive assessment could be provided if hospices are allowed sufficient time for its completion.

NHPCO also requests that CMS clarify what is required of the various IDG members, since a number of hospice providers and state associations have questioned whether this standard would require all members of the IDG to visit the patient as part of the comprehensive assessment. It is our understanding that this is not the case, and that the comprehensive assessment process will vary from patient to patient depending on the patient's specific circumstances, but may involve in-person meetings and communication, telephone calls, e-mails and team meetings.

To alleviate confusion regarding consultation with the attending physician, NHPCO requests that CMS provide clarification in the preamble to the final rule and/or the interpretive guidelines that the IDG's consultation with the patient's attending physician regarding the comprehensive assessment could occur by telephone.

As specified above, we ask that proposed 418.54(b) be revised as follows:

> (b) *Standard: Time frame for completion of the comprehensive assessment.* The hospice interdisciplinary group in consultation with the individual's attending physician, must complete the comprehensive assessment no later than ~~4~~ 7 calendar days after the patient elects the hospice benefit.

Proposed §418.54(c) *Standard: Content of the comprehensive assessment*

NHPCO has a number of concerns about the organization of this standard and believes that, as drafted, it places too much emphasis on bereavement and drug therapy, and detracts from the key purpose of the comprehensive assessment, which is to identify the patient's physical, psychosocial, emotional and spiritual needs. We also believe other key elements should be added. For those reasons we are requesting a restructuring of this proposed standard.

In addition to the elements identified by CMS, NHPCO believes the comprehensive assessment should include consideration of: (1) the functional status of the patient, which includes their ability to understand their condition and proposed treatments, their ability to participate in planning their care, and their ability to perform activities of daily living and self-care; (2) the imminence of the patient's death, because so many patients are referred to hospice in the last few days of life, and therefore it is vital to take this into consideration in determining the patient's immediate care needs and prioritizing the care and services that should be provided; and (3) the severity of the patient's symptoms, which also is essential to assist in identifying and prioritizing the patient's and family's most immediate needs.

With respect to the requirement to review the patient's drug profile, we propose changing the proposed requirement to identify "ineffective" drug therapies, to identifying the effectiveness of drug therapies. This would be more comprehensive and would better reflect the reality that most drugs are not either effective or ineffective, but rather fall somewhere along a continuum. Similarly, NHPCO proposes changing "Unwanted drug side and toxic effects" to "drug side effects", which would be more comprehensive and reflect the range of effects that

may be caused by drug therapies. We believe a "toxic" effect would fall within the definition of a "side effect", and therefore is unnecessary.

We also request that CMS acknowledge that while hospices can evaluate a patient's drug profile and identify those drug therapies they believe to be less effective and those that have potentially problematic side effects, hospices have a limited ability to dictate what drugs a patient takes. Hospices can control what drugs are included in the hospice plan of care, and therefore are paid for by hospice, but they often cannot control what drugs a patient may choose to take, or be prescribed, particularly for reasons unrelated to the terminal illness. And certainly we would like for it to be clear that identification of a patient's drug therapies as part of the comprehensive assessment does not require that those drugs be included in the hospice plan of care and provided by hospice, unless the IDG and the attending physician so determine. The statute makes clear that payment with respect to hospice care is not made for items or services that are not reasonable and necessary for the palliation and management of the terminal condition, but there have been problems with hospices being held financially responsible for any drug identified on the plan of care.

As specified above, we request that proposed 418.54(c) be revised as follows:

> (c) *Standard: Content of the comprehensive assessment.* The comprehensive assessment must identify the physical, psychosocial, emotional, and spiritual needs related to the terminal illness that must be addressed in order to promote the hospice patient's well-being, comfort, and dignity throughout the dying process. The comprehensive assessment ~~describes~~ must take into consideration the following factors:
>
> (1) The nature and condition causing admission (including the presence or lack of objective data and subjective complaints);
> (2) Complications and risk factors that affect care planning,
> (3) Functional status, including the individual's ability to understand and participate in their own care;
> (4) Imminence of death;
> (5) Severity of symptoms;
> (6) ~~*Drug therapy.*~~ Drug profile. A review of the patient's prescription and over-the-counter drug profile, including but not limited to identification of the following—
> (i.) ~~Ineffective~~ Effectiveness of drug therapy;
> (ii) ~~Unwanted~~ Drug side ~~and toxic~~ effects; and
> (iii) Drug interactions.
> (7) *Bereavement.* An initial bereavement assessment of the needs of the patient's immediate family ~~and other individuals~~ focusing on the social, spiritual, and cultural factors that may impact their ability to cope with the patient's death. Information gathered from the initial bereavement assessment must be incorporated into the bereavement plan of care.
> (8) The need for referrals and further evaluation by appropriate health professionals.

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

NHPCO is concerned about timing issues under the proposed rule because the update of the comprehensive assessment would have to be accomplished at least every 14 days, and at the time of recertification. NHPCO requests that CMS change the 14 day time frame to 15 days. Although most hospices would still update the comprehensive assessment every 14 days, the additional day would allow for flexibility to accommodate holidays. For example, if the update of the comprehensive assessment typically is accomplished at the meeting of the interdisciplinary team every other Monday, the team should be allowed to meet on a Tuesday one week if there is a Monday holiday. We also request that the requirement to update the comprehensive assessment at the time of each recertification be deleted. The update would be done as needed, but at least every 14 days, so there is no need to mandate that it also be done prior to each recertification, which in some cases will require that updates be done within just a few days of one another.

As specified above, we request that proposed 418.54(d) be revised as follows:

> (d) *Standard: Update of the comprehensive assessment.* The update of the comprehensive assessment must be accomplished by the hospice interdisciplinary group and must consider changes that have taken place since the initial assessment. It must include information on the patient's progress toward desired outcomes, as well as a reassessment of the patient's response to care. The assessment update must be accomplished—
>
> (1) As frequently as the condition of the patient requires, but no less frequently than every ~~14~~ 15 days; and
>
> ~~(2) At the time of each recertification.~~

Outcome Measures (proposed §418.54(e))

NHPCO appreciates the flexibility provided by CMS on how the data elements will be determined and how they will be integrated into the comprehensive assessment. Providers have expressed concerns that this requirement will be burdensome on small hospices, and that many hospices will need to make major changes to be able to use the data collected. For many providers in different parts of the country, data collection is in its infancy. Many hospices and state hospice associations commented that smaller hospices have difficulty understanding the value and return on investment of this requirement, especially when faced with finite resources – time, people and money. Another concern expressed is that patient outcome measures may take some time to develop and that currently, not many outcome measures are in place.

Other providers suggested that a list of possible outcome measures be provided as examples so that providers would have a clearer understanding of the intention of CMS. A possible list might include pain management, fall risk and prevention, adverse drug reactions, medication reconciliation, life closure, device-related urinary tract infections, management of

documentation, national patient safety goals implementation, wound management, adequacy of communication with the attending physician, home health aide supervision, client response to pain management strategies and medication compliance, documentation of level of care changes, and quality of care at the time of death. With a list of possible outcome measures, CMS could also provide some guidance to give hospice programs a basic foundation in what is expected under this proposed new standard.

NHPCO is able to assist the hospice industry with standardizing data elements so that they can be benchmarked between providers. Providers can also be assured that much of the data is already collected in the patient's clinical record.

NHPCO is not requesting any changes to this proposed standard.

V. PLAN OF CARE OR COORDINATION OF SERVICES (PROPOSED §418.56)

Proposed §418.56(a) ***Standard: Approach to service delivery***

In proposed §418.56(a)(1)(i) we request that CMS delete the limitation that the physician member of the IDG may not be the patient's attending physician, since the hospice medical director or other hospice physician may serve as the patient's attending physician. There are many scenarios in which this could cause unnecessary distress to the patient and family. Examples include: the physician who has been caring for the patient prior to the patient's election of the hospice benefit does not wish to act as the patient's attending physician once the patient elects hospice; the hospice medical director was already the patient's attending physician before the patient elected hospice; the patient chooses to designate a hospice physician as their attending physician rather than the physician previously overseeing their care; or, patients electing the hospice benefit do not have a relationship with a physician who can function as the attending physician, and therefore the hospice medical director or other hospice physician functions in that role.

The language in proposed §418.56(a)(1)(iv) specifying that the IDG must include a "pastoral, clergy or other spiritual counselor" is inconsistent with the statute (Social Security Act §1861(dd)(2)(B)(i)) and would unduly limit the types of counselors who could serve on the IDG. We are requesting that this be revised as noted below.

Proposed §418.56(a)(2), regarding designation of a single interdisciplinary group to establish policies governing the day-to-day provision of hospice care and services, is inconsistent with current practice and is overly prescriptive. Typically, hospices designate one of their IDGs to also establish these policies, or appoint a separate interdisciplinary group that is tasked with establishing policies and overseeing day-to-day provision of hospice care and services. Therefore, we are requesting revisions to this provision, as noted below, to allow the hospice to select and designate the individuals best suited to this role, whether or not they otherwise all serve on the same IDG.

As specified above, we request that proposed 418.56(a) be revised as follows:

(a) *Standard: Approach to service delivery.*

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

(i) A doctor of medicine or osteopathy ~~(who is not the patient's attending physician)~~.

(ii) A registered nurse.

(iii) A social worker.

(iv) A pastoral~~, clergy,~~ or other ~~spiritual~~ counselor.

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

Proposed §418.56(b) *Standard: Plan of care*

NHPCO requests that this standard be revised to accommodate the fact that the responsibilities assumed by patients, families and caregivers in providing care and services varies, and the hospice's responsibility to provide education and training to these individuals should vary accordingly. For example, a family member may be involved in making decisions but not in the actual provision of certain types of care. In that situation the hospice should not be responsible for training that person to provide the care to the patient. As set forth below, we are proposing a revision that would allow the hospice to tailor their education and training of individuals to their assumed and expected responsibilities for providing care.

As specified above, we request that proposed 418.56(b) be revised as follows:

(b) *Standard: Plan of care.* All hospice care and services furnished to patients and their families must follow a written plan of care established by the hospice interdisciplinary group in collaboration with the attending physician. The hospice must ensure that each patient and family and primary caregiver(s) receive education and training provided by the hospice as appropriate to their

responsibilities for the care and services identified in the plan of care.

Proposed §418.56(c) *Standard: Content of the plan of care*

We have a number of requested revisions regarding the content of the plan of care, which we believe will better serve the needs of patients and provide hospices with greater flexibility to meet patient needs. We believe the introductory section could be interpreted too broadly, and therefore we propose specifying that the plan of care is focused on services necessary for the palliation or management of the terminal condition. We believe this change is necessary because the Medicare statute defines "hospice care" to include any item or service specified in the plan of care and for which payment may otherwise be made under Medicare. This change would clarify that the hospice is not responsible for care planning related to treatment of the patient's health problems that are unrelated to the palliation and management of the terminal condition.

NHPCO believes proposed §418.56(c)(2) requiring a detailed statement of the scope and frequency of services is overly prescriptive and inconsistent with CMS' intended shift to an outcome-oriented and patient-centered approach. Many patients have very short lengths of stay in hospice, and because of the acuity of the condition of many patients, their needs with respect to the scope and frequency of services may change often and unexpectedly. We are proposing revisions that would give hospices more flexibility to adapt to patients' changing needs and desires without being held to specific requirements and timeframes that may no longer be appropriate after a short period of time.

We are requesting changes to §418.56(c)(6) to acknowledge that even when patients agree with the plan of care, some or all of their family may not, and the level of understanding and agreement among these individuals regarding the plan of care may vary. We believe the hospice should be able to document the patient's understanding, involvement and agreement with the plan of care, and to document discussions about the plan of care with the family, and the hospice's perceptions regarding the level to which the family understands and/or agrees with the plan of care. However, the hospice cannot assure that all family members will understand or agree with the hospice patient's plan of care.

As specified above, we request that proposed 418.56(c) be revised as follows:

> (c) *Standard: Content of the plan of care*. The hospice must develop a written plan of care for each patient that reflects prescribed interventions based on the problems identified in the initial comprehensive and updated comprehensive assessments, and other assessments. The plan of care must ~~include~~ address services for the palliation and management of the terminal condition, including ~~but not be limited to—~~
>
> (1) Interventions to facilitate the management of pain and symptoms;
> (2) A ~~detailed~~ statement of the anticipated scope and frequency of services necessary to meet the ~~specific~~ changing patient and family needs;

(3) Measurable targeted outcomes anticipated from implementing and coordinating the plan of care;
(4) Drugs and treatment necessary to meet the needs of the patient;
(5) Medical supplies and appliances necessary to meet the needs of the patient; and
(6) The interdisciplinary group's documentation of the patient's understanding, involvement, and agreement, and the family's level of understanding, involvement, and agreement with the plan of care, in accordance with the hospice's own policies, in the clinical record.

VI. QAPI (PROPOSED §418.58)

Comments that NHPCO received from providers on this condition of participation and its related standards support CMS' commitment to significantly strengthen the current quality assurance requirement. Concerns that were noted include the financial impact on small programs, and a potential for a redirection of limited resources to be used for non-patient care activities. Several providers also suggested that having domains defined in the standards would help focus outcome measurement accordingly.

Proposed §418.58(a) *Standard: Program scope.*

The hospice industry is in the early stages of development in identifying and measuring data for performance improvement purposes. It is NHPCO's hope that CMS would recognize and ensure leniency in this area.

Proposed §418.58(d) *Standard: Performance improvement projects.*

Providers had questions about the number and complexity of quality improvement projects. NHPCO would recommend some discussion in the preamble of the final rule that would answer the following questions: How is CMS going to determine measures of "complexity" for the hospice's performance improvement project? How would the complexity and scope be judged? What is an adequate number of quality improvement projects? If a hospice participates in a national quality improvement project pertaining to an issue consistent across the majority of hospices, would that satisfy this standard?

NHPCO would suggest that language in the preamble encourage hospice providers to participate in national quality improvement projects. It provides an opportunity for the whole industry to adopt and work on specific performance improvement areas that may apply to a majority of hospices in the country. A good example of a national performance improvement project would be the measurement and improvement of pain management. The appropriate management of pain is a priority for Medicare beneficiaries and is one of the national priorities in the Institute of Medicine report *Crossing the Quality Chasm*[2]. Hospices should

[2] Institute of Medicine, *Crossing the Quality Chasm*,(Washington, D.C., National Academy of Sciences, 2001

participate in developing a national response.

As specified above, we request that proposed §418.58(d) be revised as follows:

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

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

VII. INFECTION CONTROL (PROPOSED §418.60)

We believe this proposed regulation reflects current standards of practice in health care. NHPCO has no comments.

VIII. LICENSED PROFESSIONAL SERVICES (PROPOSED §418.62)

NHPCO requests that the requirement that licensed professionals actively participate in the coordination of all aspects of the patient's care be limited to the patient's hospice care, since hospices cannot control other aspects of their patients' care.

As specified above, we request that proposed §418.62(b) be revised as follows:

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

IX. CORE SERVICES (PROPOSED §418.64)

NHPCO is concerned that the revised core services provision, as drafted, could be interpreted to limit the flexibility that always has been available to hospices to use contracted staff, if necessary, to supplement hospice employees in order to meet the needs of patients during periods of peak patient loads or under extraordinary circumstances. In proposed §418.64 CMS has added a sentence to address the changes made by section 946 of the Medicare Modernization Act, which specifies that a hospice may enter into arrangements with another Medicare-certified

hospice to obtain core hospice services under certain circumstances, such as when a hospice patient travels outside the hospice's service area for a limited period of time. We request that CMS clarify that this provision does not limit hospices to contracting only with another hospice, and that hospices also may use contracted staff from a nursing registry, home health agency or other entity under extraordinary circumstances, as is currently permitted. In some areas, contracting with another hospice may not be possible, either because there are no other hospices nearby, or for competitive or other reasons the hospice may not be willing or able to provide staffing to another hospice, therefore it is essential that hospices continue to have the flexibility to use contracted staff from other sources in order to meet patient needs when extraordinary circumstances arise.

As specified above, we request that proposed §418.64 be revised as follows:

> 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, use contracted staff if necessary to supplement hospice employees in order to meet the needs of patients during periods of peak patient loads or under extraordinary circumstances. A hospice may also enter into a written arrangement with another Medicare certified hospice program for the provision of core services to supplement hospice employee/staff to meet the needs of patients. Circumstances under which a hospice may enter into a written arrangement for the provision of core services include: Unanticipated periods of high patient loads, staffing shortages due to illness or other short-term temporary situations that interrupt patient care; and temporary travel of a patient. If contracting is used, the hospice must maintain professional, financial, and administrative responsibility for the services and must assure that the qualifications of staff and services provided meet the requirements specified in this subpart.

Proposed §418.64(b) Standard: Nursing services

Although continuous care is not mentioned in CMS' proposed rule regarding core services, NHPCO wishes to comment on our continued concerns that hospices are not permitted to contract for continuous care staffing on a routine basis, even with appropriate training and communication systems in place. In all levels of hospice care, the core IDG maintains professional management responsibility for the care provided. Many hospice programs are not able to provide the level of nursing services required for continuous care due to the great fluctuation in the number of hours and the number of patients that may need continuous care at any given time. Nurses who will work PRN are less and less available, and there can be greater consistency in being able to offer this important level of care if hospices were permitted to contract with an agency. We request that a formal dialogue with CMS staff begin on this issue and its possible solutions.

Proposed §418.64(d) *Standard: Counseling services*

The requirement proposed in §418.64(d)(1)(ii) regarding the provision of bereavement counseling to residents and employees of a SNF/NF and ICF/MR or other facility exceeds the statutory authority, which requires only that hospices provide bereavement counseling "for the immediate family of terminally ill individuals." (Social Security Act section 1861(dd)(2)(A)(i)). Although hospices typically define who constitutes a patient's "family" broadly, and certainly might provide bereavement counseling to a hospice patient's roommate, friends and caregivers in a SNF/NF or ICF/MR, when appropriate, the statute does not require them to do so. In addition, hospices typically provide a broad range of bereavement-related services, including services provided to members of the community who may have had no involvement with the hospice, but these services are not required by the statute.

With respect to spiritual counseling, we request that CMS clarify in the final rule that hospices are only required to facilitate visits by local clergy or others who can support the patient's spiritual needs, and that the hospice is not required to arrange visits by out-of-town spiritual counselors.

As specified above, we request that proposed 418.64(d)(1) be revised as follows:

(d) *Standard: Counseling services.* Counseling services for adjustment to death and dying must be available to both the patient and the immediate 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 immediate family and other individuals identified in the bereavement plan of care up to one year following the death of the patient. Bereavement ~~counseling~~ services ~~also~~ may extend~~s~~ to residents and employees of a SNF/NF~~,~~ or 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).

X. STATUTORY NURSING WAIVER (PROPOSED §418.66)

We understand that the requirements for obtaining the nursing waiver addressed in proposed §418.66 are set forth in the Social Security Act, and we agree that this provision may be obsolete since it applies only to hospices that were in operation on or before January 1, 1983, and are located in an area that is not urbanized. However, CMS also has used its discretion to determine that the current nursing shortage constitutes an "extraordinary circumstance" and has allowed hospices affected by the shortage to obtain a waiver and contract for nursing services if certain conditions are met. A number of hospice providers reported there have been problems in accessing this nursing waiver throughout the country. CMS regional offices do not understand the process when hospices try to apply for the nursing waiver, and have limited hospices access to hospices for this reason. We would like the process to be more user-friendly. We also request clarification as to who is eligible for the waiver. With the nursing shortage, there is a need for the waiver in many urban areas as well as rural, since hospices serving inner city areas have problems similar to rural areas in employing nurses.

XI. NON-CORE SERVICES - PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND SPEECH-LANGUAGE PATHOLOGY, AND WAIVER OF REQUIREMENTS (PROPOSED §§418.70, 418.72 AND 418.74)

We have no comments on these conditions.

XII. HOME HEALTH AIDE AND HOMEMAKER SERVICES (PROPOSED §418.76)

Proposed §418.76(c) ***Standard: Competency Evaluation***

We request that this standard be revised to clarify that it applies to home health aide services.

As specified above, we request that proposed 418.76(c) be revised as follows:

> (c) *Standard: Competency evaluation.* An individual may furnish home health aide services on behalf of a hospice only after that individual has successfully completed a competency evaluation program as described in this section.

Proposed §418.76(e) ***Standard: Qualifications for instructors conducting classroom supervised practical training, competency evaluations and in-service training***

We request that this provision be revised to specify that a registered nurse performing or supervising the classroom training must have experience in hospice or home health care.

As specified above, we request that proposed 418.76(e) be revised as follows:

> (e) 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 hospice or home health care. Other individuals may provide instruction under the general supervision of a registered nurse.

Proposed §418.76(f) *Standard: Eligible training organizations*

We request that the exception regarding who is permitted to offer home health aide training programs should be changed from a home health agency to a hospice, since this is a hospice standard.

