Ohio
Hospice &
Palliative Care Organization

July22, 2005

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

RE: Comments related to the Hospice proposed Conditions of Participation, CMS-3844-P

To Whom It May Concern:

The Ohio Hospice & Palliative Care Organization (OHPCO), an association in Ohio working to "Promote the development and delivery of highest quality of end of life care," held a series of face to face meetings around the state, one conference call to seek hospice industry input as well as conversations and comments from our colleagues in home health industry, the extended care facility industry, and regulatory bodies on the proposed rules - **CMS-3844-P**. We have worked closely with our National Organization, the National Hospice and Palliative Care Organization (NHPCO) and agree with most of their comments. In this response we will highlight our pertinent areas of concerns brought up during our meetings and conversations.

However, before getting into the sections specifically, OHPCO wanted to comment on parts of the Introduction and preamble. While we are in agreement with the ideas and discussion in regard to the Palliative Care and Quality Standards, Patients Rights and Quality Outcomes, we feel the CoPs and preamble are in conflict at different points. We are taking this opportunity to speak more generally and philosophically on the Proposed Rules prior to specific identified areas.

First and foremost we would like to begin discuss palliative care and end of life. Hospice is palliative care and the philosophy of palliative care is holistic in nature so that the decision making that occurs in palliative care is a shared decision making model vs. the medical model where the physician is in charge and makes the care decisions. Inherent in this is the distinguishing difference between interdisciplinary vs. multidisciplinary teams of care. Hospice has been built around an interdisciplinary model of care.

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The physician and medical care is part of this interdisciplinary care. While the physician is the figure head in ordering or prescribing treatment and medications, due to the fact that palliative care is being provided vs. traditional medical care, decision making occurs around controlling symptoms vs. curing disease or even perhaps underlying infection. The decision making involving medical care is critical to the other related items going on in the patient's life and through the interdisciplinary model, the physician uses information from the team, and working with the team to determine the most appropriate care to prescribe. Throughout the proposed rules, it appears the medical care is pulled out separate, in a traditional medical model, away from the interdisciplinary team. We will suggest this is carefully considered as it appears throughout the Proposed Rules. It creates a fundamental change in the "interdisciplinary" decision making model, looking more like "multidisciplinary" traditional medical model of care. This, we feel would be a serious and grave shift in our philosophy of care and holistic shared decision making.

Another area of concern is the lifting of language from what appears to be Home Health rules and Skilled Nursing Facility rules. It is a concern to us that there appears to be an attempt to put hospice, a very different care model than either home health or skilled nursing facility care, into a similar box. Reimbursement models are different, philosophy of care is different, and the manner in which we devise our plan of care is very different not to mention our outcome is not the outcome these other industries are trying to achieve. To this end, we believe that in some areas, linking this language too closely creates conflict and misunderstanding in the philosophy and practice of hospice care. An example here is related to the Home Health Aide and supervision changes. While this is not an area that routinely shows up on any common reported area of deficit, the proposed rule would be overly costly to implement, over burdensome to manage and doesn't appear to be based or indicated on past surveys or audits except that it is similar to what is done in other industries.

While we believe there needs to be more attention paid to the coordination of the plan of care and improvements to documenting patient outcomes of care and satisfaction, we do have concerns that there is a disconnect between the collection of "data elements" and reporting outcome measures. For hospice, outcome measures should be patient driven and thus individualized. A systematic process of data collection is neither individualized nor productive in the helping to derive outcomes data around the success of comfortable dying. In fact, lots of data collection of the dying patient may even be burdensome, increase pain, and decrease meaningful time spent preparing for death. OHPCO believes the areas to expand upon would be those related to the NHPCO outcome measures (self-determination, comfort, safety and effective grieving). However, to get to the evaluation of those measures on an individual basis, one would have to consider looking at the patient's functional ability and improvement around interactions, quality of life, communications, emotional, spiritual and psychosocial interventions which help patients and family to cope and deal with impending death.

Lastly, in overview, the language around "Drug restraint" is worrisome due to end of life symptom management and the medications hospices routinely use that have not been allowed routinely in extended care facilities along with the use of the term and

description of "behavior." If a patient is in terminal restlessness and we are using haloperidol to control restlessness and provide comfort, there is a behavioral effect. The terminal restlessness is creating a behavior and physical effects that have poor outcomes. There are other examples also, but at the end of life, to create a comfortable death and control untoward physical effects, these drugs have useful indications. Hospices have worked with nursing facilities to provide this level of care. The language in the CoPs, we are afraid, would create a chilling effect to the use of these appropriate medications for situations around the dying process. In the Last Acts report "Means to a Better End, A Report on Dying in America" published in November 2004 and in the report "Achieving Balance in State Pain Policy, A Progress Report Card" (updated in Feb. 2004) by the Pain & Policy Group from the University of Wisconsin Comprehensive Cancer Center, both these reports discuss barriers toward providing adequate pain therapy. Most areas of the country did very poorly in regard to providing appropriate care at the end of life. Due to misconceptions, fear by providers, fear from patients, poorly educated practitioners and use of bad policy and language, all theses are many of the barriers discussed. The use of the term "Dangerous Drugs" is one of the cited barriers. OHPCO would suggest CMS closely look at this language consider more appropriate language (see reports enclosed).

