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Hospice
& Palliative
Care Association of New York State

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

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 <u>*aide*</u> 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 *<u>and psycho-social 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.**
- **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 <u>the home.</u>*"**
- **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).**

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 <u>*two weeks or 15 days*</u> 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

Kathy A. McMahon
President and CEO

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Southern Tier
Hospice
and Palliative Care
Our family caring for yours... when it matters most.

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, this will actually restrict a hospice patient's right to control of anxiety, terminal restlessness, pain, etc. 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 <u>*aide*</u> 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 <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. 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 <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 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

Mary Ann Starbuck
Executive Director

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Hospice
Of Central New York

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.

- 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 <u>*15 days*</u> 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 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
Cindy Baird
Executive Director

Yvonne Schwandt
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.