As specified above, we request that proposed 418.76(f) be revised as follows:

> (f) A home health aide training program may be offered by any organization except by a ~~home health agency~~ hospice that, within the previous 2 years— ...

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

We request that this standard be more flexible regarding the ordering of services, and defer to state law. A physician or nurse practitioner's order is not necessarily required for home health aide services, and in many cases the IDG could be more responsive and would appropriately determine a patient's need for such services.

We also are requesting that CMS provide clarification regarding the role of a home health aide in assisting with administration of medications that are ordinarily self-administered. In particular, we would like guidance on how this would be determined, and what assistance the home health aide may provide.

As specified above, we request that proposed §418.76(g) be revised as follows:

> (g) A registered nurse or the appropriate qualified therapist that is a member of the interdisciplinary team makes home health aide assignments.
>
> (1) Home health aides are assigned to a specific patient by a registered nurse or the appropriate qualified therapist. Written patient care instructions for a home health aide must be prepared by a registered nurse or other appropriate skilled professional (*i.e.*, a physical therapist, speech-language pathologist, or occupational therapist) who is responsible for the supervision of a home health aide as specified

under paragraph (h) of this section.

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

(i) Ordered, as required by state law ~~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.

Proposed §418.76(h) ***Standard: Supervision of home health aides***

NHPCO appreciates the importance of assuring the competence of home health aides, and the quality of services they provide. However, we have serious concerns about the requirements of this standard. We believe they would be extremely burdensome and would not offer any greater assurance of the quality of hospice services provided.

We do not have concerns with the requirement in §418.76(h)(1) that an evaluation visit by a registered nurse or qualified therapist to each individual patient's home be made at least every 14 days to assess the home health aide's services. We agree that this evaluation can provide helpful information that would allow the nurse or therapist to update the plan of care and/or provide the aide with additional information or instruction. However, we find the second section of this standard confusing. It requires that a nurse or qualified therapist 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." This could be interpreted to require that every aide be evaluated while providing care to every one of his/her patients every 28 days. However, for purposes of this comment, we are assuming that it requires that each aide be evaluated while providing care to any one patient every 28 days, and that the results of the evaluation would be documented in the home health aide's personnel record. Nonetheless, we strongly object to this requirement.

In a June 2005 presentation on these proposed regulations, a CMS staff member suggested that this requirement was related to the short length of stay for hospice patients; however we see no logical connection between that observation and the proposed requirement since the intent is to assess the aide's services and competency in general, not necessarily the home health aide services received by a particular patient.

While home health aides are paraprofessionals who are called upon to work independently, a requirement that would mandate mini-competency assessments 13 times a year is excessive. Home health aides are trained to deliver a very specific set of clearly defined services; approved training programs focus on assuring competency in these duties. Home health aides work from a patient-specific plan of care prepared by the registered nurse or qualified therapist. They receive a minimum of 12 hours of inservice training annually and periodic competency assessments. The services they provide are evaluated every 14 days to assure quality and competence and that care is being provided in accordance with the patient's plan of care.

We believe that a requirement that would find optimal balance between promoting safe, high quality patient care and wise use of resources would be to: (1) continue to require that the registered nurse or the qualified therapist complete an on-site evaluation visit to the residence of each patient when the patient's plan of care includes home health aide services (the aide would not have to be present for this visit); and (2) on a quarterly basis, require the registered nurse or qualified therapist to conduct an observation visit in order to observe and assess each aide while he/she is performing care.

As specified above, we request that proposed 418.76(h)(1) be revised as follows:

> Proposed 418.76(h)(1) *Standard: Supervision of home health aides.*
> (1) 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 observational visit to the location where ~~the~~a 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~~ quarter.

Proposed 418.76(i) ***Standard: Individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit***

Patients who have been receiving personal care aide services under a Medicaid waiver program, and who are eligible for hospice care, often have to choose between the aide services and hospice care because the State Medicaid agency has interpreted the current home health aide requirements in the conditions of participation to be duplicative of the waiver program services. The wording that has been questioned is in the current Conditions of Participation, §418.94 Home Health Aide Services, which states "Home health aide and homemaker services must be available and adequate in frequency to meet the needs of the patients." CMS has also tried to clarify this issue through regional office Program Memoranda. NHPCO requests that CMS clarify that the primary caregiver function is not a service provided by hospice. Many Medicaid waiver programs are providing the equivalent of primary caregiver or attendant care services, not a service provided by hospice.

This standard references only the qualifications of the home health aide. We would request language that would address the option of personal care services and hospice services being provided concurrently.

As specified above, we request that a sentence be added at the end of proposed 418.76(i) as follows:

(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. Personal care aide only services are not considered to be duplicative of home health aide services provided by the hospice and can be coordinated between the hospice and the personal care aide services provider.

Proposed 418.76(j) *Standard: Homemaker qualifications*

A number of providers commented that in some rural areas, home health aides are very difficult to find, and clarification on the qualifications for a homemaker would be helpful. NHPCO is requesting that CMS clarify that homemaker services could be provided by employees or volunteers who do not meet the training requirements of a home health aide.

As specified above, we request that proposed 418.76(j) be revised as follows:

(j) A qualified homemaker is a home health aide as described in §418.76 or an individual who meets the standards in §418.202(g), or a volunteer or other individual who has successfully completed hospice orientation addressing the needs and concerns of patients and families coping with a terminal illness.

XIII. VOLUNTEERS (PROPOSED § 418.78)

Proposed §418.78(e) *Standard: Level of activity*

NHPCO is requesting a revision to this standard to specify that the total patient care hours from which the 5 percent volunteer requirement is calculated is routine home care hours. With more and more hospice patients utilizing short term inpatient care in a hospice facility, the total patient care hours provided by paid staff has increased with the 24/7 staffing requirements in these facilities. In addition, some hospices find it difficult to find sufficient volunteers to meet the requirement, due to more working volunteers and the aging population.

We also request that CMS further clarify what types of volunteer hours can be used in the calculation of the 5 percent volunteer requirement. There continues to be confusion in the field about the issue, and the question has been raised in several CMS Open Door Forum calls. We are proposing the addition of a sentence at the end of 418.78(e) to address that clarification.

As specified above, we request that §418.78(e) be revised as follows:

(e) *Standard: Level of activity.* Volunteers must provide day-to-day administrative and/or direct patient care services in an amount that, at a minimum, equals 5 percent of the total ~~patient~~ routine home care patient care hours of all paid hospice employees and contract staff. The hospice must maintain records on the use of volunteers for patient care and administrative services, including the type of services and time worked. The volunteer hours that may be used in the calculation of the 5 percent requirement may include volunteer travel time, actual time worked as a volunteer, and time spent documenting services provided. Training and orientation time may not be counted for purposes of meeting the 5 percent requirement.

XIV. ORGANIZATION AND ADMINISTRATION (PROPOSED §418.100)

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

While the goal of hospice is to serve the needs of dying patients and their families, NHPCO is concerned about the language in §418.100(a) requiring that the hospice "must ensure" that the patient experiences hospice care that optimizes comfort and dignity, and "must ensure" that hospice care is consistent with the patient's and family's "desires". The hospice should be responsible for ensuring that the patient receives hospice care that is included in the plan of care and intended to optimize the patient's comfort and dignity, but the hospice cannot ensure how patients will experience the care they receive. Similarly, hospices should ensure that the hospice care provided is consistent with the patient's and family's needs, as identified in the plan of care, but hospices should not be held responsible for all of the patient's and family's desires, particularly to the extent that the family's desires are not consistent with the patient's.

As specified above, we request that proposed §418.100(a) be revised as follows:

(a) *Standard: Serving the hospice patient and family.* The hospice must ~~ensure~~provide—

(1) ~~That each patient receives and experiences~~ Hospice care that optimizes comfort and dignity; and

(2) ~~That each patient experience~~ Hospice care that is consistent with patient and family needs ~~and desires.~~ as identified in the comprehensive assessment and included in the patient's plan of care.

Proposed §418.100(e) ***Standard: Professional management responsibility***

NHPCO is quite concerned about the use of the word "supervision" in this standard as it relates to the relationship between the hospice and a contracted provider or service. While we agree that hospices have professional management responsibility for services provided under contract, we would recommend the use of the word "oversight" to more accurately reflect the relationship, and we request that the responsibility extend only to the services provided, not to the contracted staff themselves. We believe this is consistent with the statutory requirement in section 1861(dd)(2)(A)(ii)(II) which requires that when a hospice does not provide a service directly, it "must maintain professional management responsibility for all such services". It is our understanding that requiring hospices to supervise the staff of an independent contractor could be considered to create a "joint employer" relationship that could, in turn, lead to unintended liability for the hospice, including potential liability for the employment actions of the independent contractor company.

We are also concerned about the requirement in §418.100(e)(2) that staff furnishing arranged services have the "same qualifications" as hospice employees. Under normal circumstances, hospices would be contracting for services that complement hospice staff's expertise and services. Two individuals can both be qualified by training and/or experience to provide a service, but they may not have the "same qualifications". An example of this would be hospice care provided to a patient who resides in a nursing facility. While the NF aide may bathe the patient once a week and the hospice aide twice a week, the NF aide would be certified as a nursing assistant, whereas the hospice aide would be a certified home health aide. This is due to the different licensing and certification requirements for a NF versus a hospice. We would recommend that the language "qualified personnel" be used to better reflect the intention of this standard.

As specified above, we request that proposed §418.100(e) be revised as follows:

(e) *Standard: Professional management responsibility*

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

(1) Authorized by the hospice;
(2) Furnished in a safe and effective manner by ~~personnel having at least the same qualifications as hospice employees;~~ qualified personnel; and
(3) Delivered in accordance with the patient's plan of care.

Proposed §418.100*(f) Standard: Hospice satellite locations*

There have been recurring problems with inconsistent standards regarding hospice satellite locations, and we are requesting that CMS establish a consistent policy across CMS Regions for defining and approving satellite locations. CMS regional offices in some areas of the country have limited satellite locations with a specific minutes/miles drive time limitation, while in other areas satellites have been approved at great distance from the main office. In some areas, the limitation on a satellite location has been imposed because of geographic barriers (mountains), and in other areas that has not been a factor. We would also like to express concern about the length of time for approval of satellite locations – in some parts of country it currently takes up to two years for a satellite location to be approved.

XV. MEDICAL DIRECTOR (PROPOSED §418.102)

A hospice must be in an employment or contractual relationship with a physician designated to serve in the place of the medical director when the medical director is not available. In practice, often the medical director will identify another physician to provide medical director services in his/her absence. This responsibility may even be specified in the medical director's job description, developed by the hospice. Ultimately, however, it is the hospice that has the responsibility for assuring that the medical director duties are covered on an ongoing basis. Consequently, NHPCO believes that this proposed condition of participation needs to be revised to include language that provides for collaboration between the hospice and the medical director in meeting the responsibility of designating a physician to serve in the place of the medical director.

As specified above, we request that the introduction to proposed §418.102 be revised as follows:

> When the medical director is not available, the hospice assures the designation of another physician to assume the same responsibilities as the medical director. ~~a physician designated by the medical director assumes the same responsibilities and obligations as the medical director.~~

Proposed §418.102(b) *Standard: Recertification of the terminal illness*

NHPCO has concerns about the requirement that the medical director or physician designee must review "the patient's and family's expectations and wishes for the continuation of hospice care?" It is unclear what the physician would be expected to do under this standard. It is also likely to be upsetting and cause undue stress for the patient and family if the physician questions whether they want to continue receiving hospice care. Patients always have the option of revoking the hospice benefit, but if the physician questions whether they want to continue, the patient may wonder if there is a reason why they should not continue in hospice, or if they may no longer be able to continue. Since the IDG review of the patient's comprehensive assessment

and plan of care prior to the patient's recertification includes a discussion of the patient and family's expectations and wishes for the continuation of hospice care, we suggest that this provision be deleted.

As specified above, we request that proposed §418.102(b) be revised as follows:

(b) Before the recertification period for each patient, as described in Sec.418.21(a), the medical director or physician designee must review the patient's clinical information.
~~(1) The patient's clinical information; and~~
~~(2) The patient's and family's expectations and wishes for the continuation of hospice care.~~

Proposed §418.102(c) ***Standard: Coordination of medical care.***

NHPCO feels very strongly that this standard should be revised regarding the statement that the hospice physicians and IDG are responsible for the coordination of the patient's "medical" care in its entirety. This is a particularly problematic requirement, especially when viewed in conjunction with the language in the preamble that states that the hospice physician and IDG are responsible "...for coordinating a patient's medical care in all settings, even when multiple physicians are participating in the care." This requirement would exceed a hospice's professional management responsibilities that extend only to coordinating services provided related to the patient's hospice plan of care . In addition, this requirement would be particularly problematic when the hospice medical director is working with physicians in other settings. Such a standard is likely to alienate other physicians involved in the patient's care, particularly in a SNF/NF setting where the SNF/NF medical director continues to have responsibilities for the patient pursuant to that facility's conditions of participation. While assuming responsibility for the patient's hospice care, hospice physicians need to work collaboratively with other physicians and staff involved in the care of hospice patients.

We also have serious concerns about CMS' requirement that the hospice medical director or physician designee be "responsible for directing" the hospice's QAPI program. In light of the scope of the QAPI requirements, which are broad and extend beyond purely medical issues, and the fact that many medical directors are part time or volunteers, we are requesting a revision to require the medical director or physician designee "participate" in the hospice's QAPI program, but not that they direct it. Particularly in smaller hospice programs, the medical director may be a volunteer or work part-time, and may be neither willing nor qualified to assume this responsibility. In addition, this requirement appears to conflict with §418.58(e) that requires the hospice's governing body to assume executive responsibility for the hospice's QAPI program. As part of that responsibility, it would be appropriate for the governing body to appoint the most qualified individual to direct the hospice's QAPI program. In some hospices that individual might be the hospice's medical director but for the large majority, it would not.

As specified above, we request that proposed §418.102(c) be revised as follows:

> (c) *Standard: Coordination of medical care.* The medical director or physician designee, and the other members of the interdisciplinary group are jointly responsible for the coordination of the patient's ~~medical~~ hospice care ~~in its entirety~~. The medical director or physician designee ~~is also responsible for directing~~ should participate in the hospice's quality assessment and performance improvement program.

XVI. CLINICAL RECORDS (PROPOSED §418.104)

In response to CMS' query, a number of providers commented to NHPCO on the use of the Electronic Health Record ("EHR") in the hospice setting. Providers stated that the advantage of EHR is that it is accessible from any computer anywhere in the world at any time of the day or night, and is easily portable, with a clean copy that is legible if notes are typed versus scanned. The disadvantages are that the provider must have very computer literate clinical staff, often unavailable in today's environment; staff must carry a laptop from house to house, giving the appearance of a "cold machine"; theft; and risk of cross contamination between households. In addition, there are significantly increased costs for infrastructure, software, maintenance, training, and data entry. EHRs have been used successfully in facilities and physician offices, due to the nature of care and location. They also work efficiently and appropriately in those settings for billing. However, hospice uses four billing codes, one of which is used 90 percent of the time, and consequently hospices gain no billing efficiency by implementing an EHR system. The system would be more appropriately used for team communication. If only nurses are supplied with laptops, and all other disciplines use handwritten notes then there is a lag time between the note being written, transcribed, and being available in the EHR, which could be problematic for continuity of care.

A number of small and rural providers commented that they do not expect to be able to use EHRs in the near future due to cost, training of staff, hiring technical staff and need.

If a hospice uses electronic medical records, sharing of the discharge summary and/or medical record through an electronic format is possible and facilitates communication between providers. It should be possible for electronic sharing of records to include access to the record through secure internet access or other electronic access available through transferable data storage media.

Proposed §418.104(a) *Standard: Content*

We have questions about the "authorization" referred to in §418.104(a)(2) regarding the content of the patient's clinical record. Authorization has a specific meaning in the

context of the HIPAA privacy regulations, but such authorizations are required in limited circumstances and would not typically be part of a hospice patient's clinical record. Please clarify what "authorizations" CMS is referring to in this standard.

Proposed §418.104(b) *Standard: Authentication*

NHPCO has serious concerns about the proposed requirement that all entries in the clinical record must be authenticated and that the hospice must be able to authenticate each handwritten and electronic signature of a primary author who reviewed and approved the entry. Our concern is that hospice home care is so broad, (unlike other health care settings, such as hospitals, for which this standard is more appropriate) and can involve so many health professionals in so many different settings, that it may not be feasible to completely comply with the authentication standard for attending physicians, consulting physicians and other care providers throughout a hospice's service area.

NHPCO is concerned about the application of the term "primary author" and how it would apply in hospice. Those providing care are widely dispersed and hospices may receive records from dozens, hundreds or more referring or attending physicians, some of whom may refer only one patient a year to the hospice. Electronic signatures are not yet in widespread use, and it would be extremely burdensome for hospices to be required to authenticate the handwritten signatures of every one of these physicians. In addition, the environment is different for a hospice than for a hospital. It is practiced in the community setting, not in a controlled environment, such as a hospital. We would request that you take these factors into account when writing the final rule.

As specified above, we request that proposed §418.104(b) be revised as follows:

> (b) *Standard: Authentication*. All entries must be legible, clear, complete, and appropriately authenticated and dated for all hospice employees. ~~All entries must be signed, and the hospice must be able to authenticate each handwritten and electronic signature of a primary author who has reviewed and approved the entry~~.
>
> (i) The author of each entry must be identified and must authenticate his or her entry.
>
> (ii) Authentication may include signatures, written initials or computer entry.

Proposed §418.104(d) *Standard: Retention of records*

The HIPAA privacy regulations require record retention for 6 years, unless state law stipulates a longer period of time. We recommend following the HIPAA requirement as the minimum for this standard.

As specified above, we request that proposed §418.104(d) be revised as follows:

> (d) *Standard: Retention of records.* Patient clinical records must be retained for ~~5~~ 6 years after the death or discharge of the patient, unless State law stipulates a longer period of time. If the hospice discontinues operation, hospice policies must provide for retention and storage of clinical records. The hospice must inform its State agency and its CMS Regional office where such clinical records will be stored and how they may be accessed.

Proposed §418.104(e) *Standard: Discharge or transfer of care*

We are requesting that CMS change the phrase "Medicare/Medicaid-approved" to "Medicare/Medicaid-certified" or clarify the difference between the two. "Medicare-certified" is the commonly accepted term and utilization of the term "Medicare-approved" may cause unnecessary confusion.

Requiring hospices to send a copy of the patient's entire clinical record if the patient transfers, revokes or is discharged is particularly onerous, and is not necessary since the discharge summary requirements are comprehensive, and receipt of the entire printed clinical record (sometimes hundreds of pages) is not likely to be welcomed by facilities or attending physicians. In addition, such a release often would not be in compliance with the minimum necessary disclosure standard in the HIPAA privacy regulations.

Because hospice care includes care of the patient and family, hospice records often include sensitive, personal information about individuals other than the patient, such as family members or caregivers. For example, the records could include notations regarding substance abuse by a family member, which is relevant to their role as a hospice caregiver. The discharge summary is very thorough and would be disclosing the minimum amount of protected health information needed to achieve the purpose of the disclosure which, in this case, would be to ensure continuity of care with another provider. As always, additional records would be available from the hospice if needed.

As specified above, we request that proposed §418.104(e) be revised as follows:

> (e) *Standard: Discharge or transfer of care.*
> (1) If the care of a patient is transferred to another Medicare/ Medicaid-~~approved~~ certified facility, the hospice must forward a copy of the patient's ~~clinical record and the~~ hospice discharge summary to that facility.
> (2) If a patient revokes the election of hospice care, or is discharged from hospice because eligibility criteria are no longer met, the hospice must provide a copy of the ~~clinical record and the~~ hospice discharge summary ~~of this section~~ to the patient's attending physician.
> (3) The hospice discharge summary must include—

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

XVII. DRUGS, SUPPLIES, AND DURABLE MEDICAL EQUIPMENT (PROPOSED §418.106)

Proposed §418.106(b) ***Standard: Controlled drugs in the patient's home.***

NHPCO has significant concerns regarding this standard and the chilling effect that it may have on patients accepting and receiving medications adequate to control their pain. It has been well documented that untreated or under-treated pain is a major problem[3,4] and this is particularly true for patients with terminal illnesses. Patients themselves are often one of the impediments to achieving pain control, and hospices often struggle to convince patients to take the medications they need to address their pain. If hospices are required to talk to patients about the "dangers" of controlled substances during the initial assessment, this could potentially frighten patients and families and may undermine the hospice's efforts to bring the patient's pain under control. While we appreciate CMS' concerns regarding diversion of controlled substances, and the potential dangers if they are not appropriately safeguarded, we are requesting that the hospice instead be required to discuss the safe uses of controlled substances, and we believe such discussions also would address the risks of misuse or diversion of such drugs.