418.3 Definitions:
Clinical Note – We agree to add the word spiritual to the sentence "any changes in physical or emotional conditions."

Drug Restraint – Change to "Chemical" Restraint. Chemical Restraint means a chemical or medication used **with the intent** to control behavior or to restrict the patient's freedom of movement, which is not a standard treatment for a patient's medical or psychiatric condition. However, strong language needs to be included which allows for the appropriate use of medications to control terminal symptoms which may be medications that are considered "restraints" in other situations, looking at intent vs. just the drug.

With respect to medication use, the conditions outlined in this section are often inappropriate for hospice patients. Dr. Mark Beers published the hallmark article in 1991 outlining medications that are potentially inappropriate in the elderly. The article addressed concerns over medication related falls and excessive use of medications to prevent undesirable behavior (i.e. chemical restraints). Dr. Beers subsequently updated his recommendations in a 1997 publication. Both these publications serve as the basis for CMS guidelines for surveyors for appropriate use of medication in geriatric patients in long term care facilities. Although the intent of the guidelines is to prevent the use of a medication or devices to unnecessarily restrain patients who should be managed through redirection or other non-restrictive methods, they can be construed to deter the use of medications when these interventions are necessary for the control of symptoms that can not be managed through other methods or when the patient is at risk of harming themselves or others.

More desirable language would acknowledge the appropriate use of medications in hospice patients that may not be desirable in patients who are not experiencing symptoms

of life-limiting illness. Without mention of appropriate indications for medications that might not generally be acceptable in geriatric patients, barriers to the appropriate use of medications, such as haloperidol and other antipsychotic agents, opioids, and tricyclic antidepressants, which are standard of care for the treatment of many symptoms in hospice patients, could evolve.

So this issue of "Drug restraint" and the language used is very worrisome due to end of life symptom management that hospice's routinely utilize. The example of a patient that is in terminal restlessness and using haloperidol to control the restlessness and provide comfort, there could be interpreted as a behavioral effect. The terminal restlessness is creating a behavior and physical effects that have poor outcomes for patients with terminal illness and impending death. Hospices have worked hard over the last decade with nursing facilities to educate and provide this level of care with these medications. The language in the CoPs, we are afraid, would create a chilling effect to the use of these appropriate medications for situations around the dying process.

In the Last Acts report "Means to a Better End, A Report on Dying in America" published in November 2004 and in the report "Achieving Balance in State Pain Policy, A Progress Report Card (updated in Feb. 2004) by the Pain & Policy Group from the University of Wisconsin Comprehensive Cancer Center, discuss barriers toward providing adequate pain therapy. Most areas of the country did very poorly in regard to providing appropriate care at the end of life. Due to misconceptions, fear by providers, fears from patients, poorly educated practitioners and use of bad policy and language, all theses are many of the barriers discussed. The use of the term "Dangerous Drugs" is one of the cited barriers. OHPCO would suggest CMS closely look at this language and consider more therapy friendly language. (See Reports, enclosed)

Beers MH, et.al. Explicit Criteria for Determining Inappropriate Medication Use in Nursing Home Residents. *Arch Intern Med* 151:1825-1832. Sept. 1991
Beers MH. Explicit Criteria for Determining Potentially Inappropriate Medication Use by the Elderly. *Arch Intern Med* 157:1531-1536. July 28, 1997.
McLeod PJ, et.al. Defining Inappropriate Practices in Prescribing for Elderly People: a National Consensus Panel. *Can Med Assoc J* 156(3):385-91, 1997.

Facility – Definition of facility is confusing in this growing market with the use of hospice in self sustaining independent facilities, hospice leased units in nursing facilities or hospitals, with different levels of health care facilities, assisted living facilities, extended care facilities, skilled nursing facilities and freestanding hospice inpatient facilities. Look carefully at distinguishing between the differences.

Patient's residence – We would raise the same caution as above in facility. Being careful as to the separation between a hospice residence vs. a residence in another type of facility. I would also raise a question of inquiry as to how hospices are licensed in each state. If, as in Ohio, a hospice is licensed as a service and not a facility, does this language create difficulty in defining facility or residence? Are most hospices that are licensed, licensed as a service or facility? There are technical difference in Ohio which

affects programs in some different ways. In Ohio a facility can claim they are a conscientious objector and not provide DNR or life saving treatment. As a service in Ohio, which hospice is, one can not take the position of a conscientious objector? However, some attorneys for hospice programs have determined they can take the conscientious objector position for the hospice residence vs. the service. So a program may allow someone without a DNR in their program but if they need care in the inpatient unit the patient won't be accepted unless they sign a DNR.

Physical restraint – We are concerned that this section of the Proposed Medicare Conditions of Participation restricts the use of restraints to an "emergency" situation does not acknowledge that terminal agitation is a common occurrence that may require palliative sedation as patients approach death and could persist for several days. OHPCO suggests adding "or adjacent" to the sentence "means any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's.... OHPCO would also ask that CMS consider the safety of the patient, safety to self by minimizing ones ability to harm or injury oneself.

