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Passionate for the Appropriate Use of Medication

July 26, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Center for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Comment on the Proposed Medicare Conditions of Participation for Hospice, published May 27, 2005, File Reference No. CMS-3844-P

Dear Dr. McClellan,

Thank you for the opportunity to submit comments in response to the proposed rule, published in the Federal Register on May 27, 2005, revising the existing hospice conditions of participation (COPS).

excelleRx, Inc. is a Philadelphia-based prospective medication therapy management (PMTM) company that contracts with over 500 of the nation's hospice programs. The approximately 50,000 hospice patients we serve per month represent over 30% of the total hospice patient population. We have developed peer-reviewed, literature-referenced, evidence-based medication use guidelines for management of 47 symptoms and/or syndromes associated with terminal illness. As a company, we advocate for the patient's right to appropriate medication therapy. Our PMTM model achieves that goal in hospice through the active participation of palliative-care-trained pharmacists in medication care planning, supporting appropriate prescribing, monitoring patient symptoms and quality of life outcomes, and reporting endpoints and outcomes of therapy to the hospice interdisciplinary group. Application of our evidence-based guidelines assures that the pharmacotherapy is both efficacious and cost-effective. As proof of concept, physician acceptance rate of our pharmacists' therapy recommendations is 96%, and our partner hospices have documented reduction in time to palliation, avoidance of hospitalization, as well as a reduction in direct and indirect costs associated with pharmacotherapy.

Given our expertise in pharmacotherapy and experience in the hospice market, our comments focus on those requirements most pertinent to medication therapy and medication management. As you are well aware, the current hospice COPS were promulgated on December 16, 1983 – well over 20 years ago. Since then, new medications have been introduced and new preparations of standard medications have been developed. Some innovations, such as long-acting opioid preparations and convenience packaging of medications that enables rapid access during a symptom crisis, have produced significant symptom management improvements. At the same time, many new medications and modified preparations of standard medications have merely fueled the cost of pharmacotherapy without adding measurable

clinical benefit. According to National Hospice and Palliative Care Organization (NHPCO) data, the hospice spend on medications and biologicals, as a proportion of total reimbursement, has increased from 3% to 17% in just 10 years. Many hospice programs struggle to remain fiscally viable under the pressures of nursing shortages, declining length of stay on hospice, and increased costs for labor and contract services. The combined challenges of acuity of illness at the time of hospice admission and the rising costs of care make appropriate and cost-effective pharmacotherapy more important now than at any other time in the history of the industry.

While medication therapy has always been a core component of symptom management in palliative and end-of-life care, the introduction of new medications and medication classes has elevated the importance of medication selection and monitoring. Unfortunately, as proposed, the COPS do not adequately address medication therapy as a critical component of hospice care. Accordingly, our comments are intended to provide a framework for integrating current hospice-specific medication therapy management practices into the COPS and to strengthen and clarify regulatory language as it pertains to medication use. Our comments were guided by the following core principles:

1. Hospice care must be patient-centered.
2. Assessment, care planning, and treatment must be interdisciplinary and reflect current industry best practices with respect to palliation, pain management, and symptom control.
3. As far as practicable, patient care standards should be consistent across care settings.
4. COPS must be clear, consistent, and not overly burdensome, and
5. Quality improvement programs must be data-driven and reflect hospice special needs and challenges.

Our specific comments are set forth in detail below.

1. Standards for Pharmaceutical Services should be consistent across care settings, except when consistency is impractical, infeasible or unnecessary.

ISSUE: Section 418.110 provides a standard for pharmaceutical services that addresses many important aspects of medication management including dispensing accuracy, assessment and evaluation of appropriate therapy, monitoring for adverse medication events, and consultant pharmacy services. The standards set forth in Section 418.10, however, only apply to hospices that provide inpatient care directly.

RECOMMENDATION: CMS should provide a single standard for a pharmaceutical service that is consistent across all of the hospice's care settings. Such a standard should provide that the hospice provide or arrange for

(A) Medication management care planning and consultative services that:
(1) Assure appropriate medication selection, based on relevant evidence-based guidelines,
(2) Ensure appropriate prescribing,
(3) Ensure accurate dispensing,
(4) Provide ongoing evaluation of a patient's response to medication therapy services and adjustments to therapy that ensure quality patient outcomes,

(5) Monitor actual and potential adverse medication events,
(6) Recommend appropriate medication care plan adjustments, and
(7) Document initial and periodic assessments and patient outcomes of medication therapy.