NHPCO also is concerned about the use of the term "tracking" in this standard. As we understand it, the tracking procedure would require that the hospice nurse account for every dosage at every visit and make a record of the count. While we believe this procedure may be warranted in some instances, the procedure could be covered in the hospice's policies and procedures. The use of the word "monitoring" would allow the hospice to have a policy that is flexible, and to take into account the specific patient and family circumstances. We also are requesting that CMS clarify that the requirement is that the hospice develop a policy regarding tracking and disposing of controlled drugs, but such drugs are the property of the patient, and the hospice cannot dictate that patients dispose of them. In addition, state laws regarding controlled substances vary, including recently passed state laws restricting the disposal of controlled substances in the sewer system in order to protect water quality.

We specifically request that CMS delete the requirement that the hospice have a policy for "collecting" controlled drugs. A hospice would not "collect" such drugs in a patient's

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3 "Hospitals and clinicians confront a new imperative: PAIN MANAGEMENT," *Hospitals and Health Networks*, (April 1, 2005): 54

4 DE Joranson, R Payne, "Will my pain be managed?" ed. WAD Edmondson. *Improving End-of-Life Care: The Role of Attorneys General.* (Washington, DC: National Association of Attorneys General, 2003): 27-34.

home except for the purpose of disposing of them, and then only with the consent of the patient. In addition, requiring hospice personnel to collect and transport controlled substances could put them at risk.

We also feel that requiring a hospice to discuss its drug use and disposal policy during the initial assessment (the first 24 hours of care) would be counter-productive, because so much information is being shared at that time, and the patient may not even be taking any controlled drugs. As stated in our comments regarding proposed §418.52(a)(3), we would recommend that the information concerning the hospice's drug use and disposal policy be a part of the hospice's admission packet, and that this information be discussed during the comprehensive assessment period rather than the initial assessment.

As specified above, we request that proposed §418.106(b) be revised as follows:

> (b) *Standard: Controlled drugs in the patient's home.* The hospice must have a written policy for ~~tracking,~~ monitoring, ~~collecting,~~ and disposing of controlled drugs maintained in the patient's home. During the ~~initial~~ comprehensive hospice assessment, the hospice will inform patients and families of their policies ~~the use and disposal of controlled substances must be discussed with the patient and family to ensure the patient and family are educated~~ regarding the safe uses and appropriate safeguards for the use ~~and potential dangers~~ of controlled substances. The hospice nurse must document that the patient and family have received this information. ~~policy was discussed with the patient and family.~~

Proposed §418.106(c) ***Standard: Use and maintenance of equipment and supplies.***

This is not a core service, and almost all hospices contract for durable medical equipment ("DME") services. Adding the words "either directly or through contractual agreement" clarifies the responsibilities of the hospice and of the contractors they use to supply medical equipment. While the hospice is responsible for ensuring that the patient has safe, working equipment, contractors have the expertise in this area and should be responsible for writing repair and routine maintenance policies for equipment.

As specified above, we request that proposed §418.106(c) be revised as follows:

> (c) *Standard: Use and maintenance of equipment and supplies.*
>
> ~~(1) The hospice must follow manufacturer recommendations for performing routine and preventive maintenance on durable medical equipment. The equipment must be safe and work as intended for use in the patient's environment. Where there is no manufacturer recommendation for a piece of equipment, the hospice must develop in writing its own repair and routine maintenance policy. The hospice may use persons under contract to ensure the maintenance and repair of durable medical equipment.~~

(1) The hospice ensures, either directly or through contractual agreement, that there is a process for providing routine and preventive maintenance and repair of equipment, and that the equipment is safe and works as intended for use in the patient's environment.

XVIII. SHORT TERM INPATIENT CARE (PROPOSED §418.108)

NHPCO believes it should be clear that inpatient care must also be available for crises of a psychosocial nature as well as pain control, symptom management and respite. CMS manual provisions allow for a psychosocial crisis as a basis for admission for inpatient care, as stated in Medicare Benefits Policy Manual, Ch. 9, §40.1.5: "General inpatient care may be required for procedures necessary for pain control or acute or chronic symptom management, which cannot feasibly be provided in other settings. Skilled nursing care may be needed by a patient whose home support has broken down if this breakdown makes it no longer feasible to furnish needed care in the home setting...Other examples of appropriate general inpatient care include a patient in need of medication adjustment, observation, or other stabilizing treatment, such as psycho-social monitoring, or a patient whose family is unwilling to permit needed care to be furnished in the home." We request that CMS clarify the circumstances under which inpatient care is appropriate because there has been confusion among providers and intermediaries about the possible reasons for short term inpatient care.

NHPCO requests that CMS add to the introduction that short-term inpatient care may be provided in a hospice inpatient facility.

As specified above, we request that the introduction to proposed §418.108 be revised as follows:

> *Condition of participation: Short-term inpatient care.*
> Inpatient care must be available for pain control, symptom management, psychosocial crises and respite purposes, and must be provided in a participating Medicare or Medicaid facility, or a Medicare-certified hospice that meets the conditions of participation for providing inpatient care directly.

Proposed §418.108(a) ***Standard: Inpatient care for symptom management and pain control.***

NHPCO is requesting that this standard also include the provision of inpatient care for crises of a psychosocial nature. We are also requesting that CMS change the phrase "Medicare-approved" to "Medicare-certified" because we believe this is the correct terminology.

As specified above, we request that proposed §418.108(a) be revised as follows:

(a) *Standard: Inpatient care for symptom management, ~~and~~ pain control and psychosocial crises*. Inpatient care for pain control, ~~and~~ symptom management and psychosocial crises must be provided in one of the following:

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

Proposed §418.108(b) *Standard: Inpatient care for respite purposes*

We are requesting that CMS change the phrase "Medicare-approved" to "Medicare-certified", and that CMS provide an exception to the requirements referred to in §418.110(f) to allow rooms used for inpatient respite care to accommodate up to four patients. We believe this change is appropriate because patients receiving respite care typically are not actively dying patients, which would be the most compelling reason for limiting the number of patients per room to two. Eliminating this requirement would provide better access for hospices to contract with some nursing homes for respite care.

As specified above, we request that proposed §418.108(b) be revised as follows:

(b) *Standard: Inpatient care for respite purposes.* Inpatient care for respite purposes must be provided by one of the following:

(1) A provider specified in paragraph (a) of this section.
(2) A Medicare/Medicaid ~~approved~~ participating nursing facility that also meets the standards specified in § 418.110(b) and (f), except that patient care rooms used for respite purposes may accommodate up to four patients.

Proposed §418.108(c) *Standard: Inpatient care provided under arrangements*

NHPCO has two comments related to provisions in this standard at proposed §418.108(c)(3) and §418.108(c)(5). First, similar to the concern expressed regarding proposed §418.104(e), hospices do not need a copy of the inpatient clinical record since the inpatient discharge summary would provide the necessary information to ensure continuity of care, and additional information would be available upon request. We are concerned that the wording in the proposed standard, requiring that a copy of the inpatient clinical record is "available" to the hospice at the time of discharge, may be misinterpreted to mean that a hospice must obtain a copy of the entire inpatient clinical record for each patient that receives care at an inpatient facility. This would pose an inordinate burden on inpatient facilities and risk their compliance with the minimum necessary disclosure requirement of the HIPAA privacy regulations. It would also risk the hospice's compliance with the minimum necessary request requirements of the

HIPAA privacy regulations.

With regard to proposed §418.108(c)(5), NHPCO is concerned that inpatient facilities that contract with several hospice programs to provide the inpatient level of hospice care may be inundated with obligations to receive similar training from multiple hospice providers. This risks placing an unnecessary strain on relationships between hospices and the inpatient facilities with which they contract.

As specified above, we request that proposed §418.108(c)(3) and 418.108(c)(5) be revised as follows:

(c) *Standard: Inpatient care provided under arrangements.* If the hospice has an arrangement with a facility to provide for short-term inpatient care, the arrangement is described in a legally binding written agreement that at a minimum specifies --

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

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

XIX. HOSPICES THAT PROVIDE INPATIENT CARE DIRECTLY (PROPOSED §418.110)

While we appreciate CMS' effort to make inpatient care more accessible by making the requirement for 24 hour nurse staffing more flexible, we are recommending that a clear distinction be made between staffing for short term inpatient care for symptom management and pain control (§418.108(a)), and short term inpatient care for respite purposes (§418.108(b)). While we believe that the standard for nursing services in a facility providing respite care to a hospice patient should be in accordance with the patient's plan of care, which might not require 24 hour nursing care, hospice patients receiving inpatient care for pain control or symptom management typically have acute needs, and we believe a registered nurse who can provide direct patient care should be included on each shift of a facility in which such care is provided.

As specified above, we request that proposed §418.110(b) be revised as follows:

> (b) *Standard: Twenty-four hour nursing services.* The hospice facility must provide 24-hour nursing services that meet the nursing needs of all patients and are furnished in accordance with each patient's plan of care. Each patient must receive all nursing services as prescribed and must be kept comfortable, clean, well groomed, and protected from accident, injury, and infection.
>
> (1) For inpatient care provided for pain control or symptom management, as described in §418.108(a), each shift must include a registered nurse who can provide direct patient care.
>
> (2) For inpatient care provided for respite purposes, as described in §418.108 (b), nursing services must be provided to meet the needs of the patient as specified in the patient's plan of care.

Proposed §418.110(c) *Standard: Physical environment*

NHPCO has concerns regarding the safety management requirements in proposed §418.110(c)(1)(i) and §418.110(c)(1)(ii). While our concerns may not require a rewording of these provisions, we request that in the final rule and/or the interpretive guidelines, CMS provide further clarification of reporting requirements and how these requirements are consistent with or exceed the requirements of the Safe Medical Device Act. NHPCO also requests that CMS provide some examples of the "equipment failures" referred to in §418.110(c)(1)(i), and describe under what circumstances such failures would be required to be reported to appropriate State and local bodies, if this provision exceeds the reporting requirements of the Safe Medical Device Act.

Proposed §418.110(d) *Standard: Fire protection*

We had many providers comment that the most current edition of the Life Safety Code was published in 2003. It is currently used in every U.S. state and adopted for statewide use in 35 states. There is confusion that this standard still requires the 2000 edition and we request that the updated version be referenced throughout this section. In addition, the standard includes a number of incorrect citations.

Specifically, the language in proposed §418.100(d)(4) states "beginning March 13, 2006, a hospice must be in compliance with Chapter 9.2.6 Emergency Lighting." The highest section in that chapter is 9.2.4. Chapter 9 is titled "Building Service and Fire Protection Equipment" and 9.2 is titled "Heating, Ventilating and Air Conditioning." Emergency lighting is actually in Chapter 7, and is titled "Means of Egress", and Emergency Lighting is actually in Section 7.9

Another reference appears to be incorrect in proposed §418.100(d)(6)(iv). The standard states "dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code." However, Chapter 18.3.2.7 actually states

"Buildings housing health care occupancies as indicated in 18.1.1.1.2 that have rooftop heliports shall be protected in accordance with NFPA 418, Standard for Heliports." Chapter 19.3.2.7 does not exist; the highest provision in this chapter is 19.3.2.6.

Proposed §418.110(f) *Standard: Patient rooms*

In the event of hurricanes, tornadoes and other community disasters, we would like to have the flexibility for some variance in this standard, including the number of patients per room in proposed §418.110(f)(3)(iv). We are not requesting a change to the standard, but some recognition of extraordinary circumstances could be made in the preamble to the final rule and in the interpretive guidelines.

Proposed §418.110*(l)* *Standard: Meal service and menu planning*

NHPCO appreciates CMS' revision of this standard to be in keeping with the needs and desires of hospice patients, rather than requiring the provision of meals that may be inappropriate for dying patients.

Proposed §418.110(n) *Standard: Pharmacist*

We request that the phrase "if required by law" be added to the requirement in §418.110(n)(4)(iii) that a written account of the hospice's investigation of any discrepancies in the acquisition, storage, use, disposal, or return of controlled drugs be made available to State and Federal officials. If not required by law, it would be unclear to whom such an account should be provided.

As specified above, we request that proposed §418.110(n) be revised as follows:

(n) *Pharmacist.*
(4) *Drug management procedures.*
(iii) Any discrepancies in the acquisition, storage, use, disposal, or return of controlled drugs must be investigated immediately by the pharmacist and hospice administrator and where required reported to the appropriate State agency. A written account of the investigation must be made available to State and Federal officials, if required by law.

XX. SECLUSION AND RESTRAINT (PROPOSED §418.110(o))

NHPCO would like to comment on the use of seclusion and restraints in hospice care. Many providers commented that the entire issue of restraints, both physical and drug, needs further examination. Major components of what hospices do for both symptom

management and safety includes medications and practices that may be considered restraints in other settings. For instance, in hospice, haloperidol (Haldol) is used as an anti-emetic, as well as for restlessness and anxiety, not for a restraint. Some providers suggested that the condition use the phrase "accepted hospice and palliative care standards of practice" and list classes of drugs, such as anti-emetics and psychotropics, rather than specific drugs such as lorazepam and haloperidol. Others suggested language such as: "A drug is not considered a chemical restraint when used to palliate symptoms." The key is intent. Hospices' intent is to palliate a symptom, not to restrain. NHPCO received many requests for CMS to clearly distinguish how medications being used as chemical restraints in other settings are medically appropriate when used in hospice and palliative care. The plan of care should include specific indications for pharmacotherapy, obviating misunderstanding of intent.

Here are some specific examples (not meant to be all inclusive):

Hiccups: Haloperidol (Haldol), Chlorpromazine (Thorazine) – note that this works in 80% of hiccup cases when nothing else has.

Itching (pruritus): Hydroxyzine (Atarax, Vistaril), doxepin (Sinequan, Adapin), both at bedtime.

Delirium: Haloperidol (Haldol), oxazepam (Serax), midazolam (Versed).

Anxiety and panic (including anxiety associated with dyspnea): Lorazepam (Ativan), oxazepam (Serax), diazepam (Valium).

Terminal restlessness: Chlorpromazine (Thorazine), midazolam (Versed), oxazepam (Serax), phenobarbital.

Some providers commented that they hoped that "restraint" did not include bed rails or positional devices such as posey vests, since bed rails are often used to ensure the patient's safety or to assist the patient in positioning and independent functioning, and posey vests in a hospice setting would be used to help a patient sit up.

Our concerns about the appropriate use of bedrails, and nursing facilities' concerns that use of them will be considered a "restraint", is highlighted in a report issued by AARP's Public Policy Institute in November 2004, which describes end-of-life care in nursing homes from the perspective of bereaved family members or others close to the decedents in order to identify policy issues and to make recommendations for policy change and educational initiatives. A case study from this report is included below:

> **Case III**: The nursing home sent 89-year-old Mrs. X to the hospital on numerous occasions. These visits involved long waits in the emergency room while Mrs. X's daughter agonized over the burden that repeated emergency room visits and hospitalizations created for her mother. Despite the daughter's insistence that Mrs. X be treated in the nursing home, the nursing home staff continued to urge hospitalization. Mrs. X's mattress was placed on the floor of her room in the nursing home to prevent

injuries from falling, an action her daughter considered demeaning. Increasingly vigilant about her mother's care, Mrs. X's daughter was dismayed by inadequate staffing, medication errors, insensitive staff, inadequate facility responses to her complaints, and inadequate information from the staff and doctors. One doctor mistakenly talked with her about a different person's care. When ownership of the nursing home changed, hospice care was added, and, according to the respondent, conditions improved.[5]

As specified above, we request that proposed §418.110(o)(1) be revised as follows:

(1) The patient has the right to be free from seclusion and restraint, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. The term restraint includes either a physical restraint or a drug that is being used as a restraint. A physical restraint is any manual method or physical or mechanical device, material or equipment attached or adjacent to the patient's body that he or she cannot easily remove, that restricts free movement of, normal function of, or normal access to one's body. Bed rails and positional devices are not included in this definition of restraint if used for the safety or support of the patient or to assist the patient in independent functioning. A ~~drug~~ chemical used as a restraint is a medication used to control behavior or to restrict the hospice patient's freedom of movement and is not a standard treatment for a patient's hospice medical or psychiatric condition. Seclusion is the confinement of a person alone in a room or an area where a person is physically prevented from leaving.

Proposed 418.110 (o) Standard: Seclusion and restraint. Time frames and reporting

NHPCO had many provider comments on the time frames mentioned in 418.110(o)(3)(ii)(d). The time frames listed are not feasible if the medical director or physician designee must see the patient and evaluate the need for restraint within 1 hour after the initiation of this intervention. Medical directors are not on site at inpatient facilities and would not be able to evaluate the patient within that time frame. Some providers suggested that a nurse must see the patient and evaluate the need hourly when any restraint is utilized.

NHPCO also received a number of comments on the provision in 418.110(o)(7) that requires a report to the CMS regional office of any death that occurs. Because of the nature of the patient population served by hospices and their impending death from their disease process, we would recommend a change that would add the word "unexpected" to this provision in the standard.

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[5] T Wetle, J Teno, R Shield, L Welch, and S Miller, S. *End of Life in Nursing Homes: Experiences and Policy Recommendations* (Washington, D.C., AARP Public Policy Institute, 2004)

As specified above, we request that proposed §418.110(o)(7) be revised as follows:

(7) The hospice must report to the CMS regional office any unexpected death that occurs while the patient is restrained or in seclusion, within 24 hours after a patient has been removed from restraint or seclusion.

XXI. RESIDENTS RESIDING IN A FACILITY (PROPOSED §418.112)

When the Medicare Hospice Benefit was enacted, the primary site of death for Medicare beneficiaries was the hospital. The Hospice Benefit has played a role in changing that trend, by providing support to terminally ill patients and their families, making it possible for them to die at home in accordance with their wishes. This was not only a preferable option for many patients/families, but also proved to be cost effective for Medicare.

Now, the demographics have changed, longevity has increased, and people are living longer with multiple chronic illnesses and significant deficits in their ability to perform activities of daily living. As a result, the percentage of Medicare beneficiaries who die while residing in nursing facilities has increased, and hospices have responded by entering into agreements with nursing facilities to make hospice services available to their residents. Research has indicated that a successful collaboration is beneficial to all concerned: patients, families, and staff of both providers.[6] A study published in the July 13, 2005 issue of the *Journal of the American Medical Association* indicates that simple communication efforts can improve the quality of end-of-life care and increase the use of hospice in nursing homes. A randomized controlled trial evaluated the impact of a "case finding" intervention and found that referrals to hospice were increased and that families' satisfaction ratings with the care their loved ones received at the end of life improved. The study also shows that simple communication interventions about hospice may also decrease the use of acute care resources.[7]

Over the past several years, NHPCO has developed educational tools and provided educational workshops to address issues important to forming partnerships between hospices and nursing facilities. While we feel that the addition of this provision to the hospice conditions of participation is appropriate, we are concerned about the incongruence between the proposed hospice conditions and the existing nursing facility conditions of participation. We understand that CMS is aware of these problems, and that the nursing facility conditions of participation are in the process of being updated, but we are concerned that these hospice provisions will become effective before the nursing facility conditions are updated, and hospice providers will be unable to comply with some of the standards in this condition.

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

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

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

NHPCO requests that the title of this condition be revised to remove the reference to "other facilities" because the term is too vague, and the proposed standards themselves clearly contemplate a SNF/NF or ICF/MR setting. In the absence of federal regulations applicable to "other facilities" such as assisted living facilities, personal care homes, foster homes, and board and care facilities, the standards in this provision would not be applicable. For example, not all such "facilities" provide medical services, have care plans for their residents, or employ medical directors. State regulations of these types of facilities also vary widely. Therefore, throughout proposed §418.112 we request that CMS delete the references to "other facilities", so that the remaining references to "facility" or "facilities" will apply to SNF/NFs and ICF/MRs.

As specified above, we request that title and introductory provisions of proposed §418.112 be revised as follows:

> §418.112 *Condition of Participation: Hospices that provide hospice care to residents of a SNF/NF~~,~~ or ICF/MR~~, or other facilities~~*
>
> In addition to meeting the conditions of participation at §418.10 through §418.116, a hospice that provides hospice care to residents of a SNF/NF~~,~~ or ICF/MR~~, or other residential facility~~ must ~~abide by~~ comply with the following additional standards.

Proposed §418.112(a) ***Standard: Resident eligibility, election, and duration of benefits***

Consistent with the rationale discussed above, we are proposing that the reference to other facilities be deleted and a reference to ICF/MR be added.

As specified above, we request that proposed §418.112(a) be revised as follows:

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

Proposed §418.112(b) ***Standard: Professional management***

Hospices' professional management responsibility is already addressed in proposed §418.100(e) and is duplicative in this section. We also note that this is often an area of conflict between the hospice and nursing facility staff, because the nursing facility conditions of participation also require the nursing facility to maintain professional responsibility. This issue is further complicated because the protocols in nursing facilities are oriented toward cure and

rehabilitation, where hospice protocols are focused on palliative care. We are concerned about the words "full responsibility" for it may cause greater conflict between the two staffs and would recommend the deletion of the word "full."