Representative – means an individual who has the authority under State Law to authorize or terminate medical care or to elect or revoke the election of hospice care (able to sign for the beneficiary on the election form) on behalf of a hospice eligible beneficiary who is mentally or physically incapacitated. This may include a legal guardian.

Satellite location – Agree with the definition, should not have to independently meet the CoPs as a hospice.

Seclusion – Pull this definition out or question the use of a locked unit for Alzheimer's patients. We would not want this type of unit considered "seclusion" for patients with Alzheimer's or a similar disease process.

418.52 CoP: Patient's Rights:
a. Standard: Notice of rights:
1.) From an association perspective, this is critical at least in the most common basic languages, however, it is unreasonable to expect all languages be in written format.

EXAMPLE of DIFFICULTY: While working to develop Advance Directives in Spanish what we learned in Ohio was that the interpretation could occur very easily. What was lost was in the interpretative written words was the understanding and meaning in that translation. To just have the words translated doesn't equate to having the meaning translated.

It took an additional nine months to have legal authorities rewrite the document to get the correct legal interpretation. This is very concerning with some languages having many variations or dialects. To get someone to look at the intent of the language after the text interpretation was laborious, time consuming (nine months) and potentially very costly.

A hospice should provide adequate interpretation of documents and forms in a manner that most individuals of a dialect would understand, in an acceptable format, either written, visual, verbally through family or an interpreter.

2.) Clarify under the advance directive section, the sentence "including a description of applicable State Law?" Is this in regard to the state's policy on providing information to the patient or the State accepted Advance Directive forms, or the state's governing policy on the acceptance of advance directives by healthcare providers?

3.) Section concerning informing the patient and family of the hospice's drug policies especially tracking and disposing of medications. While we agree that this needs to occur, this just adds to informational overload at admission. Language should state that a hospice needs to inform but should broaden the time frame a program has to inform. As far as tracking medications, OHPCO would suggest that the interpretative guidelines state that surveyors should focus on the state's governing policy and discuss disposal specifically but with the understanding that once an order is written and filled that the medication is now within the patient's property and the hospice has limited rights in the individual's patterns or activities. The hospice should always observe for patterns of abuse, misuse or misdirected medications but only from the normal day to day activities they are associated with and with their tools, role and environment of care.
These medications in the home belong to the patient and it is a gray line in regard to tracking vs. personal property and an individual's civil rights we believe. State policy should provide guidance here.

OHPCO believes there needs to be clarification on the word "demonstrated" in this section in regards to the patient or representative has demonstrated an understanding of these rights. Is this a form or documentation under clinical notes?

b. Standard: Exercise of rights and respect for property and person:
1.) Language here should include the right of the patient to refuse treatment as determined by the Patient Self-Determination Act. While we use the NF CoPs Section 418.10 OHPCO would suggest that it is a referred to piece and that this section is used as an example is not stated verbatim. OHPCO would suggest that throughout the document, whether it is NF or HHA rule we are referring to, it is a reference and not the hospice language. It seems that the language is mixed, some places it aligns hospices' with other industry interpretations while at other areas the issue is that our patient population is different. OHPCO would suggest that the population is different and as we referred to previously, the philosophy of care is different and trying to lay another industry's language within the hospice language without individualizing it creates other problems due to the different health outcome goals and philosophy of care.

Tracking of Complaints: OHPCO agrees that hospices' should have compliance programs and complaint tracking to document concerns, issues, problem areas and areas for changes. However, OHPCO strongly encourages a division of degree in reporting. On one side is incident reporting for programs to use and on the other are issues that are more egregious. The rules need to allow for investigation, documentation and resolution

of the issue/concerns based on the degree of the issue. Incident reporting should be reported by aggregate numbers but not in detail to CMS. CMS should only review specifically those issues that present patient safety (abuse/neglect), environment of care or program violation in regards to following Medicare's rules and/or CoPs or patient abuse, neglect or potential injury.

(ii) The area of "voice grievances" would seem to fall into more of incident reporting vs. a voiced complaint and reporting to CMS. Does CMS have a better definition or explanation of this term?

3.) OHPCO believes there needs to be more specific information to discuss: "If a State Court has not adjudged a patient incompetent, any legal representative designated by the patient in accordance with State law may exercise the patient's rights to the extent allowed by State law." This statement alone speaks to anyone. OHPCO believes there is an assumption that CMS is trying to get to the issue of medical capacity to make decisions but don't say that. If an individual has capacity, then they should be able to make all decisions. However, if the beneficiary is incapacitated then their appointed durable power of attorney or an individual or individuals as defined under state law should be the one(s) that make decisions for the beneficiary.

4.) Language should be included here (i) that states "when the hospice becomes aware of the incident." Not 5 days after it occurred. The other question that is raised here is "what is the appropriate agency in the state" that one reports to? OHPCO assumes it would be the agency that has the ability to perform a survey if a complaint was made outside the hospice? However, this could be a barrier also if this agency and the industry do not have a good working relationship, an understanding and ability to accept complaints and definition of which complaints to report and not report. Or does CMS want these complaints to go to the FI or QIO?