As specified above, we request that proposed §418.112(b) be revised as follows:

> (b) *Standard: Professional management*. The hospice must assume ~~full~~ responsibility for professional management of the resident's hospice care, in accordance with the hospice conditions of participation and make any arrangements necessary for inpatient care in a participating Medicare/Medicaid facility according to § 418.100.

Proposed §418.112(c) ***Standard: Core services***

NHPCO is requesting that this standard be removed in its entirety from this condition of participation since hospices' core services obligations are already addressed in proposed §418.64. The proposed language in this standard does not offer any additional clarification for core services when the service is provided in a nursing facility, and therefore the standard is redundant.

As specified above, we request that proposed §418.112(c) be deleted:

> ~~(c) *Standard: Core services*. A hospice must routinely provide all core services. These services include nursing services, medical social services, and counseling services. The hospice may contract for physician services as stated in § 418.64(a). A hospice may use contracted staff provided by another Medicare certified hospice to furnish core services, if necessary, to supplement hospice employees in order to meet the needs of patients under extraordinary or other non-routine circumstances, as described in § 418.64.~~

Proposed §418.112(d) ***Standard: Medical director***

We are proposing that the title of this standard be changed to "physician services". This more accurately reflects its contents, which refer to the role of the medical director and physician designee. We also are proposing that the content of this standard be revised and formatted to better reflect the roles of the hospice physician, the attending physician, and the facility medical director, and their need to communicate regarding the patient's care. We also are requesting that CMS clarify that the required "communication" between the hospice medical director or physician designee and the other physicians involved in the patient's care may include telephone calls, faxes and e-mail communication, and does not require face-to-face interaction.

As specified above, we request that proposed §418.112(d) be revised as follows:

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

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

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

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

Proposed §418.112(e) *Standard: Written agreement*

We are proposing a number of changes to this standard, which we hope will better clarify the roles and responsibilities of hospices and nursing facilities providing care to the same patient. We continue to have concerns about nursing facilities' acceptance of some of these provisions due to their obligations to comply with the nursing facility conditions of participation, and we urge CMS to work with and educate state surveyors of nursing facilities regarding these requirements.

We are requesting that CMS clarify what is meant in §418.112(e)(1), requiring that the written consent of the patient for hospice services be included in the written agreement between the hospice and facility. If the requirement is that a written and signed consent document be provided by the hospice to the nursing facility for all patients, we would agree. If, however, an individual patient's consent agreement is required to be included in the written agreement between the hospice and nursing facility, we would not agree. The patient consent is a part of the individual patient's medical record and should not be a part of the agreement between the hospice and nursing facility, which typically applies to all of the hospice's patients residing in the facility, and not to a specific patient. There was a great deal of confusion about the language in this standard. We are requesting that CMS clarify that the requirement in §418.112(e)(1) would be fulfilled by the hospice providing the facility with the patient's hospice election form, which would include the patient's or representative's signature.

We are requesting that CMS significantly restructure proposed §418.112(e)(2) to separately identify the roles and responsibilities of the hospice and the nursing facility. Traditionally this has been an area of confusion and conflict, and we believe separating these into

two subsections would better clarify the issues. Most of the services to be provided by the hospice currently are set forth in proposed §418.112(e)(7), but we are requesting that they be moved. The language we are proposing regarding services to be provided by the nursing facility is adapted from State Operations Manual §2082A.

We are requesting that CMS delete proposed §418.112(e)(4) requiring that the written agreement include a provision that the nursing facility must notify the hospice immediately if a life-threatening condition appears. All hospice patients have life-threatening conditions or they would not be eligible for the hospice benefit, and unexpected events or changes are already addressed in proposed §418.112(4)(i).

We request that CMS delete proposed §418.112(e)(6) and (7) since these provisions would now be addressed in the language we are proposing to add to §418.112(1) and (2).

We are requesting several changes to proposed §418.112(e)(8). We want to clarify that the hospice's ability to use the facility's nursing personnel to provide certain services will be determined by applicable State law, as well as the facility, and to note that the hospice patient's plan of care is to be a coordinated plan. We also want to clarify that the hospice may use the facility's nursing personnel to implement the plan of care to the extent that the hospice would utilize the services of a hospice patient's family if the patient resided with them. The reality is that many family members and caregivers of hospice patients perform skilled nursing care, after having been trained and educated by hospice staff. While nursing services are a core hospice service, it is important to clarify that nursing facility staff can provide certain nursing services to hospice patients residing in the facility, to the extent that the hospice would have relied on the patient's family to do so in other settings, and to enhance patient safety and comfort. A good example would be the hospice patient who needs to be suctioned in the middle of the night. Hospice staff would have trained the family to provide suctioning so that the patient remains comfortable; in the same way, they would train the nursing home staff to do the suctioning until the hospice nurse is able to visit the patient.

<u>As specified above, we request that proposed §418.112(e) be revised as follows:</u>

(e) *Standard: Written agreement.* The hospice and the facility must have a written agreement that specifies the provision of hospice services in the facility. The agreement must be signed by authorized representatives of the hospice and the facility before the provision of hospice services. The written agreement must include at least the following:

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

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

<u>(2)) Services to be provided by the hospice</u>

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

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

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

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

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

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

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

(i) A significant change in the patient's physical, mental, social, or emotional status occurs;

(ii) Clinical complications appear that suggest a need to alter the plan of care;

~~(iii) A life threatening condition appears;~~

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

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

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

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

~~(7) A delineation of the hospice's responsibilities, which include, but are~~

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

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

Proposed §418.112(f) ***Standard: Hospice plan of care***

Developing a coordinated care plan is a challenging task in the nursing facility. It is extremely difficult because the nursing facility's Resident Assessment Instrument is so prescriptive regarding the completion of the assessment and care plan, which is focused on attaining "highest practicable functioning". Nursing facility staff are reluctant to abide by a care plan that deviates from the norm and focuses on comfort, rather than cure. Changes need to be made in the nursing facility regulations and guidelines applicable to hospice patients before it is realistic for hospices to comply with this standard. However, NHPCO appreciates the flexibility allowed in this standard by not specifying the number of care plans, but rather the need for coordination. We are suggesting a modification to this standard to refer to a comprehensive assessment of the patient's needs and unique living situation in the facility.

NHPCO is requesting the deletion of proposed §418.112(f)(3), requiring that the plan of care be reviewed at least every 14 days, "in conjunction with representatives of the facility". Pursuant to other provisions of the proposed rules, the hospice is required to perform a comprehensive assessment and review the plan of care for every patient, including those residing in a nursing facility, at least every 14 days. The nursing facility conditions of participation only require review of the plan of care every three months, and therefore we are concerned that the nursing facility staff will consider this requirement to be extremely burdensome. In performing the comprehensive assessment, the hospice would communicate and confer with nursing facility staff, and we are proposing changes to subsection (4) to make clear that any changes in the plan of care must be communicated with the nursing facility.

We also request that CMS clarify that the requirement to "discuss" changes in the plan of care can include fax, email, and other forms of communication.

As specified above, we request that proposed §418.112(f) be revised as follows:

(f) *Standard: Hospice plan of care.* A written plan of care must be established and maintained for each facility patient and must be developed by and coordinated with the hospice interdisciplinary group in consultation with facility representatives and in collaboration with the attending physician. All care provided must be in accordance with this plan. The plan must reflect the hospice's policies and procedures in all aspects and be based on ~~an~~ comprehensive assessment of the patient's needs and unique living situation in the facility. It must include the patient's current medical, physical, social, emotional, and spiritual needs. Directives for management of pain and other symptoms must be addressed and updated as necessary to reflect the patient's status.

(1) The plan of care must identify the care and services that are needed and specifically identify which provider is responsible for performing the respective functions that have been agreed upon and included in the plan of care.
(2) The plan of care reflects the participation of the hospice, the facility, and the patient and family to the extent possible.
~~(3) The plan of care must be reviewed at intervals specified in the plan but no less often than every 14 calendar days.~~
(43) Any changes in the plan of care must be discussed ~~among all caregivers~~ between both providers and must be approved by the hospice before implementation.

Proposed §418.112(g) *Standard: Coordination of services*

NHPCO considers this standard to have the greatest potential for strengthening the partnerships between hospices and nursing facilities, and improving patient care and outcomes. We particularly urge CMS to accept our request to add a requirement that the hospice have a system of communication with the facility to assure integration of hospice and SNF/NF or ICF/MR care and services. We also are proposing to re-order the list of information that the hospice must provide to the facility, to better correspond with the order in which the documents are normally gathered.

As specified above, we request that proposed §418.112(g) be revised as follows:

(g) *Standard: Coordination of services.* The hospice must designate a member of its interdisciplinary group to coordinate services ~~the implementation of the plan of care~~ with the representatives of the ~~facility~~ SNF/NF or ICF/MR. The hospice must have a system of communication with the facility to assure integration of hospice and SNF/NF or ICF/MR care and services. The hospice must provide the facility with the following information:

(21) Patient's or patient's representative hospice informed consent form,

election form and any advance directives.
(2) Physician certification and recertification of terminal illness.
(~~1~~3) Hospice p~~P~~lan ~~of~~ for palliative care.
(~~3~~4) Names and contact information for hospice personnel involved in hospice care of the patient.
(4~~5~~) Instructions on how to access the hospice's 24-hour on-call system.
(~~5~~6) Medication information ~~specific to the patient~~
(~~6~~7) Physician orders.

Proposed §418.112(h) ***Standard: Transfer, revocation, or discharge from hospice care***

NHPCO requests that CMS delete the second sentence in this standard. Hospices are not in a position to influence the eligibility of patients to continue to reside in a SNF/NF or ICF/MR.

As specified above, we request that proposed §418.112(h) be revised as follows:

(h) Standard: Transfer, revocation or discharge from hospice care. Requirements for discharge or revocation from hospice care, § 418.104(e), apply. ~~Discharge from or revocation of hospice care does not directly impact the eligibility to continue to reside in an SNF, NF, ICF/ MR, or other facility.~~

Proposed §418.112(i) ***Standard: Orientation and training of staff***

We are proposing changes to this standard to require that hospices ensure that nursing facility staff have been oriented and trained in the hospice philosophy and hospice practices, but not require redundant training. Some nursing facilities have agreements with several hospices, and each hospice should not be required to orient all nursing facility staff in hospice concepts and practices if, for example, another contracted hospice has recently conducted an orientation. As written, proposed §418.112(i) could be quite burdensome for both hospice and nursing facility staff, and is not necessary to achieve the goals of the standard.

As specified above, we request that proposed §418.112(i) be revised as follows:

(i) *Standard: Orientation and training of staff.* Hospice staff must ~~orient~~ ensure facility staff furnishing care to hospice patients have been oriented in the hospice philosophy, including hospice ~~policies and procedures~~ protocols and practices regarding methods of comfort, pain control, symptom management, as well as principles about death and dying, individual responses to death, patient rights, appropriate forms, and record keeping requirements.

XXII. PERSONNEL QUALIFICATIONS (PROPOSED §418.114)

CMS has proposed significant revisions to the personnel qualifications for hospice employees, and in particular is proposing that where personnel qualifications are not statutory or do not relate to a specific payment provision, CMS would simply require personnel to meet State licensure or certification requirements. This proposed change has particular relevance in the case of social workers. The current hospice regulations require that social workers have at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education; however, some states allow licensure of social workers who do not meet this qualification. As requested by CMS, NHPCO solicited comments from the field on the issue of social work qualifications, and received a high volume of responses.

Although we received a wide range of comments, overwhelming provider consensus was to continue to require that personnel functioning as hospice social workers have at least a bachelor's degree in social work. NHPCO recommends that the requirement for social work remain at the current level, requiring that social workers be licensed and have a bachelor's degree from a school accredited or approved by the Council on Social Work Education.

As specified above, we request that proposed §418.114(b) be revised as follows:

(b) Personnel qualifications for physicians, speech-language pathologists, social workers, and home health aides.
The following qualifications must be met:

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

(2) *Speech language pathologists.* Speech language pathologists must meet the qualifications specified in section 1861(ll)(1) of the Act. The individual must have a master's or doctoral degree in speech-language pathology and must—

(i) Be licensed as a speech-language pathologist by the State in which the individual furnishes such services, or,

(ii) In the case of an individual who furnishes services in a State which does not license speech-language pathologists, must:

(a) Have successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating such supervised clinical experience),

(b) Have performed not less than 9 months of supervised full-time speech language pathology services after obtaining a master's or doctoral degree in speech-language pathology or a related field, and successfully completed the Praxis National Examination in Speech-Language Pathology.

(3) *Social workers.* Social workers must have at least a bachelor's degree from a school accredited or approved by the Council on Social Work

Education, and be licensed by the State in which the individual furnishes services, if such licensure is required.

~~(3)~~(4) *Home health aides.* Home health aides must meet the qualifications required by section 1891(a)(3) of the Act and implemented at § 484.75.

XXIII. CRIMINAL BACKGROUND CHECKS (PROPOSED §418.114(d))

Most states and many liability insurers now require hospices to obtain criminal background checks on employees. Providers who commented perform these checks currently, and do not object to this practice due to potential liability issues. However, NHPCO has concerns with the proposed requirement that hospices obtain a criminal background check on EACH employee. Many programs require background checks only for those employees involved with patient care, or who have contact with financial information. There was also a concern raised about the language in the preamble stating that such background checks would be required "before employment".

NHPCO is uncertain of CMS' intent in this standard. Would hospices be prohibited from hiring individuals with certain backgrounds; could they be hired conditionally; could they be hired provided they had no patient care or financial contacts? Many companies that provide background checks have a response time of 30 days; it is common practice in many hospices to conditionally hire the employee until the criminal background check results are in, and use that time for orientation and non-patient care related training activities. Some hospices commented that it should be sufficient for the hospice to obtain background checks in accordance with state law.

There was a concern raised about current volunteers and employees. One provider commented, "we do object to having to check employees and volunteers who were working with us prior to our initiating this practice years ago. We will lose volunteers who will take it as a personal affront." We request that in the final rule CMS address the issue of hospices' responsibility regarding current employees and volunteers.

As specified above, we request that proposed §418.114(d) be revised as follows:

d) *Standard: Criminal background checks.* The hospice must obtain a criminal background check on ~~each~~ hospice employees ~~and contracted employee before employment at the hospice.~~ in accordance with state law. Hospice contracts must require that all contracted entities obtain criminal background checks on contracted employees in accordance with State law.

Conclusion

NHPCO conducted extensive outreach to the hospice community during the comment period and incorporated many comments from the field in this comment letter. We are pleased to provide our thoughts and recommendations on the proposed Hospice Conditions of

Participation, and look forward to working with CMS and with hospice providers to prepare for the implementation of the final rule.

Should you have any questions or wish to discuss any of these issues with us, we would be happy to work with you.

Respectfully submitted,

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Passionate for the Appropriate Use of Medication

July 26, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Center for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
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Re: Comment on the Proposed Medicare Conditions of Participation for Hospice, published May 27, 2005, File Reference No. CMS-3844-P

Dear Dr. McClellan,

Thank you for the opportunity to submit comments in response to the proposed rule, published in the Federal Register on May 27, 2005, revising the existing hospice conditions of participation (COPS).

excelleRx, Inc. is a Philadelphia-based prospective medication therapy management (PMTM) company that contracts with over 500 of the nation's hospice programs. The approximately 50,000 hospice patients we serve per month represent over 30% of the total hospice patient population. We have developed peer-reviewed, literature-referenced, evidence-based medication use guidelines for management of 47 symptoms and/or syndromes associated with terminal illness. As a company, we advocate for the patient's right to appropriate medication therapy. Our PMTM model achieves that goal in hospice through the active participation of palliative-care-trained pharmacists in medication care planning, supporting appropriate prescribing, monitoring patient symptoms and quality of life outcomes, and reporting endpoints and outcomes of therapy to the hospice interdisciplinary group. Application of our evidence-based guidelines assures that the pharmacotherapy is both efficacious and cost-effective. As proof of concept, physician acceptance rate of our pharmacists' therapy recommendations is 96%, and our partner hospices have documented reduction in time to palliation, avoidance of hospitalization, as well as a reduction in direct and indirect costs associated with pharmacotherapy.

Given our expertise in pharmacotherapy and experience in the hospice market, our comments focus on those requirements most pertinent to medication therapy and medication management. As you are well aware, the current hospice COPS were promulgated on December 16, 1983 – well over 20 years ago. Since then, new medications have been introduced and new preparations of standard medications have been developed. Some innovations, such as long-acting opioid preparations and convenience packaging of medications that enables rapid access during a symptom crisis, have produced significant symptom management improvements. At the same time, many new medications and modified preparations of standard medications have merely fueled the cost of pharmacotherapy without adding measurable

clinical benefit. According to National Hospice and Palliative Care Organization (NHPCO) data, the hospice spend on medications and biologicals, as a proportion of total reimbursement, has increased from 3% to 17% in just 10 years. Many hospice programs struggle to remain fiscally viable under the pressures of nursing shortages, declining length of stay on hospice, and increased costs for labor and contract services. The combined challenges of acuity of illness at the time of hospice admission and the rising costs of care make appropriate and cost-effective pharmacotherapy more important now than at any other time in the history of the industry.

While medication therapy has always been a core component of symptom management in palliative and end-of-life care, the introduction of new medications and medication classes has elevated the importance of medication selection and monitoring. Unfortunately, as proposed, the COPS do not adequately address medication therapy as a critical component of hospice care. Accordingly, our comments are intended to provide a framework for integrating current hospice-specific medication therapy management practices into the COPS and to strengthen and clarify regulatory language as it pertains to medication use. Our comments were guided by the following core principles:

1. Hospice care must be patient-centered.
2. Assessment, care planning, and treatment must be interdisciplinary and reflect current industry best practices with respect to palliation, pain management, and symptom control.
3. As far as practicable, patient care standards should be consistent across care settings.
4. COPS must be clear, consistent, and not overly burdensome, and
5. Quality improvement programs must be data-driven and reflect hospice special needs and challenges.

Our specific comments are set forth in detail below.

1. Standards for Pharmaceutical Services should be consistent across care settings, except when consistency is impractical, infeasible or unnecessary.

ISSUE: Section 418.110 provides a standard for pharmaceutical services that addresses many important aspects of medication management including dispensing accuracy, assessment and evaluation of appropriate therapy, monitoring for adverse medication events, and consultant pharmacy services. The standards set forth in Section 418.10, however, only apply to hospices that provide inpatient care directly.

RECOMMENDATION: CMS should provide a single standard for a pharmaceutical service that is consistent across all of the hospice's care settings. Such a standard should provide that the hospice provide or arrange for

(A) Medication management care planning and consultative services that:
  (1) Assure appropriate medication selection, based on relevant evidence-based guidelines,
  (2) Ensure appropriate prescribing,
  (3) Ensure accurate dispensing,
  (4) Provide ongoing evaluation of a patient's response to medication therapy services and adjustments to therapy that ensure quality patient outcomes,

(5) Monitor actual and potential adverse medication events,
(6) Recommend appropriate medication care plan adjustments, and
(7) Document initial and periodic assessments and patient outcomes of medication therapy.

RATIONALE: As CMS is aware, the majority of hospice services are provided in patients' homes. We believe that high-quality pharmacy services provided to patients in any setting where they receive hospice care reduces suffering and increases quality of life for patients and their caregivers. Because medication therapy is such an important component of hospice services, and the right to receive effective pain management and symptom control is not limited to patients receiving inpatient hospice care, the COPS should ensure access to a defined set of pharmacy services, regardless of care settings where patients receive hospice services. Of course, we recognize that the standard would also need to be consistent with the SNF and hospital COP so that providing care under arrangements would continue to be feasible.

2. PATIENT RIGHTS

ISSUE 1: Hospice care is patient centered. This means that providers seek to treat patients with respect and dignity and with the highest regard for personal choices. In many non-hospice care settings, both the Congress and CMS have given voice to a patient's right of self-determination by providing clear patients' or residents' rights provisions in the COPS. As proposed, the hospice COPS clearly require hospices to provide the patient with notice of rights, and clearly provide that the patient has a right to exercise his or her rights as a patient of the hospice, but there is no clear, comprehensive enumeration of what those rights are.

RECOMMENDATION: To promote consistency and clarity, we strongly recommend that CMS enumerate the rights of hospice patients. Specifically, rights that should be specifically enumerated include: (1) the right of each hospice patient to be fully informed about palliative care and treatment options, to make informed decisions, and to participate in care and treatment planning, and (2) the right of each patient to refuse care or treatment.

RATIONALE: Federal COPS for hospitals, nursing facilities, home health, and ICF/MR all provide a clear statement of rights that include the rights of a patient/resident to be informed about treatment of options, to participate in care planning, and to refuse treatment. These core civil rights are no less important in the hospice environment where patients receive end-of-life care.

ISSUE 2. Information regarding medication disposal policies – Proposed 42 C.F.R. § 418.52 provides that "[t]he hospice must provide the patient or representative with verbal and written notice of the patient's rights and responsibilities…during the initial evaluation visit in advance of furnishing care" and that "[t]he hospice must inform the patient and family of the hospice's medication policies and procedures, including the policies and procedures regarding the tracking and disposing of controlled substances." 42 C.F.R. § 418.106 (b) requires that the hospice's policies regarding the use and disposal of controlled substances must be discussed with the patient and the patient's family during the initial hospice assessment."

RECOMMENDATION: If it is CMS's intent that the hospice provide the patient and family with information about disposal of controlled substances *during the initial evaluation visit prior to*

furnishing care, then we recommend that this requirement be modified to require hospices to provide *written* information about the disposal of controlled substances during the initial evaluation visit and *discuss* these polices and procedures during the four day assessment period following hospice enrollment.

RATIONALE: We fully support policies and procedures to reduce, and hopefully, eliminate the potential for diversion of controlled substances in the community. However, we believe that patient and family understanding of and compliance with policies for medication disposal that will generally take place at the time of the patient's death is more likely if they are approached when the issue has direct relevance. This change in regulatory language will reduce the burden of information assimilation during a highly stressful time (i.e., when the patient and family are hearing about hospice care for the first time). Our position is consistent with and fully supports the position of the National Hospice and Palliative Care Organization (NHPCO).

ISSUE 3 - Right to Pain Management, 42 C.F.R. § 418.52(c), provides that "[t]he patient has the right to receive effective pain management and symptom control from the hospice."

RECOMMENDATION: To ensure that this right can be realized, specific language addressing medication therapy must be incorporated into the standards for assessment and care planning processes, and in the quality assurance/performance improvement standards. We refer you to our comments pertaining to the following sections:

1) Comprehensive Assessment of the Patient [42 C.F.R. § 418.54 (c)(1)(ii)];
2) Interdisciplinary Group Care Planning and Coordination of Services [42 C.F.R. § 418.56 (c)(1)];
3) Quality Assessment and Performance Improvement [42 C.F.R. § 418.58 (a)(1)];

RATIONALE: While we emphatically support the patient's right to timely and effective pain management, that right cannot be realized if the COPS that address care planning, assessment, treatment, and quality assurance fail to clearly incorporate standards regarding the assessment, monitoring, and active management of medication therapies to address pain and symptom control. Medication therapy is a key component of pain management and symptom control. *Effective* pain management and symptom control at the end of life requires thorough evaluation and assessment of the patient's medical condition, history, and response to therapy. Specific reference to medication therapy should, therefore, be incorporated into the standards for assessment, care planning, and treatment. *Effective* pain management and symptom relief also requires the specialized knowledge and expertise of pharmacists with experience in end-of-life care. While consultant pharmacy is required for inpatient hospice settings, we are recommending that medication management care planning by a pharmacist be carried over into all hospice patient care settings, regardless of venue. Finally, to promote compliance with the hospice patient's right to effective pain management and symptom control, we are recommending that pain management be included as an integral element within the standards for quality assurance and quality improvement programs.

3. COMPREHENSIVE ASSESSMENT OF THE PATIENT.

ISSUE: We agree that "[t]he 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." However, this standard does not go far enough to identify the elements needed to assess medication therapies, a critical aspect of modern hospice treatment.

RECOMMENDATION: We recommend that this requirement be expanded to include a **thorough assessment** of the patient's prior, current, and ongoing pharmacotherapy or medication care plan. Specifically, we recommend that proposed 42 C.F.R. § 418.54(c)(1)(ii) be amended to include the critical elements of medication therapy management. The CMS proposed language and our proposed amendments are depicted in the following table.

Comprehensive Assessment 42 C.F.R § 418.54 (c) (1)(ii)	
CMS proposed language (May 27, 2005)	**excelleRx's recommended revisions**
(ii) *Drug therapy*. A review of the patient's prescription and over-the-counter drug profile, including but not limited to identification of the following - (A) Ineffective drug therapy; (B) Unwanted drug side and toxic effects; and (C) Drug interactions.	(ii) ***Medication** therapy*. A **thorough** review **and assessment** of the patient's prescription and over-the-counter **medication** profile, including but not limited to identification of the following – (A) Ineffective **medication** therapy; (B) **Medication therapy deemed unnecessary and/or not consistent with the patient's goals of therapy**; **(C) Medication therapy requiring dosage optimization;** **(D) Therapy that is inappropriate according to evidence-based guidelines;** (E) **Duplicate medication therapy**; (F) **Missing medication therapy necessary to prevent or address a symptom experienced by the patient**; (G) **Medication therapy requiring laboratory monitoring and evidence that the monitoring is being performed (e.g., warfarin and INR)**; (H) Unwanted **medication** side and toxic effects; and (I) **Actual or potential medication** interactions.

RATIONALE: Medication-related problems (MRP) are significant in the hospice population, possibly leading to increased morbidity, decreased quality of life, unnecessary hospitalization, and even premature death. In March of 2005, we examined the prevalence of medication-related problems in a sample of 250 hospice patients (excelleRx, Inc.; company data on file). We found that 37% of patients

had been prescribed at least one inappropriate therapy (potential for drug-disease interaction; drug-drug interaction, drug-age interaction, or the medication was not the best choice for other clinical reasons); 30% had one or more indications for therapy without appropriate therapy prescribed; 32% of patients required dose adjustments (prescribed dose was too high or too low); 10% exhibited potential or actual adverse drug reaction; and 5% were receiving a medication with no discernable indication. Based upon our experience in hospice care, we believe that the above eight elements of medication therapy assessment represent the minimum standard that should be applied in the hospice setting to assure the safety and efficacy of medication therapy.

4. INTERDISCIPLINARY GROUP CARE PLANNING AND COORDINATION OF SERVICES

ISSUE 1. – Composition of the interdisciplinary group. The proposed rule at 42 C.F.R § 418.56 omits mention of the important role played by pharmacists in the care planning and coordination process.

RECOMMENDATION: While we are not recommending that the COPs *require* that a pharmacist is included in the interdisciplinary group, we strongly recommend that CMS urge hospices to include in their care planning process a pharmacist who can provide expert medication therapy management in palliative pharmacotherapy.

RATIONALE: As new pharmacotherapy options have become available during the past two decades, hospice clinicians have been challenged to stay abreast of new developments along with myriad other changes in the industry, including applied pharmacogenomics. Pharmacists are a logical and necessary addition to the hospice interdisciplinary team. While pharmacists are not mentioned in the statute pertaining to hospice services, neither is the spiritual counselor, another cornerstone of comprehensive hospice care. CMS has the authority to recognize necessary participation of additional professionals on the hospice interdisciplinary team who will improve patient outcomes. Because of the importance and complexity of appropriate medication care plans in achieving positive outcomes, it is vital to integrate a pharmacist onto the IDG so as to provide pharmaceutical consultative services early in the process, before treatment regimens are finalized.

ISSUE 2. – Plan of Care. We support CMS language in 42 C.F.R § 418.56(c) that "the hospice must develop a written plan of care for each patient that reflects prescribed interventions based on the problems identified in the initial comprehensive and updated comprehensive assessments, and other assessments." As noted below, we recommend specific language change regarding required elements of the care plan.

RECOMMENDATION: The CMS proposed language and our proposed amendments to 42 C.F.R. § 418.56(c)(1) are depicted in the following table.

Interdisciplinary Group Care Planning and Coordination of Services 42 C.F.R. § 418.56(c)(1)	
CMS proposed language (May 27, 2005)	**excelleRx's recommended revisions**
(c)...The plan of care must include, but not be limited to – (1) Interventions to facilitate the management of pain and symptoms.	(c)...The plan of care must include, but not be limited to – (1) Medications **and non-pharmacologic** interventions **necessary for effective pain** management **and symptom relief.**

RATIONALE: This change is consistent with our recommendations to strengthen and clarify care planning requirements to address medication issues, to ensure consistency with the patient's right to effective pain management and symptom relief, and to ensure access to high quality pharmaceutical services for all hospice patients regardless of care setting.

5. QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT (QAPI)

ISSUE: As advocates of evidence-based clinical care, we fully support CMS's expansion of the hospice conditions to include a quality assessment and performance improvement focus. However, we do not believe CMS has gone far enough to identify required elements of an effective QA program.

RECOMMENDATION: We are recommending that hospice track data around certain core elements related to medication therapy and outcomes of that therapy. Specifically, 42 CFR § 418.58 (a) should be amended to read as depicted in the following table.

QAPI 42 CFR § 418.58 (a)	
CMS proposed language (May 27, 2005)	**excelleRx's recommended revisions**
(1) The program must be at least capable of showing measurable improvement in indicators for which there is evidence that improvement in those indicators will improve palliative outcomes and end-of-life support services. (2) The hospice must measure, analyze, and track quality indicators and other aspects of performance that enable the hospice to assess processes of care, hospice services and operations.	(1) The program must be at least capable of showing measurable improvement in indicators for which there is evidence that improvement in those indicators will improve palliative outcomes and end-of-life support services **including, but not limited to, pain relief, and adverse patient events, including adverse medication events such as avoidable medication-related hospitalizations.** (2) The hospice must measure, analyze, and track **such** quality indicators and other aspects of performance that enable the hospice to assess processes of care, hospice services and operations.

RATIONALE: Our recommendation promotes compliance with the patient's right to effective pain management and symptom relief and is consistent with promoting a single, consistent standard for pharmaceutical care across all hospice care settings. Pain relief is recognized within the industry as one of the key measures related to symptom outcomes. While we believe that CMS should require hospices to track pain relief, hospices should have flexibility in choosing the methodology. As one methodology to achieve that standard, we support the CMS *recommendation* that hospices adopt the NHPCO End Result Outcomes measures. Secondly, we believe that hospices should track adverse patient and medication events. Hospice patients as a group are uniquely vulnerable to medication related problems (MRPs) and adverse medication events (also known as adverse drug events, or ADEs), secondary to medication therapies on the one hand, and under-treatment of symptoms that leads to prolongation of unnecessary suffering on the other. With our hospice partners, we have developed and deployed short, easily administered questions and data collection strategies to document patient self-reported outcomes: the gold standard for symptom and quality-of-life assessment. These strategies are being used today to track outcomes for over 50,000 hospice patients per month. By tracking **adverse patient events, including adverse medication events,** we have significantly enhanced patient outcomes, such as time to palliation, and reduced adverse outcomes that can lead to increased suffering and higher costs.

ISSUE 2: The term "adverse patient event" is not defined.

RECOMMENDATION: 42 C.F.R. § 418.3 *Definitions* should be *amended* to include the following definitions:

> *Adverse patient event* means an unanticipated, non-therapeutic response or injury including an adverse medication event.
>
> *Adverse medication event* means a patient injury or avoidable medical intervention resulting from medication therapy

6. CLINICAL RECORDS

ISSUE: In the preamble to the proposed rule, CMS requests comments on the following:

> 1) What are the components of an electronic health record (EHR)? What are the advantages or disadvantages of using EHR in a hospice setting?
> (2) Should an EHR include a personal health record, which is accessible to the patient? What are the positive and negative consequences of personal health records?
> (3) What are the barriers (technical and clinical) to implementing an EHR system in hospice?

CMS expressed interest in knowing about hospice experience thus far and how EHRs have impacted patient care and outcomes.

RESPONSE: excelleRx has developed and has been using an electronic medication record for every hospice patient we have served since 2001. Currently we have over 45 million patient-days worth of data including demographic, diagnosis, pharmacotherapy, and clinical outcomes. These data enable us to both ensure the most appropriate care for individual patients and to track their progress longitudinally. We also mine this data to generate clinical insights and make our Medication Use

Guidelines more robust. All patient records are available via a secure Internet-based platform to our client hospices. excelleRx has also had success in interfacing with other clinical software providers so that clinicians can share data needed to treat and manage the patients we serve. The push for EHR within Medicare is encouraging and consistent with the general direction of the healthcare industry.

In our experience, electronic medication records enable us to reduce errors; provide multiple access points for both data entry and information retrieval (Internet, interactive voice response (IVR) and fax scanning); collect, analyze, and report data at both the patient level and macro-level more easily and cost-effectively; conveniently access records regardless of time or place; and reduce clinical time required for documentation and research.

At the same time, some of the challenges associated with using electronic health records include a cost burden to hospices and access to the data online being constrained by the bandwidth available to the user.

7. SECLUSION AND RESTRAINT

ISSUE: We appreciate that CMS has addressed the critically important issues of seclusion and restraint in the revised COPs. However, we are concerned that the requirements set forth reflect insufficient consideration of the unique patient care issues that are present in hospice care.

RECOMMENDATION: CMS should convene a task force of experts to examine the issues around chemical restraint in end of life care and provide evidence and consensus-based recommendations to CMS. Given our expertise and experience with the administration and management of medications, including opioid analgesics, in hospice care, we would welcome the opportunity to participate on such a Task Force. We further recommend that guiding principles for this work group should include:

(1) The appropriate selection, use, monitoring, and titration of psychotropic medications to manage symptoms in terminally ill patients should be based on clinical assessment;
(2) Response to therapies must be monitored and adjustments based on clinical assessment;
(3) Criteria should be established for use of palliative sedation for those patients with such severe end-of-life symptoms that conventional interventions (pharmacologic and/or non-pharmacologic) have been exhausted and documented such by the palliative care team.

RATIONALE: Hospice patients are unique in several important ways. First, their illness trajectory is such that, even with optimal symptom management, their symptoms are likely to progress as they approach the end of life. Medications such as opioids and psychotropic medications that might be inappropriately applied to restrict patients' movement or manage their behavior in other settings are regularly and ***appropriately applied, often in escalating doses***, to manage symptoms and increase patient comfort as the end of life approaches. We believe that the proposed regulatory language, including the definition of a medication restraint, does not reflect a sufficient understanding of the appropriate use of sedating and analgesic medications in the hospice setting. We are gravely concerned that if these regulations are finalized, they will negatively impact on patient comfort, increasing their suffering when they are most vulnerable and most dependent on their professional caregivers to ease their pain and symptoms so that they can die comfortably. The proposed regulation will act as a deterrent to appropriate symptom management in much greater proportion to any reduction in

inappropriate patient restraint, as clinicians will hesitate to use medications that have become a mainstay of palliative pharmacotherapy in doses necessary to relieve treatable symptoms.

We believe, therefore, that it is premature to adopt regulatory language that has the risk of increasing patient suffering at the end of life without evidence of a problem that needs improvement. Given the critical role that medications play in pain relief and symptom management in hospice, CMS should await recommendations of an expert Task Force before finalizing these regulations. We understand that CMS has used similar approaches when developing restraint regulations for other care settings such as residential psychiatric settings and nursing homes. Further, we believe that with the recommendations made herein to assure that a pharmacist is involved in the medication care planning process, including the monitoring of adverse events, the risk of an inappropriate therapy for use as a 'restraint' is minimized.

We thank you again for the opportunity to provide you with comments on the proposed hospice COPS. We welcome the opportunity to engage in further discussion and to work collaboratively with CMS to resolve outstanding issues.

Sincerely,

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Providence | Health System

July 25, 2005

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

RECEIVED - CMS
2005 JUL 26 P 3:07

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

Dear Dr. McClellan:

On behalf of the Providence Health System, I want to thank you for the opportunity to provide our comments on the changes proposed by the Centers for Medicare and Medicaid Services (CMS) to the Conditions of Participation for hospice agencies that are certified to provide Medicare or Medicaid services. CMS published these changes as part of its Notice of Proposed Rule Making in the Federal Register on May 27, 2005. The Providence Health System is a faith-based, non-profit health system that operates eight certified hospice agencies in Washington State, Oregon, and California along with hospitals, physician groups, home health agencies, assisted living, senior housing, PACE programs, and a health plan. In 2005 the Providence Health System provided 895,392 hospice and home health visits.

As a Catholic health care system striving to meet the health needs of people as they journey through life, Providence is committed to improving the quality of life for those it serves – including the experience of dying for terminally ill patients. Providence has a longstanding history of providing supportive care to the terminally ill and their families that predates the Medicare program's coverage of hospice as a benefit. For example, Providence Hospice of Seattle is the Northwest's oldest hospice agency having just celebrated its thirtieth year of service and one of Providence's hospice agencies in Portland was among the initial 26 demonstration sites chosen by the Health Care Financing Administration in 1979 to assess the cost effectiveness of hospice care and to help determine what a hospice care should include as a benefit under the Medicare program. As a result of these and similar efforts Providence has been recognized nationally as a leader in hospice care. In 2003 Providence was a recipient of the prestigious Circle of Life Award for its innovative programs in palliative and end-of-life care and Providence is a founding member of "Supportive Care of the Dying: A Coalition

for Compassionate Care;" an organization that has greatly contributed to improved understanding of how best to meet the needs of the terminally ill. It is with this perspective and understanding that Providence provides its comments and recommendations to CMS on the proposed rule.

Before commenting on specific issues, Providence would like to commend CMS for its proposal. While many of the proposed regulations are consistent with current and emerging standards of practice – particularly for those agencies operated by Providence and others that are already accredited by the Community Health Accreditation Program [CHAP] or the Joint Commission for the Accreditation of Healthcare Organizations [JCAHO] – the proposal is a marked improvement over the existing regulatory text and framework. However, because these rules provide the minimum standards for *all* certified hospice agencies Providence believes that the standard of care being advanced in this proposal is worthy of adoption after due consideration of comments that are submitted as part of this rulemaking process. Particularly noteworthy are the provisions that recognize the importance of patient rights (42 CFR §418.52) and the "cycle of care" framework that facilitates continuous integration of the patient assessment, care planning, care delivery, and care evaluation processes (42 CFR §418.54, 418.56, and 418.58).

Once final rules are adopted Providence would note that it is equally important for CMS to modify its survey processes (along with obvious modifications to the interpretative guidelines) to reflect these changes and the expressed regulatory philosophy that underlies the entire proposal: The survey process can either facilitate or frustrate the ability of CMS to achieve its articulated vision of a "patient and family centric" regulatory policy that stresses actual patient outcomes; ***especially if the agency intends to achieve these worthy goals while facilitating "flexibility in how a hospice meets performance expectations."*** Providence is committed to further working with your agency to accomplish this end. However, notwithstanding its overall assessment and support of the direction set forth by CMS, there are a number of areas where Providence believes changes or clarification would serve to improve the proposed revisions. These changes are discussed in the text that follows.

42 CFR §418.52 Patient's Rights

As noted previously, as an organization with a core value of respect Providence agrees that each patient has the right to be informed of their rights and that the hospice must protect and promote the exercise of these rights. With regard to the provision in 42 CFR § 418.52(a) ["Notice of Rights"] Providence believes that the following two clarifications will make the regulatory expectations more coherent:

- As written, the text in 42 CFR § 418.52(a)(1) requires that in addition to receiving verbal notice of their rights each beneficiary has a right to receive *a written copy in a language that the patient understands*. Taken literally, this albeit well-intentioned provision goes beyond the requirements established by the Office of Civil Rights for services provided to those with limited English proficiency and would impose significant cost burdens on many agencies serving a disparate

group of non English-speaking patients. For example, one of our agencies currently serves a patient population with over 20 distinct languages. While such a standard might be ideal, it is in fact impractical. **Providence would recommend that CMS explicitly recognize in the text that this provision does not create a regulatory requirement beyond that already established by the Office of Civil Rights with respect to agencies serving non English-speaking beneficiaries**[1]. Additionally, the intent of this provision – namely that all beneficiaries are notified of their rights in a language they understand – can be easily be met through the provision of language interpretive services provided directly or through a telephone service when to do so in writing is not required, would be impractical, and is burdensome.

- The text in 42 CFR § 418.52(a)(4) requires the hospice to maintain documentation that the patients and their family have demonstrated an understanding of these rights. In order to provide a precise understanding of the regulatory standard and expectations **Providence would recommend that the text be amended to state simply that a hospice must maintain written documentation whereby the patient or their Representative acknowledges that they have been informed as to their rights enumerated in 42 CFR § 418.52(b).**

While Providence has a number of concerns with respect to the additional obligations imposed on a hospice regarding the tracking and disposing of controlled substances noted in 42 CFR § 418.52(a)(3), those comments are reflected in our discussion of 42 CFR § 418.106(b).