(ii) Define abuse and neglect. Is a family member's inability to get to the beneficiary's home in a timely fashion, even though during this time frame the beneficiary was not harmed, but the plan of care is for someone to be with this individual ATC? Is this neglect? How subjective or objective does the hospice need to be here? How does one evaluate reasonable means in the home setting or "to a reasonable extent?"

(e) Patient liability: This is a growing area of concern for hospices. There is great difficulty in meeting this requirement due to the inability of CMS - Medicare/Medicaid to pass along Patient / Beneficiary liability and spin down costs information to hospices. This forces us to be held to a level of accountability that we are unable to do through normal business practice. OHPCO has asked for this information to be passed on to hospice providers for years and we have been unable to get it, it goes to the individual's residence, traditional home or nursing home. In this instance we believe CMS should provide this information to the hospice provider caring for the patient or have an information data center where a hospice provider can get this information.

Another issue here as well is the changing room and board rates which in Ohio that information goes to individual nursing facilities on a quarterly basis. While it becomes a hospice's responsibility to bill Medicaid for R&B with beneficiaries in nursing facilities, payment information follows the patients and goes to their residence, meaning the NF. Hospices have to track down this information and it is very difficult to do so. How can a hospice meet this requirement if Medicare/Medicaid won't give the information to hospices?

As for the ABN's, these questions were submitted to Palmetto GBA in May 2005. Their response was to refer to CMS Change Request 3416 dated October 22, 2004. Section 60.3.3 states that providers must decide which condition and notice requirement is appropriate to the billing situation and use only one of the options provided in each case. These questions were asked because providers are finding it difficult to determine which option best fits the hospice situation. Further guidance here would be helpful.

While we understand and support CMS' Benefit Notice Initiative's purpose of giving beneficiaries "the opportunity to timely exercise their rights and protections in a well-informed manner," it is often difficult to fit the required notice forms into hospice scenarios.

Please review the following scenarios and, for each, advise as to which notice should be used and which provider would issue it.

Scenario 1: Beneficiary is referred to hospice; already has oxygen in the home. At the time of the hospice election, the Beneficiary is informed that the hospice agency works with a different oxygen vendor and that the equipment will need switched out. The beneficiary states that she prefers to remain with the current vendor. The hospice informs her that she has the right to make that decision but that she would then be responsible for paying for the oxygen out-of-pocket; she chooses that option.

Scenario 2: Beneficiary chooses to continue obtaining medications for the terminal illness from a non-contracted pharmacy. She is informed of her right to do so and that, if she makes that choice, that she will be responsible for paying for the medications herself. She has no other prescription coverage.

Scenario 3: A hospice patient has been at general inpatient level of care. The problem that necessitated GIP has been resolved; the hospice informs the family that the patient will be discharged home the next day. Although the previous caregiving system remains intact, the family refuses to take the patient home. The hospice informs the family that, if they refuse to take the patient home, the beneficiary will be liable for payment to the inpatient facility.

Scenario 4: Although proper education has been completed and documented, family members take a patient to the emergency room for a non-emergency situation without contacting the hospice. The hospice directs the hospital to bill the beneficiary.

Scenario 5: The hospice determines that a beneficiary is no longer eligible due to lack of terminality and informs the family that the patient will be discharged. The family wishes to continue hospice care and feels that Medicare should continue to pay for it.

Should the hospice issue an ABN to the family? The wording on that document states that Medicare "probably will not pay for" the service and allows the beneficiary to request that a claim be submitted to Medicare. Both seem problematic—if the hospice has already determined that the patient no longer has the required prognosis, the use of the word "probably" is misleading. Also, what process would the hospice use to submit a claim that would provide PGBA with sufficient information about the situation?

How far does CMS expect a hospice to go in giving information regarding medications and the cost of meds that are not covered by the hospice program? How specific are hospices suppose to be in "case management" of the medications prior to admission related to the drugs related to the terminal illness and those not related to the terminal illness? Is a hospice responsible for informing a patient they need or don't need certain "other" medications that are the responsibility of the attending or specialty physician that the patient is working with to oversee those particular non-related issues?

418.54 Comprehensive assessment of the patient:
General comment here is that OHPCO doesn't see the concept of "patient's goals" referred to in this section, hopefully this is an oversight and it should be added. This is part of the foundation of the Plan of Care and is spoken to in the preamble but seems to have gotten lost here.

(a) Initial Assessment: One difference here between states and regional FI interpretation is "what is needed to start care" considering a physician's referral to evaluate a patient vs. when is the "order", or do you need an "order" to then initiate the care. Perhaps there is a difference between receiving admission orders and an order to admit to hospice. Should there be a stipulation between the two? Does a request for evaluation automatically initiate care if the evaluation determines hospice care is needed?

This standard needs to differentiate between the timing to start care vs. evaluate a patient vs. when that time frame is not within 24 hours due to circumstances related to the care of the patient or that the patient or family may not be ready for a couple of days. The assessment may be more appropriate at a later time frame. Perhaps "contact" within 24 hours would be more appropriate.