The regulations found in 42 CFR § 418.52(b) ["Exercise of Rights and Respect for Property and Person"] set forth a number of explicit rights for individuals receiving hospice services and create corresponding obligations incumbent upon an agency to respect those rights. While we can find no fault with the proposed text enumerating the rights, Providence is concerned that the language in subsections 42 CFR § 418.52(b)(4)(ii) and (iii) could erroneously suggest that it is within the ability and the responsibility of the agency to immediately investigate and take corrective action in every situation where an alleged violation of rights has occurred. To be sure, hospice beneficiaries are often vulnerable and unable to fully protect their own rights. Thus, it is only reasonable to require that the agency at a minimum report even suspected violations as required by 42 CFR § 418.52(b)(4)(i). However, it has been the experience of our agencies that most situations involving mistreatment, neglect, abuse, and misappropriation of property described in the regulation are often perpetrated by a family member or authorized patient representative. In such cases, beyond establishing the affirmative obligation for an agency to report these concerns to (more) appropriate

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[1] Office for Civil Rights, "Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons," August 4, 2003

investigative agencies, there are very real limits as to what a hospice can do in these situations: Often they are first observed by a home health aide or homemaker aide in the patient's home where the alleged perpetrator is present and there are concerns about the safety of the patient and caregiver alike. Because of the prevalence of these type of fact situations **Providence believes the final regulations must take these instances into consideration and not impose an obligation upon a hospice beyond that of reporting found in 42 CFR § 418.52(b)(4)(i). Of course, distinctions can obviously be made for those unfortunate situations where the individual who may have been involved in violating the rights of a patient is an employee of the agency or acting under arrangement with the hospice.** In these circumstances the additional responsibilities of the agency enumerated in the proposed text are clearly appropriate. We would further note that this recommended approach is consistent with the regulatory expectations of a home health agency under 42 CFR § 484.10(b)(5).

42 CFR §418.54 Comprehensive Assessment

As the first step in the cycle of care a 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. The comprehensive assessment is continuously updated and is a critical element that provides the foundation for subsequent care planning, care delivery, and care evaluation processes. As noted previously, Providence is extremely supportive of this overall Condition.

Subsection 42 CFR § 418.54(a) further requires that a registered nurse must make an initial visit within 24 hours of receiving a physician's order for care as part of an "Initial Assessment." Providence would offer the following comments concerning this specific requirement:

- It has been our experience that **the primary presenting needs of the patient should govern the choice of a specific discipline to make this initial visit.** For example, it may be that the most important issue needing resolution is the choice of a residence for the patient. In these cases an initial visit conducted by a social worker may be more responsive to the immediate needs of the patient than a visit conducted by a registered nurse as the proposal is currently drafted. The regulatory text should be amended to permit this flexibility. Of course, the requirements concerning the comprehensive assessment appropriately recognizes the interdisciplinary nature of hospice care planning and delivery.
- **Providence would recommend that the reference to a "physician's admission order for care" as the event that initiates the initial assessment be clarified.** As Providence's administrative and clinical leadership for hospice care reviewed this text it was *presumed* that this order was referencing the physician's certification of the patient's terminally ill status. In any event, given the important time-sensitive actions which are triggered by this event a more appropriate description should be incorporated into the final regulation.

- Finally, as drafted the initial assessment visit must be completed within 24 hours of receiving this order unless ordered otherwise by the physician. Providence supports a requirement for a timely and effective response and the 24-hour standard is appropriate in most circumstances. However, **Providence would recommend that another exception be added to this standard to take into account those situations where additional time is requested by the patient or their Representative.** Often these types of visits are delayed at the patient's request because the patient wants their family to be present. As CMS appropriately moves to create a more patient and family-centric approach to its regulations, this is but one example of where the typical regulatory approach of a single hard and fast standard needs to accommodate the preferences of the patient and their family in order to not frustrate these essential relationships.

Subsection 42 CFR § 418.54(b) establishes the time frame for completion of the comprehensive assessment. As drafted, this assessment must be completed by the hospice interdisciplinary group – in consultation with the patient's attending physician - within four calendar days of when the patient elected the hospice benefit. While the completion of the comprehensive assessment is a key element in the cycle of care and it would be highly desirable to complete it within the proposed time frame. However, notwithstanding our commitment to providing care twenty-four hours a day, seven days a week it is our experience that the proposed four-day requirement is unrealistic. **Providence recommends that a more appropriate standard of seven days be established.** This is especially important for the first comprehensive assessment as it is more important to get a thorough assessment completed rather than a fast one. Providence would note that the first five-day assessment required by Medicare for patients in a Part A stay can extend up to day eight using the concept of "grace days." While Providence is certainly not arguing for an extension of the regulatory framework for skilled nursing facilities to hospice care, this notion of "grace days" may provide a helpful approach to the regulatory requirements for completing the first comprehensive assessment for hospice patients.

While Providence fully supports the continued involvement of the patient's attending physician in the patient's ongoing hospice care unfortunately that is often not the case. For example, many patients first elect the hospice benefit after deciding not to pursue chemotherapy or participate in a clinical trial recommended by their attending physician who is a medical oncologist. Once the hospice benefit is elected the physician may in turn elect not to follow the patient. However, this very common situation appears not to be permitted by subsection 42 CFR § 418.54(b): That text requires the comprehensive assessment to be completed in consultation with the attending physician. It is impractical for CMS to hold the hospice accountable for the performance of the attending physician in these situations. Consequently, **Providence would recommend that the text be changed to require that the hospice seek to promote the continued involvement of the patient's attending physician in the completion of the comprehensive assessment as evidenced by the physician's written approval of the assessment. In situations where this level of involvement is not forthcoming the hospice should document its**

efforts to engage the physician in the patient's assessment. Providence will discuss similar concerns with respect to the language set forth in 42 CFR § 418.56(a).

42 CFR §418.56 Interdisciplinary Group Care Planning and Coordination

As proposed, this Condition would require that the hospice designate an interdisciplinary group which, in consultation with the patient's attending physician, must prepare a written plan of care for each patient. The plan of care must specify the hospice care and services necessary to meet the patient and family-specific needs identified in the comprehensive assessment as it relates to the terminal illness and related conditions. Subsection 42 CFR § 418.56(a) establishes the interdisciplinary approach to service delivery that has been a longstanding characteristic of hospice care. We would particularly commend the agency for its recognition of the need for an increased emphasis on the coordination of care, the continuous assessment of the patient and family's needs, and for ongoing evaluation of the implementation of the care plan. These efforts will be greatly enhanced by the provision calling for the appointment of a licensed health care professional who is designated by the interdisciplinary team as being responsible for these activities. Many of our agencies have had found that their comparable case management models have been an important element to achieving these outcomes.

In describing the composition of the interdisciplinary team charged with the development of the patient's plan of care, the proposed regulation states that the physician serving on that group - typically the hospice medical director - cannot be the patient's attending physician. However, for the reasons noted in our commentary at 42 CFR § 418.54(b), the medical director often becomes the default attending physician for the patient. Consequently, the prohibition proposed in 42 CFR § 418.56(a)(i) will complicate the hospice's ability to engage even their own medical director to serve on the interdisciplinary team. If CMS accepts the revised language Providence recommends in 42 CFR § 418.54(b) and the hospice agency is able to secure the continued engagement of the patient's attending physician then this issue will become moot. However, in the more likely scenario that the hospice medical director becomes the default attending physician for the patient then the prohibition is unworkable. For these reasons **Providence recommends that the phrase "who is not the patient's attending physician" found at 42 CFR § 418.56(a)(i) be deleted.**

In advancing this recommendation Providence would stress that such an outcome is not at odds with the best interests of the patient. Fortunately, many physicians are beginning to recognize the special skills and knowledge held by a doctor who is credentialed in palliative care. Consequently they acknowledge that it is often in the best interest of a patient to be seen by the medical director/attending physician who specializes in this type of care; much in the way a primary care physician appropriately refers a patient with significant cardiac issues to a cardiologist. At the very minimum the regulation should be

amended to at least allow the patient to elect to have the hospice medical director serving on the interdisciplinary group also serve as their attending physician.

Section 42 CFR § 418.56(b) also states that the plan of care must be developed in consultation with the patient's attending physician. Again, as desirable as that standard may sound the proposal is often not workable. Quite frankly, it is Providence's experience that increasingly many physicians are unwilling to see any Medicare patients, much less a patient with the complex medical management needs typical of most hospice beneficiaries. **Providence would recommend that the language already proposed in 42 CFR § 418.56(d) requiring the collaboration of the attending physician in the updating of the care plan only "to the extent possible" be incorporated into the text at 42 CFR § 418.56(b).**

As noted previously, Providence supports 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; including care *that is not limited to the palliation and management of the terminal illness and related medical conditions*. A comprehensive assessment should not be narrowly construed. However, the language found in section 42 CFR § 418.56(c) states that the written plan of care must be based upon the problems identified in the comprehensive assessments. As written, the language could have the unintended consequence of broadening the responsibility of the hospice to engage in comprehensive care planning far beyond the condition that gave rise to the patient's decision to elect the benefit. The practical effect of such an interpretation would be to expand the scope of services that a hospice is obligated to provide and even run counter to the longstanding tradition and care philosophy that hospice represents. For these reasons it is essential that clarifying language be added. **Providence would recommend that CMS make explicit in the final rule that while the comprehensive assessment should identify the totality of the patient's and family's needs, the interdisciplinary care plan is not required to address all of these issues but rather focus on those interventions necessary to facilitate the management of pain and symptoms related to the palliation and management of the patient's terminal illness and related medical conditions.**

42 CFR §418.58 Quality Assessment and Performance Improvement

Before offering its comments Providence would note that this area is worthy of commendation as it represents a significant improvement over the current regulations found at 42 CFR §418.66. For agencies that are accredited these new elements are nearly identical to the standards of practice mandated by these accreditation organizations. However, it is worth noting that an unaccredited agency will not be able to demonstrate compliance with a typical effective date of 60 days following publication of the final rule in the Federal Register. **Consequently, without delaying the implementation of these improvements unnecessarily, if CMS elects to move quickly in adopting the proposed regulatory framework at 42 CFR §418.58 then Providence would**

recommend an implementation approach for this specific section that provides additional time for the effective date of this requirement.

Furthermore, as drafted 42 CFR §418.58(a)(2) mandates the tracking of "adverse patient events". Providence fully supports the tracking of certain significant negative events but would note that the inclusion of the word "adverse" may in fact cause unintended confusion. As CMS is well aware that phrase has a specific and well-defined meaning when used by the CHAP program just in the same way that JCAHO has reserved the use of the phrase "sentinel events." Rather than use either term **Providence would recommend that CMS borrow heavily from these definitions and establish a clear threshold delineating the types of events that require special tracking and consideration.**

42 CFR §418.102 Medial Director

Overall responsibility for the direction of the Quality Assessment and Performance Improvement [QAPI] program is affixed with the hospice medical director under language proposed in section (c) of 42 CFR §418.102. **Providence finds no fault with creating a standard requiring the "active involvement" of the medical director in this program but cannot support a mandate that they actually be responsible for directing it.**

In offering this comment Providence would note that oversight and responsibility for ensuring that the QAPI program reflects the complexity of patients served and scope of the services provided by the hospice is properly established at the governance level (see the statement of the Condition at 42 CFR §418.58). Specifying that the program direction must be placed with the medical director may actually distort this intended scope and focus of the QAPI program by reflecting a more medical orientation. **Providence believes that responsibility for direction of the QAPI program should more appropriately be assigned to the interdisciplinary group as this body is more aligned with the desired approach for the QAPI program and can have the greatest impact on actual patient outcomes.**

42 CFR §418.104 Clinical Records

Section (e) of 42 CFR §418.104 requires that a hospice provide a copy of the patient's clinical record and the discharge summary (plan of care, physician orders, any other relevant information to assist in continuity of care) to a facility where the patient is transferred and to the attending physician if the patient revokes their election. Providence has a longstanding commitment to furthering a vision of a continuum of care within the delivery and even financing of health care services. Rather than treating each patient's discharge as an end to our responsibility, we view these events more appropriately as transitions in an ongoing process of care. The benefits of this approach are perhaps best demonstrated in our two PACE programs. Notwithstanding this orientation, we believe that the documentation to be provided to the new provider is excessive in most cases. Instead **Providence would recommend that the hospice be obliged to provide to those**

who need to know for treatment purposes, only that relevant clinical information necessary to promote ongoing continuity of care in a safe and effective manner for the patient.

42 CFR §418.106 Drugs, Controlled Drugs and Biologicals, Medical Supplies, and Durable Medical Equipment

Section (b) of 42 CFR §418.106 requires a hospice to track, collect, and dispose of controlled medications in the home. Further text in the regulatory preamble states that the hospice retains primary responsibility for these controls. While no one can argue with the desirability of maintaining appropriate controls over these medications – especially in the case of controlled substances – there are very real limits to the hospice's ability to control for all of these issues when (1) the medications are owned by the patient and (2) they are most often stored and administered by others in the patient's home environment. The hospice has no standing to track and often we are not able to collect unused medications: While the hospice can and should advise patients and their families on safe disposal there is often no effective way to enforce or monitor this expectation. Obviously this is not to assert that a hospice should not be otherwise responsible for monitoring the patient's medication regimen and Providence has even had to discharge patients from its care when the patient or their family member are knowingly diverting these medications. However, **the current regulatory language found at 42 CFR §418.96(b) ["Controlled Drugs in the Patient's Home"] should be retained in lieu of the proposed text as it represents a more realistic appraisal of what can be expected of the hospice: The hospice should have a policy and notify the patient and the family of their rights and responsibilities under it.**

Finally, Providence would express a concern with the language contained in 42 CFR §418.106(b) concerning the uses and dangers of controlled substances. The comments that follow should not be construed as anything less than a complete appreciation for the importance of informed consent. However, hospices have often struggled to overcome the misconceptions concerning the appropriate role of these medications in the management of pain and other symptoms related to the patient's terminal illness. **Providence would encourage some modification to the text that would acknowledge these pre-existing concerns while recognizing that a proper discussion of these issues would of necessity speak to the beneficial effects of these medications in addressing the needs of the patient and family identified in the comprehensive assessment.** Otherwise the effect of the text as proposed along with the discussion of this issue in the preamble may be to create an unintended barrier for the patient's effective symptom and pain management.

Another area where **this approach should also be incorporated is in the discussion of "drug restraints" as they are defined in 42 CFR 418.3.** As CMS is well aware, hospices quite often appropriately utilize psychotropic medications for the symptom relief of terminal agitation rather than a presenting psychiatric condition. The use of these medications is palliative in nature and not intended as a restraint, yet the regulation

as drafted has incorporated a litany of requirements based upon the presumption of restraint as its intended use. To lose access to these effective interventions - the probable end result – would be a disservice to the patients who could knowingly benefit from this use. This outcome is most likely if the patient is in a facility as that organization will want to avoid the potential liability associated with the use of "drug restraint"' especially given the negative connotations associated with such measures and the real resource requirements to meet the stated standards.

CONCLUDING REMARKS

Notwithstanding the recommended changes noted above, Providence appreciates the efforts of CMS to improve these regulatory provisions and select an approach that fosters improved quality of care and quality of life for those patients electing the hospice benefit. In general, we urge CMS to move forward with many of the proposed changes as modified by the comments Providence has provided. Thank you again for the opportunity to comment on this proposal and for your thoughtful consideration of our remarks. If you have any questions, please contact Chuck Hawley, Vice President of Government Affairs, at (206) 464-4237 or via e-mail at chuck.hawley@providence.org.

Sincerely,

John Koster, M.D.
President/CEO
Providence Health System

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KAISER PERMANENTE®

Kaiser Foundation Health Plan, Inc.

July 25, 2005

Via: Overnight Mail

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

Re: Comments on Proposed Hospice Conditions of Participation
42 CFR Part 418
File Code CMS-3844-P

Dear CMS Hospice Staff:

Kaiser Foundation Hospitals, Inc. ("Kaiser") operates 14 hospices in California and one hospice in Oregon. As such, Kaiser is a key provider of hospice services and is profoundly invested in ensuring a high quality of care for hospice patients. Kaiser hereby submits a summary of its review of and comments on the proposed revisions to the Medicare hospice Conditions of Participation ("CoPs") to the Centers for Medicare & Medicaid Services ("CMS").

General Thoughts on Proposed Rules for Hospice COPs:

In general, Kaiser notes that the proposed revisions to the COPs fit well within the current hospice practice of JCAHO accredited programs. We are encouraged by CMS' emphasis on quality and outcomes for patient care, instead of focusing solely on monitoring of processes that may not result in improved quality of care. Also, we notice that the proposed regulations are moving towards implementing current standards imposed by the industry on itself or using home health agency standards as CMS' model for hospice. In some cases, the regulations propose the same standards as the home health COPs. However, in some cases, the proposed regulations unnecessarily exceed the home health requirements. We are in agreement with the basic philosophy, but believe that CMS must be realistic about the practical application and feasibility of some of these proposed requirements.

Kaiser also believes that the CMS estimates of time and cost to implement these new COPs are too low, especially the requirements under Comprehensive Assessment, QAPI and Care for Facility-Based Residents. These proposed regulations will have a significant financial impact on Hospice.

Comment #1: PATIENT'S RIGHTS – Section 418.52

Walnut Center
Pasadena, CA 91188

Standard (b) – Exercise of Rights and Respect for Property. This standard should include the patient's right to refuse treatment.

Standard (b)(4). The reporting rule for "alleged" violations of abuse seems excessive. This proposed regulation states that hospices must report all alleged violations to the state survey agency within 5 working days "of the incident." Kaiser notes that the timing of this requirement is vague, since the "incident" may have occurred long before it is actually reported to hospice staff. Kaiser further notes that it is unclear whether this requirement applies only to incidents involving hospice staff or whether it applies to any alleged abuse, etc., that may be reported that involves the patient's family or caregivers. Kaiser also notes that some of the alleged incidents are proven to be without basis through internal investigations. Kaiser believes it would be more appropriate to require the investigation of all alleged incidents and the reporting of actual, investigated, actionable violations to the survey agency. In addition, hospices should be required to comply with any other state reporting requirements for elder abuse, etc.

Comment #2: COMPREHENSIVE ASSESSMENT OF PATIENT.

Sections 418.54(a) and (b)

The proposed rule regarding the comprehensive assessment of the patient will drastically increase the administrative requirements of the hospice and set standards that are vague and unrealistic. The proposed rules require that the Initial Assessment be completed within 24 hours of care and that the Comprehensive Assessment be completed within four calendar days (not business days). The Comprehensive Assessment must be updated every 14 days.

The proposed hospice COPs for comprehensive assessment is unnecessarily more onerous that the similar COP for home health agencies. The Home Health COPs, Section 484.55, require an assessment to be completed every 60 days (rather than the 14 days proposed for hospice), or more frequently where there is a beneficiary elected transfer, a significant change in condition resulting in a change in the case-mix assignment, or a discharge and return to the same HHA during the 60-day episode. The initial home health assessment is required to be completed within 48 hours of referral (rather than the 24 hours for hospice) and the comprehensive home health assessment is required to be completed within five days (rather than the four days proposed for hospice). Agency professional staff is also required to promptly alert the physician to any changes that suggest a need to alter the plan of care.

Kaiser is confused with the vagueness and interpretation of the time periods and seeks clarification regarding the time frames as they will be used practically. For the initial assessment, 24 hours is too short a time frame. Many times the physician has ordered the hospice care, but the patient has not accepted the care and the physician has not completed the Certificate of Terminal Illness. It is unclear whether the hospice will be held to 24 hours from the date the physician faxed the order to the hospice, even though the patient has not accepted the order for hospice and/or the hospice has not accepted the patient for hospice care either. The hospice may not be able to be equipped to provide care to that patient and may not be able to accept that patient. As the proposed rules are currently worded, it is not clear when the clock starts ticking and, in any case, 24 hours is too short a time period to finalize this process. In addition, it is

important to note that often the patient and/or family do not wish to have a visit within 24 hours of the time the hospice receives the physician certificate of terminal illness or "order" for hospice services.

Kaiser recommends the following suggestions listed below:

Request for Change of Proposed Rule for Assessments

We agree that there should be timelines on the initial assessment, comprehensive assessment and updates of the comprehensive assessment. However, we do not agree with the timeframes suggested in the proposed rule. We would suggest that the time frames should mimic home health time frames or the standards of practice in the industry, which is longer than 24 hours. We ask to accommodate all the changes and nuances of starting care that the proposed rule for initial care is re-written to state:

a) "A registered nurse will make an initial assessment visit to determine the patient's immediate care and support needs within ~~24~~ **48** hours after the hospice has received the physicians order and the patient and family have signed on or accepted hospice service, or later, as requested by the patient/family or physician."

b) We also ask that the four calendar days to complete the comprehensive assessment be lengthened to seven days, as the Interdisciplinary Group (IDG) meet weekly and this will result in hospices being able to comply with this requirements.

c) We ask that the 14 day comprehensive assessment update be less frequent that every 14 days and be more in-line with the 60 day home health requirement. If the assessment update is required at the end of each certification period, then the assessment results will be more useful for recertification purposes. The rule should include that the assessment update can and should be done more frequently if the patients condition changes. We understand the urgency and more dynamic nature of a hospice patient's health, who is terminally ill, versus a patient under home health requires a more frequent update to care than 60 days. However, we want the patients' needs to be met and not spend unnecessary time and energy on just administrative paperwork. The IDG should be focused on meeting the plan of care needs should they change the rule should include references to require more frequent assessments when there are changes in the patients condition, including psychosocial, emotional, etc.

Comment #3: PLAN OF CARE or COORDINATION OF SERVICES
Section 418.56

Standard (b) Plan of Care – This proposed rule should be changed to clearly state that only one POC is required and that a separate POC is not required for the family.

Standard (C) Content of the plan of care – The proposed regulation should be changed to require that the hospice IDG must document patient and family understanding and involvement with the plan of care. The word **agreement** should be deleted.

During the NAHC Teleconference, Mary Rossi-Coajou and Danielle Shearer (from CMS) presented the concept of the Comprehensive assessment in ways that seemed to indicate it was a combination of Assessment and Plan of Care. This needs to be clarified for all aspects of compliance to the Assessment COP and the Medical Record COP. It is significant as it pertains to content of the POC, versus content of the assessment; the timeframes and the content requirements seem to overlap. Are they one in the same document? There were many questions relating to this, but the answers did not clarify the difference. For example, Section 418.54(e) states the comprehensive assessment must include the data elements. Section 418.56 states the content of the POC must include measurable outcomes, but no reference to the data elements. Section 418.104(a) states the content of the POC must include the data elements. It is unclear where CMS expects the data elements to be documented.

Standard (e)(4). Kaiser requests clarification of the type of "system" CMS is expecting for communication with outpatient settings/contract services. Would this be above and beyond the normal documentation of telephone communication and case conferences? The COP mandating the IDG review the patient care every 14 days would accomplish this. How does CMS expect to see compliance demonstrated to the requirement to have a "system?"

Comment #4: Quality Assessment Performance Improvement (QAPI) - Proposed: Section 418.58 [User Term in Comments: "QAPI"]

The regulation would require that a hospice to create a Quality Assessment Performance Improvement Program ("QAPI"), which include no specific data elements and no requirements for reporting to improve palliative care outcomes and access to end of life supportive services. The hospice is allowed develop their own data elements and measurement process as part of its quality assessment and performance improvement program or could use the suggested NHPCO measures and must focus on high risk, high volume problem areas and track adverse patient events, analyze their causes, and implement preventive actions that include feedback and learning and to demonstrate how staff contribute to the quality improvement program, and must performance improvement projects and to measure and document these projects. The hospice governing body would be responsible for the QAPI program and the specific requirements of monitoring the quality of care. Additionally, in a later part of the proposed rule, under Medical Director, 418.102, it requires the Medical Director or the physician designee to be responsible for the QAPI.

Kaiser has three concerns with the QAPI proposal as described above and in the rule and requests three changes to correspond to these concerns. The concerns are:

a) The future intent of the QAPI for a mandatory assessment tool;
b) The requirement of the Medical Director to be responsible for the AQPI.
c) The vagueness of the QAPI and the application to survey;

General Comment on the QAPI Proposal:

Kaiser extremely concerned about the eventual mandatory implementation of a tool like the Outcome Assessment Information Set (OASIS) for hospice. The OASIS tool has failed the

patient and home health by turning it into an academic tool that is largely unusable for home health care and is instead focused on "getting paid." In hospice, it will harm providers who take patients where they only will get to provide them 2-3 services and then death will result. It will bring down their scores and make it a disincentive to provide care to the very sick seeking hospice care at the end stages of life – which is what most hospice care is for non-home health agency hospices. Also, it is also unclear what would be considered an "adverse event" in Hospice. Without prescribing a defined element, this requirement seems difficult to monitor in a meaningful, consistent method across the industry.

Kaiser also has some concern that there is a requirement to create data sets and collect outcomes without a valid and reliable common set of measures in the industry. This is especially onerous considering the concept that CMS may require specific data measures in the future that may cause Hospices additional burdens of changing systems, documentation and processes to convert to a prescribed system, not mandated now. Kaiser requests that CMS either delete these proposed requirements or specifically define for the hospice industry the standards that CMS will require to measure outcomes-based performance.

Request for Change of Proposed Rule for QAPI:

1) Kaiser requests that CMS either delete these proposed requirements or specifically define for the hospice industry the standards that CMS will require to measure outcomes-based performance. We would ask that the proposed rule indicates that any future discussions of developing a set of measures will occur as a result of industry wide input to come up with outcome management program that is based on compassionate care (rather than developed in an academic setting such as Home Health's OASIS and OBQI) and will include provider stakeholders from across the nation and will outreach to state associations representing home health and hospice to enlist their membership to participate.

2) We would also request that the Medical Director or the physician designee not be responsible for the QAPI, as the proposed rule references in Section 418.102. The proposed rule charges the Hospice Governing Body with oversight. However, the reference to the Medical Director as the responsible entity is in conflict with the proposed rule in the QAPI Section, 418.58 (e), which states that the Governing Body is responsible. Additionally, it is in conflict with current COPs, Section 418.52, indicates: "A Hospice must have a governing body that assumes full legal responsibility for determining, implementing and monitoring policies governing the hospices' total operation. The governing body must designate an individual who is responsible for the day to day management of the hospice program. The governing body must also ensure that all services provided are consistent with accepted standards of practice." Therefore, we recommend that the proposed rules strike the reference to the Medical Director of the Hospice being responsible for the QAPI program, as the governing body will be responsible and, per current regulations, is allowed to select an individual to oversee the body. The hospice should have the option of having the Medical Director review it. However, it should not be required that the staff for this requirement be the Medical Director.

3) We would like to go on record regarding the vagueness of the QAPI program and the application to certification surveys. When an agency is surveyed, it should be written clearly in

the interpretive guidelines that surveyors use to probe that the Hospice should have to show their policy and procedures on the QAPI program, but that it is specific to the hospice, as the indicators are not set. The survey mechanism should be lenient and not stringent, as often occurs in surveys.

Standard (e) - Governing Body – We recommend referring to JCAHO Home Care Standards for Leadership 1.20 elements 1 through 7 in this regulation.

Comment #5: NON-CORE SERVICES – PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND SPEECH-LANGUAGE PATHOLOGY – Proposed Sections 418.72 and 418.74

Kaiser does not believe that it is necessary to have PT, OT and SLP services available on a 24 hour basis. Hospice patients seldom need rehabilitation services and when they are needed, these can be provided on a non-urgent basis. Common patient and family needs are instruction in use of mobility devices (e.g. use of walker) or in assisting with patient transfers. These are basic skills that nurses do or should have. It would be more practical to require that Hospices assure RN competency in these areas and availability of RN intervention in these areas 24 hours/day than to continue with the rehab service (PT, OT, and SLP). Kaiser requests that this standard be changed to waive this requirement for all hospices without requiring a waiver process.

We also recommend adding dieticians to this section as a non-core service

Comment #6: SUPERVISION OF HOME HEALTH AIDES - Proposed: Section 418.76 (h)

Under current Medicare hospice law, Section 418.94 (a) of the Conditions of Participation state, "A registered nurse must visit the home site at least every two weeks when aide services are being provided, and the visit must include an assessment of the aide services." The current hospice requirements do not include a joint visit. Current Medicare home health agency law requires a supervisory non-joint visit every 14 days for patients receiving skilled care and supervisory joint visits every 60 days if the services performed are provided to a person not receiving skilled care. Joint is only required for the skilled care when the home maker/home health aide is getting a performance evaluation.

The proposed rule would expand the rule to require a joint supervisory visit once a month. This would be an entirely new requirement that exceeds the home health joint visit requirement which is every 60 days and/or during performance evaluations.

The proposed rule would require Certified Home Health Aide providing care to a patient receiving no skilled services to be more frequent than 60 days.

Important Note: The proposed rule background in the paragraph two of the third column on page 30852, indicates that the new 14 day requirement would relieve the requirement of a joint supervisory visit required in Section 484.36(d)(2). A joint visit is currently ***not*** *a requirement for a CHHA. This is only a requirement if they are performing a performance evaluation of the*

CHHA. Therefore this is inaccurate. California Regulations, Title 22, Section 74709, (a) (2) provides even more detail of this federal law as it is modeled after it.

Under current Medicare home health agency law, home health aide supervision for patients receiving skilled care is required every 14 days and is **not a joint visit**, unless part of performance evaluation is occurring. Current law requires that beneficiaries receiving non-skilled care are required to have a joint supervised visit every 60 days.

Request for Change of Proposed Rule for Joint Visits every 28 days:
Current requirements for hospices are nurse visits every two weeks and assessment of the services, but are not joint visits. We agree with the logic that there should be a periodic joint visit, which is not required currently. However, we ask that the hospice COP for joint aide visits mirror the current Federal Home Health COPs, which require a joint visit every 60 days.

Additionally, we ask that CMS clarify that the supervision is not by a specific person, but may be performed by either a nurse or therapist (under the conditions in which they apply). The wording in the proposed regulation is vague regarding supervisor and infers that it can only be done by the aide's immediate supervisor. We would ask that it be clarified and re-worded to say that the supervision may be conducted by either a nurse (if patient is receiving skilled nursing care), or the appropriate therapist, if receiving another skilled service and that it is not required to be performed by a specific supervisor.

Comment #7: Section 418.64 - CORE SERVICES
Standard 418.64(d): Bereavement Services
We do not feel that the hospice should be responsible for services to the employees of a facility as part of our core services.

Comment #8: ORGANIZATION AND ADMINISTRATION - Section 418.100

Standard 418.100(f). The definition of "satellite locations" needs to be clarified. Does the definition include staffing locations or locations where staff pick up supplies and drop off paperwork?

Comment #9: Initial/Recertification Certification of Terminal Illness - Proposed: Section 418.102 – "MEDICAL DIRECTOR".

This proposed regulation would add new requirements for how physicians make decisions on terminal illness and require them to include more information to prove the six month terminal illness qualification and would require the medical director of physician designee to complete a clinical review and a written certification of terminal illness in order to begin hospice care (initial certification). Subsequent certifications would also require review of clinical and the patient and family's expectations and wishes for hospice care on an ongoing basis and before each updated assessment every 14 calendar days **and** at the time of recertification. The rule also makes the medical director of physician designee responsible for the hospice's quality assessment and performance improvement program (which we addressed in the QAPI section and will address below).

Our concerns in this section are as follows:

1) Certification and Recertification Content Requirements
2) Integration of Recertification Content Requirements into new Assessment requirements every 14 days
3) Medical Director or Physician Designee Responsibility for QAPI

General Comment: Current law, 418.22 (a) indicates what hospice personnel can certify the terminal illness, the time periods of certification, as well as the requirement for written certification "content" for terminal illness definitions to qualify for hospice care. The content requires that the prognosis for life expectancy must be 6 months or less. No other content is required to certify the terminal illness. Under the proposed rules, the Medical Director would have to review the clinical information and provide written certification. The proposed rule does not specify what the clinical review entails and what written certification means.

Request for Change of Proposed Rule for Medical Director

1) We request that the current certification and content requirement stay the same for the **initial certification and recertification** of terminal illness diagnosis. Each Medical Director is different in how they make their decision on terminal illness. We do not need to place new burdens on current Medical Directors, but need to examine placing federal requirements on Doctor curriculum that includes classes and rotations on end-of-life care that include understanding how to make a terminal diagnosis and the important questions and methodologies to use to make that important assessment for terminal diagnoses.

2) This new initial and re-certification requirements are included **every 14 days** at the time of each update of the comprehensive assessment (and visa versa with each recertification the assessment is updated). This new rule will have unintended consequences and will likely result in a disincentive for referral to hospice care as the medical director must prove each time when a patient is clearly terminal. Our providers are already experiencing many barriers to getting patients referred to hospice when they need hospice care. We do not want new regulations that create new barriers and disincentives to make it more difficult for the terminally ill to get hospice care. Therefore we request that you leave the initial and recertification process as is and remove it from the proposed 14 day comprehensive assessment update.

We take exception with the timeline of 14 day assessment, as required in 418.24 (d), Home Health COPs, Section 484.18(b) requires an assessment to be completed every 60 days, or more frequently where there is a beneficiary elected transfer, a significant change in condition resulting in a change in the case-mix assignment, or a discharge and return to the same HHA during the 60-day episode. Agency professional staff promptly alerts the physician to any changes that suggest a need to alter the plan of care. We agree that there should be timelines on the initial, comprehensive and update of the comprehensive. However, we do not agree with the timeframes suggested in the proposed rule or all of the content included in the assessment, including the recertification content.

3) We would also request that the Medical Director or the physician designee to not be responsible for the QAPI, as the proposed rule references in Section 418.102. The proposed rule

charges the Hospice Governing Body with oversight. However, the reference to the Medical Director as the responsible entity is in conflict with the proposed rule in the QAPI Section, 418.58 (e), which states that the Governing Body is responsible. Additionally, it is in conflict with current CoPs, Section 418.52, indicates: "A Hospice must have a governing body that assumes full legal responsibility for determining, implementing and monitoring policies governing the hospices' total operation. The governing body must designate an individual who is responsible for the day to day management of the hospice program. The governing body must also ensure that all services provided are consistent with accepted standards of practice." Therefore, we recommend that the proposed rules strike the reference to the Medical Director of the Hospice being responsible for the QAPI program, as the governing body will be responsible and, per current regulations, is allowed to select an individual to oversee the body. The hospice should have the option of having the Medical Director review it. However, it should not be required that the staff for this requirement be the Medical Director. This would be a substantial increase in responsibilities for the medical director. Currently, it is difficult to obtain a medical director. This would make it even more difficult with unrealistic responsibilities being required.

Comment #10: RECERTIFICATION - Section 418.102(b) – It is recommended that the phrase "patient/family expectations and wishes" for hospice care must be reviewed. This should be changed to "hospice goals and POC must be reviewed by patient/family".

Comment #11: CLINICAL RECORDS – Section 418.104
Standard (b) Authentication - The proposed regulation states that "All entries must be signed and the hospice must be able to authenticate each handwritten…signature…". This is not realistic. Examples that would present compliance problem include contracted nursing home and facility staff and infusion vendors who provide hospices with progress notes.

Standard (e): Discharge or transfer of care
We do not feel that a complete record should be sent to another hospice or to a physician. This is a time intensive and expensive process that does not add value for the patient nor will the physician or hospice use this on a regular basis. A discharge summary should be sufficient.

Comment #12: CONTROLLED DRUGS IN PATIENT HOME – Proposed Section 418.106 (b) – [DRUGS, SUPPLIES, and DME]

This proposed regulation adds a new requirement for a hospice to track, collect and dispose of controlled substances.

General Concern: Hospice agencies have no responsibility for and control over the medication when they are not in the home and this requires the hospice to take on a responsibility that they can not feasibly be responsible over in a person's home. Also, the medications are the property of the patient, not the hospice. Making a hospice responsible for this care will put them at risk for scenarios and situations that they can not control. CMS can not require a hospice agency to pick up the medications for the patients and not all hospices dispose of controlled substances. It is also dangerous for staff to carry controlled substances anywhere for disposal. Also, if the family refuses to dispose of them at the time of death, hospices do not want staff in a position of being required to take them from the home and dispose of them.

It would be helpful to have the intent of the drug control standard specified in the COPS. This is an area of conflict between local medical examiners and hospice's. It should be clearly defined what Hospice's are and are not responsible for. For example we are responsible for patient/family/caregiver education regarding drug disposal and safety but not disposal of the drugs or control of the drug inventory in the home. The words "tracking" and "collecting" suggest more of an enforcement role than an educational one by the hospice. The drugs are the property of the patient and family and we feel that the role of the hospice is education, not enforcement.

Additionally, the CMS discussion of this item states, "During the initial assessment, the hospice policy regarding the use and disposal of controlled drugs would be required to be discussed with the patient and family." We take exception to the hospice having to cover this during the initial assessment with the family and the patient. The patient is in pain and until the patient has an order for drugs, then it should not be necessary to review a policy and procedure that is not relevant to the patient and family. During the initial assessment, the family and patient should not be overwhelmed with technical details that are not relevant.

Request for Change of Proposed Rule for Drugs Supplies and DME

1) We would like the entire section requiring a hospice to be responsible for tracking, collecting and disposing of controlled substances to be deleted from the proposed regulation.
2) The hospice must discuss the use of controlled drugs with the patient and family, but it should not be required to collect, track or dispose. It should only have this discussion once the patient has an order for drugs and not before that time.

Comment #13 – DME MANAGEMENT REPAIR – Proposed 418.106 (c) – DME Management Repair

The new regulation requires a hospice to be responsible for the maintenance of equipment and supplies, and to ensure adequate training and instruction ("the how and when") to family regarding the equipment and supplies.

Concerns: This proposed rule does not take into consideration the differences between states. This regulation implies that hospices have their own equipment. In California, home health agencies and hospices do not oversee the use of the DME and, in fact, can not bill for DME or supplies. They contract with licensed DMEs to supply the product and service. DMEs are required to be licensed through Department of Health Services, Food and Drug Department and are required to get Medical Device Retailers License, which have strict requirements. The hospice doesn't have anything to do with the DME. Therefore, it does not make sense to make hospices responsible for this care as they are not supplying the DME. Requiring this will only result in problems and confusion for California hospice providers.

Request for Change of Proposed Rule for DME Management Repair

The proposed rule indicates that "the hospice may carry out this responsibility through a contractual arrangement with others, but would continue to maintain primary responsibility." We ask that this section is changed to adequately deal with states where hospices do not own and/or

provide the DME equipment to the state and rely on professional DME companies. We suggest that the sentence is clarified as such: "The hospice may use persons under contract and those persons would maintain primary responsibility for the services and the care.

Comment #14: SHORT TERM INPATIENT CARE – Section 418.108. This Condition should be rewritten to also allow this level of care for psychosocial/family crisis.

Comment #15 – Hospice Care in a Facility – Proposed 418.112 - "RESIDENTS RESIDING IN A FACILITY"

The new regulation expands the role of the Hospice Medical Director and expects them to play an expanded role in providing medical supervision to the hospice interdisciplinary group and overall coordination of the patient's plan of care. The medical director must now also communicate with all facility physicians and the attending physician for the patient. This would result in a barrier to patients receiving care and could result in a delay of services or no services because of a lack of compliance, and therefore, hospices **not taking patients who need facility level care.** This does not take into consideration that, most of the time, the Medical Director of the Hospice is the attending physician, and that the Medical Director of the SNF is different from SNF to SNF. This requirement takes only into consideration the SNF approach. The Hospice approach is that the Hospice has the professional judgment of the Hospice. The proposed rule seems to suggest that CMS is requesting the Hospice to take on more and more of the SNF role, when the hospice is not on site for 24 hours a day. By making the Medical Director of the Hospice responsible to consult with

The proposed rule indicated the following, "We are preparing a separate regulatory document to address long-term care facility obligations regarding residents receiving hospice services." We suggest that the Hospice CoPs do not include regulations regarding residents residing in a facility UNTIL the report regarding long-term care facility obligations regarding hospice services is complete. This will allow us to adequately respond to this section of the proposed rules which include added new requirements for hospices in SNFs, because we will know what CMS will be requiring of SNFs.

Concern:
With more hospice recipients needing hospice services in the community and not in the home, this added requirement on the Medical Director could lead to major issues and disincentives to getting a patient in one of these types of institutional settings. Part of the proposed rule, which states, "The medical director of the 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" is of great concern for hospices. The concern is specifically related to the reality of the request. Currently, hospices also provide care to the hospice patient. Asking the Hospice Medical Director to consult with all Doctors is unrealistic because, often times, the Medical Director of the SNF is the attending physician for the patient.

Request for Change of Proposed Rule for Residents Residing in a Facility
We would suggest that the proposed rule is changed to require notification of the Medical Director of the SNF regarding the update of the plan of care. However, it should not be

mandatory to talk with all physicians at the SNF and require it in order to do a plan of care. It should be optional and encouraged, especially when there is a development. With the plan of care being required, under the ASSESSMENT TIME FRAMES, Proposed Rule 418.54, for every 14 days, this requirement is impractical and unfeasible for real world scenarios. While CMS is hoping to encourage a lively and thorough discussion for the patient to help them achieve the best outcomes, it will result in the opposite. It will result in either non-compliance or physicians of hospices and nursing homes developing a quick check off ability. We should ensure that physicians are encouraged to communicate with each other periodically at important time points to examine important outcomes for the patient.

As this proposed rule is shifting much of the burden and responsibility onto a hospice to deliver care, even though the SNF or facility has responsibility for non-terminal care as well, it becomes more illogical to require the Hospice Medical Director to consult even more frequently with a SNF as they are to provide less care than before under this proposal..

We would also agree with language that stated, The Hospice Medical Director shall notify in writing or verbally the SNF facility physicians regarding the POC every 30 days to confer regarding the patients overall coordination of care.