However, when patient is ready to be admitted, a patient / family initial assessment should be completed within 24 hours to ensure appropriate admission to hospice and services, 24/7, 365 days a year. The Comprehensive Assessment needs to have some flexibility in it to allow for the needed services of care for the imminently dying individual and one that will have a long LOS. Long and comprehensive assessments may be burdensome, create more suffering, and allow less time with family, this needs to be balanced and decided upon within the core team providers. It would seem the IDG could determine this need upon initial assessment and in the building of the POC. If the patient

is anticipated to die within seven days, more time and energy is spent on the immediate care needs vs. burdensome requirements.

While Ohio agrees that the vast majority of the time, an RN is the most acceptable discipline of the team to go do an initial assessment, we also discussed the need to have the ability for the Social Worker to be involved in the initial assessment depending on the identified terminal illness, needs of the patient / family, and the environment of care. In some situations it may be more appropriate to have the Social Worker do the initial assessment vs. the RN.

(b) Time frame for completion of the comprehensive assessment: OHPCO would agree that 7 days for the overarching Comprehensive Assessment is recommended. OHPCO believes the language in the first paragraph should read the "individual's attending physician and/or hospice medical director must complete the comprehensive assessment no later than 7 calendar days…."

(c) Content of the comprehensive assessment: OHPCO believes this language should read something to the effect: "The comprehensive assessment must identify the physical, psychosocial, emotional, and spiritual **needs related to the patient's terminal illness, their trajectory of illness and family care** that must be addressed in order to promote the ….." Where does the family as the unit of care come into play? This needs to be individually driven.

(3)(i) Should the category "financial" also be considered or added to this section?
(3)(ii) Drug Therapy – Language should state that when a hospice case manages a patient's prescription and over the counter drug profile, this is done due to the inherent nature of certain drug interactions and evaluating the need for continuing therapy. It is not the hospice's responsibility to cover all said medications but only those related to the terminal illness and those that are reasonable and necessary for the palliation or management of terminal illness.

What is "ineffective drug therapy?" This is very vague and depending on the disease, illness trajectory, response and multiple other variables, "ineffective" is very subjective. Effective drug therapy for an individual without a terminal illness and effective drug therapy for a terminal patient to minimizing symptoms is often not appreciated between the curative medical model and end of life model of care. Palliative vs. curative.

(d) Update of the comprehensive assessment: OHPCO would rather this read two weeks instead of every 14 days. How detailed is this comprehensive assessment, is this ensuring that each patient and their case is at least discussed every two weeks? Depending on the definition of comprehensive, this full assessment every 14 days could become extremely burdensome and not needed. The assessment should be based on patient needs and outcomes, not on a subset of standardized elements to measure.

(e) Patient outcome measures: This sounds very much like JCAHO. This section appears to lack direction towards outcome measures that one could use for benchmarking

across the hospice spectrum. OHPCO thought it would be driven more that way. Time frames are rather thin for many patients, what is the realistic expectation that hospices collect data on those that die within a short time frame? Also, the terms "must" in # (2) limits the hospices ability to compare two different parameters against each other. OHPCO would recommend removal of these terms or restructure the format of the sentences. Generally, quality improvement is measuring something to check and see if results are what we believe them to be, to correct or address issues and concerns, and to improve the outcome or develop new ways to address the area being monitored and see if improvement is made. OHPCO would hope it is the desire of CMS and the industry to measure a "quality death." And if you are successful, and there isn't any thing to improve, then it isn't quality improvement but maybe a quality outcome. OHPCO believes there is still much confusion about the direction here.

OHPCO would suggest movement towards the International Classification of Functioning as a consideration in looking at outcomes of care, improvement of care, functional changes and quality of life. This would provide a common language that at sometime could be utilized across the health care environments.

418.56 CoP – Interdisciplinary group care planning and coordination of services: OHPCO believes the RN should be the disciplined professional identified to oversee the team and we see difficulty in having other professionals assume this role. Also, consider changes to language as below:

(a) Approach to service delivery: (1) Second sentence – **Interdisciplinary group members must provide core services and care offered by the hospice, and the Interdisciplinary core members must supervise the care and services.**

One question here is the term "supervise," does this have EEOC implications, giving all core members a level of management responsibility?

(a)(1)(i) – Add language to read to allow hospice medical director to act also as the patient's attending. In (iv), remove "spiritual" before counselor. OHPCO is concerned about this change and the shift in focus this might bring to programs where the counselor is used in a more general sense.

(b) Plan of care: – Is the family/patient involved in the Plan of Care? There should be a statement in this section to that fact. "IDG in collaboration with the attending physician, patient, primary caregiver and family...."

(c) Content of the plan of care: What is the general definition of Plan of Care? This varies between hospice to hospice greatly.

(1) Interventions to facilitate the management of the beneficiaries pain and symptoms, psychosocial, emotional and spirituals needs related to the terminal illness.