Needing a written agreement per patient with consent and specific clarification per care plan for which services the hospice will provide, and which the facility will provide will increase the amount of time needed to admit, document, and provide oversight for facility residents. Especially significant is that the hospice may only use the facility nursing personnel for those tasks which would ordinarily have been done by a resident's family in implementing a care plan. How does that impact SNF licensed caregivers needing to provide care as needed?

Comment #16 – HOSPICES THAT PROVIDE INPATIENT CARE DIRECTLY – Section 418.110.

Standard (f) Patient rooms – **Agree** that patient rooms must provide at least 80 square feet with no more than 2 beds to a room requirement.

Comment #17 - PERSONNEL QUALIFICATIONS – Section 418.114

The proposed rule asked for comments on the issue of changing the current requirement of a bachelor's degree for a social worker under Hospice to a Masters level. We would advise that this not occur. Currently, our state and federal requirements for a social worker in a home health setting requires a Master's Degree from a school of social work accredited by the Council of Social Work Education, with one year of social work experience in a health care setting. This has limited provider's abilities to be able to find social workers. A Masters in Social Work should be required OR a baccalaureate degree from a school of social work accredited by the Council of Social Work AND a least one year experience in a health care setting.

Request for Change of Proposed Rule for Social Work Definition
We would advise that CMS keep the Bachelor's degree requirement and additionally add a social work assistant as a type of social worker in a hospice. Adding the social work assistant to the

rules would open up the opportunity for a hospice to attract caring candidates who are suitable for hospice care services who have studied related disciplines (psychology; sociology; other social work related field) without penalizing potential employees who have already finished their bachelor's degree. Additionally, we would also ask that the regulations pattern the assistant social worker for persons with doctorates in fields that are not social work, such as psychology. We have heard of providers who could not hire a PhD in Psychology who was interested in the social worker position at a hospice because he had changed his focus in life and wanted to work in hospice, but could not because of the current regulations. The regulations need to be flexible to allow for PhDs in other fields, as well.

Standard (d) – Criminal background checks – **Strongly recommend keeping this new standard.**

Comment #18 - ELECTRONIC RECORDS

Regarding CMS's request for comments regarding electronic records we can add the following:

Benefits

- Facilitates improved coordination of care, especially with nurses on different shifts
- There are numerous challenges/limitations in Hospice's ability to make changes in software to meet regulatory requirements and quality initiatives. Paper records are more flexible, easier to adapt to changes.

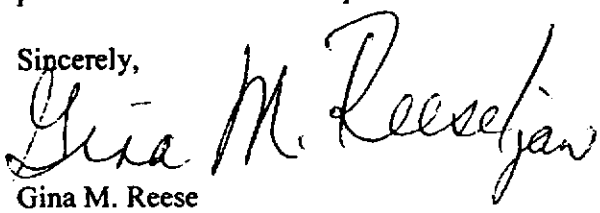
Disadvantages

- Cost
- Often decreases in staff productive adding to cost and reducing time spent with patients
- When computers fail (hardware or software) information is not accessible. Patient care and business processes revolve around the information system, if the computer is not accessible patient care, intake and referral can become paralyzed

Patients should be able to access at least some parts of their records (e.g. medication list, test results, plan of care). Ideally, this would occur through a secure internet site.

It is concerning to think that it might be mandated in future regulations. The cost may be prohibitive for smaller hospices.

Sincerely,



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July 14, 2005

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Attn: File Code CMS-3844-P

***Re:* Comments on Medicare and Medicaid Programs: Hospice Conditions of Participation, Federal Register Volume 70, No. 102, Friday May 27, 2005, CMS Reference #CMS-3844-P**

Dear Dr. McClellan:

AseraCare, Inc. has hospice locations in sixteen (16) states. All AseraCare agencies are Medicare/Medicaid certified. We are pleased to offer comments on CMS' proposed changes to 42 CFR 418.

Initially, AseraCare would express our support of and assent to, the comments to be provided by the National Association for Home Care (NAHC). AseraCare is an active member of both NAHC and the National Hospice and Palliative Care Assocation (NHPCO). AseraCare participated in the recent CMS/NAHC conference call and have joined with NAHC in preparing the comments they will be presenting on behalf of the hospice industry. We would encourage you to give careful consideration to the comments of these organizations.

In addition to supporting NAHC comments on the proposed regulations, we would offer the following comments and specific observations by AseraCare staff in hopes they are helpful to you in analyzing the impact the proposed regulations would have on hospices operating across the country. Our comments are organized by reference to the regulations amended under the Federal Register notice, followed by the comments of AseraCare, noted in bold type below the particular regulation being amended. We would be glad to further explain or discuss the comments, and to answer any questions you may have. Thank you for your attention to the concerns of AseraCare, Inc.

<u>42 CFR §418.3 Definitions</u>

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.

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AseraCare would support NAHC's recommendation that the language "within a hospice program" be added after the words "psychiatric condition" in the proposed definition above, to recognize the use of drugs in hospice for specific symptoms not commonly used as treatment for the same symptoms by other healthcare providers.

42 CFR §418.52 Patient Rights

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.

AseraCare would support NAHC's recommendation that it be permissible to ensure the patient understands his/her rights through an interpreter (family member or other).

42 CFR §418.54(a) Initial assessment
The hospice registered nurse must make an initial assessment visit within 24 hours after the hospice receives a physician's admission order for care (unless ordered otherwise by the physician), to determine the patient's immediate care and support needs.

AseraCare supports NAHC's recommendation that the assessment visit be made within 24 hours of receipt of the Medicare certification, as opposed to the physician's order. We would further suggest that CMS give consideration to permitting other disciplines, such as social workers, to perform the initial assessment.

42 CFR §418.54(b) Time frame for completion of the initial assessment

The hospice interdisciplinary group in consultation with the attending physician, must complete the comprehensive assessment no later than 4 calendar days after the patient elects the hospice benefit.

AseraCare supports an expansion of the requirement, and that the comprehensive assessment be completed no later than 7 calendar days after election, and supports NAHC's additional comments to this requirement adding language that the attending physician be included if he or she desires.

CFR §418.54(e)(1) Patient outcome measures
The comprehensive assessment must include data elements that allow for measurement of outcomes. The hospice must measure and document data in the same way for all patients. The data elements must take into consideration aspects of care related to hospice and palliation.

AseraCare supports the development of standard patient outcome measures to improve the delivery of hospice care and services. AseraCare utilizes NHPCO

quality measures, and other internal data collection tools for benchmarking in our quality improvement program.

CFR §418.56(b)(6) Plan of care
The interdisciplinary group's documentation of patient and family understanding, involvement, and agreement with the plan of care, in accordance with the hospice's own policy, in the clinical record.

AseraCare supports NAHC's comments that the word "agreement" in this context could be problematic if the patient and/or family disagreed on what was appropriate for the plan of care. This could be especially difficult to administer in light of the myriad of existing advance directive and substituted decision making laws in the various states.

CFR §418.56(d) Review of the plan of care
The medical director or physician designee and the hospice interdisciplinary team (in collaboration with the individual's attending physician to the extent possible) must review, revise, and document the plan as necessary at intervals specified in the plan but no less than every 14 calendar days. . .

AseraCare suggests that the specific reference to the medical director or physician designee is unnecessary and repetitive, since this individual is already a member of the interdisciplinary team.

CFR §418.58(b)(1) Program data
The program must utilize quality indicator data, including patient care, and other relevant data, in the design of its program.

As stated earlier, AseraCare supports the movement toward national standards for benchmarking quality indicator data. We suggest that this process be implemented in phases, first with the implementation of QA/QI outcomes, then in the future, once a recognized standard system is selected, that hospices move to begin more defined adverse event tracking and reporting. We would further recommend that at that point, CMS specify what would be the acceptable data source and benchmark as the outcomes standards are further defined. This approach would allow hospice programs to first install the quality data initiative while benchmarking is being further identified and standardized for the industry.

CFR §418.58(c)(2) Program activities
Performance improvement activities must track adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospice.

AseraCare would assert that hospices are not prepared at this time to meet this requirement. We suggest that CMS first begin to implement QA/QI processes, before moving toward collection of adverse event data. We suggest that this process

be implemented in phases, first with the implementation of QA/QI outcomes, then in the future, once a recognized standard system is selected, that hospices move to begin more defined adverse event tracking and reporting. We would further recommend that at that point, CMS specify what would be the acceptable data source and benchmark as the outcomes standards are further defined. This approach would allow hospice programs to first install the quality data initiative while benchmarking is being further identified and standardized for the industry.

CFR §418.58(d)(2) Performance improvement projects
The hospice must document what quality improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.

AseraCare recommends that CMS adopt a phased-in approach to implementing this requirement. This will permit CMS to achieve its goal of understanding more about hospice quality improvement projects, while not placing an undue burden on the agency staff and the delivery of hospice services. We suggest that this process be implemented in phases, first with the implementation of QA/QI outcomes, then in the future, once a recognized standard system is selected, that hospices move to begin more defined adverse event tracking and reporting. We would further recommend that at that point, CMS specify what would be the acceptable data source and benchmark as the outcomes standards are further defined. This approach would allow hospice programs to first install the quality data initiative while benchmarking is being further identified and standardized for the industry. If this provision is retained, consideration is needed to allow the hospice to first install the addition to the QA/QI outcome data gathering and adverse event collection. This will create a burden on the hospice if a phased in approach is not allowed for implementation.

CFR §418.58(e)(2) Executive responsibilities
The hospice's governing body is responsible for ensuring . . . [T]hat the hospice-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety, and that all improvement actions are evaluated for effectiveness. . .

AseraCare would point out that this will require a significant commitment of time by the governing body to accomplish this task. The governing body is comprised of hospice staff members with significant additional responsibilities in addition to serving on the governing body. We understand the importance of QA standards, but suggest that the governing body already has overall responsibility for everything in the program, and this specific focus on QAPI is not necessary.

42 CFR §418.64(d)(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 patients are met.

AseraCare supports NAHC's comments to this provision, and believe that it provides flexibility to the hospice without compromising care of its patients.

42 CFR §418.76(j) 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 of and concerns of patients and families coping with a terminal illness.

AseraCare supports this clarification of homemaker qualifications with regard to their completion of hospice orientation.

42 CFR §418.76(g)(2) Home health aide assignments and duties
A home health aide provides services that are (i) ordered by the physician or nurse practitioner. . .

AseraCare supports NAHC's comments that as the aide's services are included in the IDG plan of care, there should not be a need for a separate physician's order for this care. Such language is redundant could become confusing.

42 CFR §418.76(h)(1) Supervision of home health aides
. . . 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.

AseraCare would suggest that the supervisory requirement frequency be extended from every 28 days to every 60 days. We believe that this would fit in more easily with existing staffing patterns in hospices while not compromising patient care.

42 CFR §418.100(a)(2) Serving the hospice patient and family
The hospice must ensure . . . that each patient experience hospice care that is consistent with patient and family needs and desires.

AseraCare agrees with NAHC's recommendation that the language "desires" is inappropriate in this setting. Rather, AseraCare would suggest that the hospice be required to provide care that is consistent with patient and family needs "as set out in the plan of care". The family participates in the plan of care, and tying this standard back to the plan of care ensures that hospices and surveyors are not confused by implementing care patient consistent with vague language such as "desires".

42 CFR §418.100(e) Professional management responsibility
A hospice that has a written agreement with another agency, individual, or organization to furnish any services under arrangement, must retain administrative and financial management, and supervision of staff and services to ensure the provision of quality care.

Arranged services must be . . . (2) furnished in a safe and effective manner by personnel having at least the same qualifications as hospice employees.

AseraCare and NAHC would suggest that the word "supervision" be replaced with "oversight" as the supervision would be conducted by the actual contracted employee. Also the language "at least the same qualifications as hospice employees" could be problematic and should be replaced with "by qualified personnel".

42 CFR §418.100(f)(1) Hospice satellite locations

(1) All hospice satellite locations must be approved by CMS before providing hospice care and services to Medicare patients. The determination that a satellite location does or does not meet the definition of a satellite location, as set forth in this part, is an initial determination, as set forth in §498.3. (2) The hospice must continually monitor and manage all services provided at all of its locations to ensure that services are delivered in a safe and effective manner and to ensure that each patient and family receives the necessary care and services outlined in the plan of care.

AseraCare joins NAHC in their praise of CMS' efforts to clarify this issue. We have no problem with the language proposed in this standard, but would ask for additional clarification of the distinction between "satellite locations" and "alternate sites". These terms are used in the industry, and clarification from CMS of the different standards applied to each would clear up some confusion among the various states.

42 CFR §418.102(b) Recertification of the terminal illness

Before the recertification period for each patient, as described in §418.21(a), the medical director or physician designee must review. . . (2) the patient's and family's expectations for the continuation of hospice care.

AseraCare would assert that it is unclear what is meant by patient/family "expectations" for care. Retaining such vague language sets the hospice up for failure both in determining and meeting those "expectations". Rather, AseraCare would suggest that the medical director review information provided by the IDG, including the patient and family's response to the hospice plan of care on a ongoing basis and before each updated assessment

42 CFR §418.102(c) Coordination of medical care

The medical director or physician designee is also responsible for directing the hospice quality assessment and performance improvement program.

Asseracare suggests that this requirement would be very difficult and may not be appropriate. The day to day duties of the QAPI program can and should be assigned the appropriate hospice leadership such as the Director of Clinical Services, as in other programs (i.e., nursing facilities, home health), with the medical director maintaining oversight. The Medical Director is active participant on the

team, but can't be responsible for directing the day to day responsibilities for the QAPI program. Retaining this requirement could affect ability of hospices to recruit medical directors. In addition, the hospice should designate an alternate medical director, because of the vital nature of this role.

42 CFR §418.104 Clinical records
. . . The clinical record may be maintained electronically.

EHRs would improve coordination of care, however, one barrier that we currently have in hospice is lack of standardized plans of care, and certifications of terminal illness. The ability of multiple providers to access EHRs would require additional technology and effort. Hospice today has no standardized system for documentation of the plan of care. Everyone uses different forms. AseraCare suggests that we move slowly to implement such a requirement.

42 CFR §418.104(b) Authentication
All entries must be legible, clear, complete, and appropriately authenticated and dated All entries must be signed, and the hospice must be able to authenticate each handwritten and electronic signature of a primary author who has reviewed and approved the entry.

AseraCare and NAHC agree that the origin of this requirement is from hospital COPs, and the nature of hospice care is much broader than that provided in an acute care setting. The application of this standard is unclear with respect to certain individuals and classes of provider, e.g., all consulting or covering physicians, all contracted nursing home and facility staff who care for hospice patients, and contracted infusion vendors who provide hospices with progress notes.

42 CFR §418.104(d) Retention of records
Patient clinical records must be maintained for 5 years after the death or discharge of a patient, unless State law stipulates a longer period of time.

We suggest that the retention be changed to 6 years to mirror the requirement under HIPAA.

42 CFR 418.104(e)(1) Discharge or transfer of care
If the care of a patient is transferred to another Medicare/Medicaid approved facility, the hospice must forward a copy of the patient's clinical record and the hospice discharge summary to that facility.

Like NAHC, AseraCare suggests that other providers will not want the complete clinical record, and a copy of the discharge summary will be adequate coupled with the option for the receiving facility or MD to be able to request additional information from the hospice. This change will enable appropriate documentation and information to follow the hospice patient upon discharge, without unreasonably burdening either the transferring facility or the facility accepting the patient.

42 CFR 418.106(b) 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.

The word "collecting" in this standard is problematic. A better substitute would be the word "monitoring". Further, use of the words, "potential dangers of controlled substances" could influence acceptance of narcotics necessary to make the patient comfortable. The hospice patient's family's focus is and should be on the control of the patient's pain. While it is important to educate the patient and family members, the language of these regulations must be sensitive to this focus. We believe that deletion of the words "and potential dangers" would balance the need to educate the family on the safe delivery, disposal, and appropriate use of controlled substances in the patient's home with the focus remaining on the control of pain.

42 CFR §418.106(c) Use and maintenance of equipment and supplies
(1) The hospice must follow manufacturer recommendations for performing routine and preventive maintenance on durable medical equipment. The equipment must be safe and work as intended for use in the patient's environment. Where there is no manufacturer recommendation for a piece of equipment, the hospice must develop in writing its own repair and routine maintenance policy. The hospice may use persons under contract to ensure the maintenance and repair of durable medical equipment. (2) The hospice must ensure that the patient, where appropriate, as well as the family and/or other caregiver(s) receive instruction in the safe use of durable medical equipment and supplies. The patient, family, and/or caregiver must be able to demonstrate the appropriate use of durable medical equipment to the satisfaction of the hospice staff.

AseraCare and NAHC agree that this provision should be rewritten to state that when DME is provided under contract, the vendor is responsible. This maintains the appropriate focus on the role of the hospice to provide "professional management" for oversight of contracted services. Hospices do not have the expertise to do what the medical equipment experts are trained to do. The DME company must be held primarily responsible for delivering safe and appropriate equipment and supplies.

42 CFR §418.108 Short term inpatient care
This proposed regulation would eliminate existing requirements at §418.100(a)(2) requiring RN to provide direct patient care on each shift.

Due to the anticipated timeline for implementing the new hospice COPs, we request consideration from CMS to issue a specific memorandum to give immediate relief to the existing standard for 24 hour RN coverage, similar to earlier memorandums providing relief for staffing contracting with extenuating circumstances. AseraCare

applauds CMS for recognizing the staffing shortages giving rise to the necessity of providing relief to the 24 hour RN requirement. However, we would emphasize the need for immediate relief from this requirement, and would state that we do not believe patient care would be threatened by isolating this requirement by making the relief it would provide immediately available to hospice providers.

42 CFR §418.110(l) Meal service and menu planning
The hospice must furnish meals to each patient that are – (1) Consistent with the patient's plan of care, nutritional needs, and therapeutic diet; (2) Palatable, attractive, and served at the proper temperature; and (3) Obtained, stored, prepared, distributed, and served under sanitary conditions.

AseraCare joins NAHC is applauding CMS for this language, which is significant for what it omits. We support removing language requiring the hospice to serve 3 meals at regular times with no more than 14 hours between the breakfast and evening meals. Doing so respects the needs of the patient, rather than forcing the patient to adhere to rigid and artificially established meal times.

42 CFR §418.110(o)(1) Seclusion and restraints
. . . A drug used as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard treatment for a patient's medical or psychiatric condition. . .

AseraCare would join NAHC in calling CMS' attention to the fact that hospice programs commonly use drugs for treatment of terminal restlessness which are viewed in other settings as chemical restraints. We would urge CMS to confine the definition of drug restraint to medication used to control behavior or restrict patient's freedom of movement and which are not a standard treatment for a medical or psychiatric condition within a hospice program.

42 CFR §418.112(d) Medical director
The medical director and physician designee of the hospice must provide overall coordination of the medical care of the hospice resident that resides in an SNF, NF, or other facility. The medical director and physician designee must communicate with the medical director of the SNF/NF, the patient's attending physician, and other physicians participating in the provision of care for the terminal and related conditions to ensure quality care for the patient and family.

AseraCare joins NAHC in suggesting it would be best for the IDG to be responsible for this function and continue the current practice of assigning a registered nurse to coordinate the care. If the facility medical director is also the hospice patient's attending physician, it would then be appropriate to communicate with the facility medical director.

42 CFR §418.114(c)(7) Social worker
A person who has a baccalaureate degree from a school of social work accredited by the Council on Social Work Education.

AseraCare strongly believes that a BSW should continue as the standard for social work qualification for hospice social workers. BSWs have the needed skills for providing for the needs of hospice patients. Imposing a requirement for MSWs will increase hospice staffing difficulties without providing significant benefit to the patient.

42 CFR §418.114(d) Criminal background checks
The hospice must obtain a criminal background check on each hospice employee and contracted employee before employment at the hospice.

AseraCare agrees with the need for obtaining background checks on hospice employees prior to employment, but disagrees with a requirement that this process be followed for contracted employees. Hospices should be required to ensure that background checks on contracted employees have been obtained, but should be able to accomplish this through a written agreement rather than maintaining primary responsibility for doing so directly.

Sincerely,

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Hospice and Palliative Nurses Association

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July 22, 2005

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

Dear Sirs:

The Hospice and Palliative Nurses Association (HPNA) is submitting their comments in response to the Federal Registry Part II 42 CFR Part 418 Medicare and Medicaid Programs: Hospice Conditions of Participation; Proposed Rule.

HPNA represents nearly 8,000 nurses throughout the United States who deliver hospice and palliative care to Medicare and Medicaid recipients. Our comments reflect our desire to assure the delivery of nursing care meets expectations of the Department of Health and Human Services.

We thank DHHS for allowing us the opportunity to provide documentation for the need for clarification and expansion in the roles of the nursing team in providing hospice care as we move forward to the future.

Sincerely,

Judy Lentz

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Chief Executive Officer

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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.**

	(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.	

	(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.**

	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?**

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**

		"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.**