(c)(2) This is too prescriptive for some of the types of care and intermittent services provided. Scope and frequency needs to be removed, PRN needs to be included. The emotional rollercoaster that the patient and family goes through related to pre-grief, grief, conflict and anticipatory morning episodes along with other emotional concerns and issues are not necessarily routine. They are individualized and the utilization of staff and disciplines at different junctions of care cannot speak to the specific services and needs on a scheduled basis. This is very acute medical care model and doesn't take into account the palliative holistic nature of hospice and our patients. This is trying to shove hospice into being "like" other medical models of care.

(c)(4) – Add language here "for the palliation and/or management of the terminal conditions or related symptoms."

(c)(6) – Would change as follows "The interdisciplinary group's documentation of patient and family understanding, involvement, agreement/**disagreement** with the plan of care." Not all family may agree with the patient's desires and plan of care. Hospice should document those concerns and identify interventions to address these issues. For example, conflict is normal in family situations period. At end of life, for many reasons, this conflict is often heightened. Part of the role of hospice providers is identifying this conflict and working to resolve the issues and concerns to help the patient and family experience a quality death.

(d) Review of the plan of care: OHPCO believes the medical director is already part of the interdisciplinary team and doesn't need to be pulled out separately here.

(e) Coordination of services: (3) remove the word all and insert "most current assessments."

418.58 CoP: Quality assessment and performance improvement:
(b)(3) – "specified by the hospice's identified Interdisciplinary Group." Remove "governing body." The governing body or the board approves the overarching plan but not the frequency and detail of data collection.

(c)(1) (i) – Hospices should use a cause and analysis approach to data collection while looking for items that improve quality of life and comfortable dying. More detailed descriptions about "adverse events" needs to be included here. Adverse event tracking and evaluation may be very different than Quality Outcome Measurements. In some areas CMS seems very vague about the data elements to monitor, here they seem to believe there is cause and affect issues that needs to be looked at, a negative approach towards improving quality outcomes. One approach is to find problems, try and fix them to improve care the other is to say this is the outcome we want, let's measure items which would demonstrate that outcome and if we aren't obtaining the outcome then let's investigate and see why not, correct the situation and re-measurer.

(e) Executive responsibilities: Does this related to the whole organization or just areas that related to patient care? Should the organization be proactive or reactive, does the process promote one direction vs. another? Is there a process generally followed?

418.62 CoP: Licensed professional services: (b) Add the word "hospice" after "patient's" so it reads "Licensed professionals must activity participate in the coordination of all aspects of the patient's hospice care, in …."

418.64 CoP: Core Services: Consider changes to the fifth sentence – "A hospice may, under extraordinary or other non-routine circumstances, enter into a written arrangement with another healthcare organization to provide the necessary disciplinary specific services to supplement hospice employee/staff to meet the needs of patients."

This section, with all the workforce issues here and on the horizon, doesn't make sense to believe that competitors would actually work with each other in a manner such as this. In many areas, extreme competition or lack of specific providers would prohibit programs from contracting with each other. Also due to other issues identified in this section and paragraph, an aging population, workforce shortage, we need broader language here for those non-routine, high acute issues that occur from time to time and allow providers to contract occasionally with services to support the care of terminally ill patients.

(a) If contracting with an attending physician, does this section put them under the direct supervision of the medical director? Essentially, the medical director is responsible for their actions? If a patient travels to the ER due to getting anxious and the attending orders some tests, blood work, ect. Is the hospice now liable due to the supervision of the medical director over this physician by hospice contract such that the issue becomes between the medical director and attending to settle vs. the hospice saying "that wasn't related to the terminal illness?"

(a)(1) This is too broad, this section needs to specifically state "related to the terminal illness."
(a)(3) Need to specify that the physician employee is responsible for meeting the medical needs related to the terminal illness. The attending may be responsible to other medical needs of the patient and the hospice should not become responsible for these needs if the attending or covering physician is not available.

(b) Clarify, is a home health aide considered under "nursing services"? Many of their activities fall under the delegation of an RN and nursing services.

(c) Clarify qualified vs. licensed. Social workers are often involved in counseling and that should be added here. OHPCO believes that psychosocial assessment needs to be addressed in this section also. Define psychosocial support and counseling. Does the section need to consider adding non-core services specific to SW in here as well as a reference to 418.70.

(d) Counseling Services: Consider calling this section "Support Services" vs. Counseling Services.

(i) OHPCO believes this section should make sure this is covering educational experience or work experience/knowledge. Hospice is the arena where most of this education or experience is gained. Broadening this allows us to continue being a training ground for individuals in Bereavement counseling.

(ii) OHPCO would suggest considering "support" vs. counseling, under (ii), "bereavement support."

418.70 Furnishing of non-core services: Dietician should be a non-core service.

418.76 Home Health Aide and homemaker services:
(a) Pull out details of training program and list here also and list state to state differences in the training of home health aides.

(c) Add "aide" following home health in the introduction sentence.

(e) In the next to the last sentence, add "hospice" so the sentence reads "…Of which must be in hospice or home health care…"

(f) Would suggest substituting "hospice" for the words "home health agency" in the beginning of the standard.

(g) Home health aide assignment and duties: 2 (i) and (ii) – Many items here for the aide may not need a physician order, please clarified this.

(h) Remove "qualified" or define this term. Remove observation visit every 28 days. OHPCO doesn't believe there has been any reason to change the current review of the home health aide and the work they do. It does not come up in the frequently identified issues at the state or FI level of review. Has there been issues here? This change seems over burdensome and unneeded.

(iv)We oppose this provision. In states where aides have been authorized to work in this fashion there is much more education and specialization in their duties than what is prescribed here. Due to the home care environment and inability to assist aides in the home environment during this activity, we are in opposition.

(h) Supervision of home health aides:
Supervision is much too frequent and obtrusive as well as costly. Issues and concerns related to hospice care and complaints occur much less than any other provider, this should not be an area to waste time and money on. It appears to be a change to make hospice more like other providers, yet we don't have the issues identified as other heath care providers have, especially related to home health aide care. OHPOC would suggest this language stay as it currently is.

(j) & (k) Homemaker: "Homemaker services" are not a reimbursed service. Current language state that "a hospice **may** provide homemaker services but they are not reimbursed for this care." It should not be defined and if it is the language should specifically state that hospices are not necessarily responsible for this care.

418.78 Volunteers
(e) Level of activity: Spell out that 5% excludes fundraising.

418.100 Organization and administration of services:
(a) Serving the hospice patient and family. The hospice must **work towards** ensuring - (work to demonstrate a desire to reach the process of "ensuring." "Promote" would be too passive.
Under (2): That each patient experience hospice care that is consistent with patient and family needs and self-determined, individualized goals.

(b) Governing body and administrator: OHPCO questions what is meant by the term "qualified" and what are qualifications?

(e) Professional management responsibility: OHPCO supports removing the term "supervision". Also, the requirement for personnel having "at least the same qualifications as hospice employees" is troublesome when considering the care given in other settings. How does this related to an aide, volunteer, etc. in a NF with a hospice patient, when the mode of care is not related to the terminal illness? Perhaps "having the necessarily qualifications" to provide appropriate care to hospice patients.

418.102 Medical Director: Last sentence of this section starting out should read: "The medical director and physician designee **collaborate** with other physicians and health care professionals **to coordinate with** the **interdisciplinary team** to ensure that each patient experiences care that reflects the hospice **philosophy**."

(a) Initial certification of terminal illness: Does this provision change certification of illness from two physicians initially to one?

(c) Coordination of medical care: The medical director role here should not include "directing the hospice's quality assessment and performance improvement program. For many physicians this is unrealistic as their time is split between many other duties outside hospice let alone their responsibilities within the hospice program. Oversight is provided by the governing body and the IDT, of which the medical director is a part of in one or perhaps both. The hospice director should oversee or appoint a member of the program to oversee the QAPI program.

Elaborate on "another qualified professional."

418.104

(b) Authentication: What or who is a primary author? Authentication of staff and hospice personnel is doable however, obtaining consultant signatures and the multiple physician signatures would be very burdensome, costly and a logistics nightmare. Hospice care is so spread out; involving community providers and hospice programs working together, this is over burdensome.

(e) Discharge or transfer of care: Add Advance Directives to number (3). Also, we would note it is very burdensome to include the entire chart to other entities and not necessary. Suggest that a discharge summary and copy of the medical record is made available upon request. HIPAA requirement would be that hospices follow minimum six year standard.

418.106 Drugs, controlled drugs and biologicals, medical supplies, and durable medical equipment. OHPCO would recommend putting the language from 418.110 (m) in here somewhere.

(b) Controlled drugs in the patient's home: Collecting items owned by the hospice becomes an issue if the owner or responsible party doesn't want to relinquish those items. It seems inherently an overstepping of boundaries to include "collecting" in these statements when the property isn't yours to just collect. Suggest changing collect to dispose.

Would this policy and education better serve the hospice, patient and family if it were discussed near the discharge vs. admission? Perhaps, even getting the family to sign off on a form documenting the policy has been discussed and medication disposal or non-disposal noted.

Means to a Better End, a Robert Wood Johnson sponsored study looking at the issues and concerns with dying in America pointed out many state barriers to adequate pain control and the reason so many states perform so poorly in this area is related to terminology such as "potential dangers" of controlled substances. This places a negative value on controlled substances when in fact all drugs, not used correctly, have potential dangers. The placement and use of this terminology places a negative connotation on the use of and delivery of adequate pain control and needs to be removed.

(c) Use and maintenance of equipment and supplies: Work with the DME companies and language in a programs contract on how to work with concerns or issues with equipment. Remove suggested language here, over burdensome, costly and not the expertise of hospice programs.

418.108 Short-term inpatient care: Included psychosocial/emotional/dysfunctional family issues within this first paragraph.

Inpatient care for symptom management and pain control: OHPCO recommends that for GIP service 24 hours nursing coverage, on site, (RN – LPN) is required for this level of care.

Inpatient care for respite purposes: OHPCO would recommend removing the requirement for 24 hour nursing care for this patient. Perhaps if we understood what 24 hour nursing **services** meant here, this would be OK language. Also remove the requirement that for respite care this has to occur in a Medicare Certified facility.

Inpatient care provided under arrangements: Clarify the "whole clinical record." The whole hospice record is not needed within this environment. Number (4) is not under hospice's control. While it might be a part of the contract between the two parties, it is not a program piece that hospice has control over. Remove this or clarify that this entire section is related to the contract and elements within the contract.

Needs to be language in here discussing an understanding that with multiple hospice providers there is not a need to duplicate multiple similar educational programs. The hospices and NF should coordinate programming.

(f) Patient Rooms: OHPCO believes that the square foot minimum should be at 100 square feet for new construction projects.

(o) Seclusion and restraint: Hospice often uses medications to treat pain and other symptoms such as nausea. Many of these medication are not used in NF because they have been targeted related to other issues than the intended use in hospice care. The use of medications here should discuss intent vs. behavior. A cardiac drug controls behavior of the patient. Terminology here should focus on the intent and use of medication to control symptoms (e.g. Haldol for nausea, high dose narcotics for pain, etc).

(7) Insert the term "unexpected, adverse or unpredicted" prior to "any **unpredicted** death that occurs while the patient…."

418.110 Hospices that provide inpatient care directly.
(a) Staffing: How is acuity measured, suggest deleting this term, acuity.

(m) Pharmaceutical services: Hospices should be able to contract with their pharmaceutical services and bring those medications into facilities when serving their patients.

(o) Seclusion and restraint: Each hospice should have a written policy for restraints and seclusion in place.

(o)(3)(ii)(c) Delete "physician must see within 1 hour."

(o)(7) Recommend changing form CMS to Medicare state surveying body.

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

(d) Medical director: Coordination of care is OK with an oversight capacity. The attending physician should also communicate with the physician most identified as the patient's doctor in the NF, however, this is generally the attending already. Seems to OHPCO that the real collaboration is between the hospice medical director, the attending physician, hospice staff with the NF staff-team caring for patients in the NF. The outline here otherwise would be impossible to do time wise. The bulk of communications should occur between the IDT and NF staff caring for the patient. Physician to NF physician communication on a patient to patient basis here is unrealistic. This would be a barrier to care as well as a mandate trying to force a new "standard of care" practice between physicians.

Define "physician designee."
Does CMS view medical care and hospice care as the same?

(e) Written Agreement:
(1) Notation in the Written Agreement should stipulate that a written consent regarding the patient or the patient's representative that hospices services are desired should accompany each admission.

(f) Hospice plan of care:
Is there another plan of care for the patient from the facility side of things? Or, is there now an overarching plan of care? What about items not related to the terminal illness?
(g) Coordination of services: This section makes it apparent that the NF will have their own plan of care also, as it is today.

OHPCO believes the responsibility for the NF/Hospice patient falls between the two entities, and would suggest a comment in the preamble in regards to this shared responsibility. Attached is a "Roles and Responsibility" worksheet developed by NF/Hospice workgroup as well as a worksheet related to developing contracts between the two disciplines.

(i) Orientation and training of staff:
Should be a statement regarding coordination of education efforts between NF and Hospices, if more than one hospices, so duplication of educational programming is minimized, NF aren't inundated with hospice providers and appropriate topics are covered.

418.114 Personnel qualifications for licensed professionals:
Comment from providers here in Ohio overwhelmingly support the loosening of requirements in regard to Social Work, allowing state licensure to criteria to be the determining factor vs. graduation from an accredited school as currently written in the CoPs. This is one of the areas that are most difficult for us to fill in rural areas. Maintaining the current level of qualification is difficult, any attempt to increase that level of qualification would render many of our programs undue hardship in meeting the responsibilities regarding core staff members. However, we would support and believe that a Social Worker needs to be at minimum licensed, same with RNs. If state legal

authorization fell below these levels we would be concerned in regard to the education and knowledge needed to care adequately for hospice patients.

Criminal Background Check:
Concerns rose about the ability to attract volunteers in some areas. Specify that all volunteers with patient contact and/or volunteers exposed to confidential information be included.
With mandating this provision the federal government needs to describe the type of background check needed and extensiveness of the background checks. CMS also needs to ensure the resources are available for the programs doing the checks are there to ensure a timely turn around. The manual process, not uncommonly, takes more than 30 days requiring you to fire or put the individual in a non-working status until the paperwork comes through. This is a burdensome process for many of our smaller programs, which incidentally makes up about 50% of our hospice provider population.

Do Not Resuscitate:
DNR: OHPCO is surprised that somewhere in the rules CMS did not take the opportunity to discuss the philosophy of hospice and issues/concerns, conflicts in individuals not being a DNR yet choosing hospice and with the concepts of not wanting life prolonging treatment or therapy. Our suggestion would be to give hospice the ability to set their own policy around the DNR issue or be a conscientious objector.

Thank you for the opportunity to responds to CMS-3844-P, Hospice Conditions of Participation. If we can answer any questions or further explain our position(s) please don't hesitate to contact us at the address below.

Sincerely,

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