RATIONALE: As CMS is aware, the majority of hospice services are provided in patients' homes. We believe that high-quality pharmacy services provided to patients in any setting where they receive hospice care reduces suffering and increases quality of life for patients and their caregivers. Because medication therapy is such an important component of hospice services, and the right to receive effective pain management and symptom control is not limited to patients receiving inpatient hospice care, the COPS should ensure access to a defined set of pharmacy services, regardless of care settings where patients receive hospice services. Of course, we recognize that the standard would also need to be consistent with the SNF and hospital COP so that providing care under arrangements would continue to be feasible.

2. PATIENT RIGHTS

ISSUE 1: Hospice care is patient centered. This means that providers seek to treat patients with respect and dignity and with the highest regard for personal choices. In many non-hospice care settings, both the Congress and CMS have given voice to a patient's right of self-determination by providing clear patients' or residents' rights provisions in the COPS. As proposed, the hospice COPS clearly require hospices to provide the patient with notice of rights, and clearly provide that the patient has a right to exercise his or her rights as a patient of the hospice, but there is no clear, comprehensive enumeration of what those rights are.

RECOMMENDATION: To promote consistency and clarity, we strongly recommend that CMS enumerate the rights of hospice patients. Specifically, rights that should be specifically enumerated include: (1) the right of each hospice patient to be fully informed about palliative care and treatment options, to make informed decisions, and to participate in care and treatment planning, and (2) the right of each patient to refuse care or treatment.

RATIONALE: Federal COPS for hospitals, nursing facilities, home health, and ICF/MR all provide a clear statement of rights that include the rights of a patient/resident to be informed about treatment of options, to participate in care planning, and to refuse treatment. These core civil rights are no less important in the hospice environment where patients receive end-of-life care.

ISSUE 2. Information regarding medication disposal policies – Proposed 42 C.F.R. § 418.52 provides that "[t]he hospice must provide the patient or representative with verbal and written notice of the patient's rights and responsibilities…during the initial evaluation visit in advance of furnishing care" and that "[t]he hospice must inform the patient and family of the hospice's medication policies and procedures, including the policies and procedures regarding the tracking and disposing of controlled substances." 42 C.F.R. § 418.106 (b) requires that the hospice's policies regarding the use and disposal of controlled substances must be discussed with the patient and the patient's family during the initial hospice assessment."

RECOMMENDATION: If it is CMS's intent that the hospice provide the patient and family with information about disposal of controlled substances *during the initial evaluation visit prior to*

furnishing care, then we recommend that this requirement be modified to require hospices to provide *written* information about the disposal of controlled substances during the initial evaluation visit and *discuss* these polices and procedures during the four day assessment period following hospice enrollment.

RATIONALE: We fully support policies and procedures to reduce, and hopefully, eliminate the potential for diversion of controlled substances in the community. However, we believe that patient and family understanding of and compliance with policies for medication disposal that will generally take place at the time of the patient's death is more likely if they are approached when the issue has direct relevance. This change in regulatory language will reduce the burden of information assimilation during a highly stressful time (i.e., when the patient and family are hearing about hospice care for the first time). Our position is consistent with and fully supports the position of the National Hospice and Palliative Care Organization (NHPCO).

ISSUE 3 - Right to Pain Management, 42 C.F.R. § 418.52(c), provides that "[t]he patient has the right to receive effective pain management and symptom control from the hospice."

RECOMMENDATION: To ensure that this right can be realized, specific language addressing medication therapy must be incorporated into the standards for assessment and care planning processes, and in the quality assurance/performance improvement standards. We refer you to our comments pertaining to the following sections:

1) Comprehensive Assessment of the Patient [42 C.F.R. § 418.54 (c)(1)(ii)];
2) Interdisciplinary Group Care Planning and Coordination of Services [42 C.F.R. § 418.56 (c)(1)];
3) Quality Assessment and Performance Improvement [42 C.F.R. § 418.58 (a)(1)];

RATIONALE: While we emphatically support the patient's right to timely and effective pain management, that right cannot be realized if the COPS that address care planning, assessment, treatment, and quality assurance fail to clearly incorporate standards regarding the assessment, monitoring, and active management of medication therapies to address pain and symptom control. Medication therapy is a key component of pain management and symptom control. *Effective* pain management and symptom control at the end of life requires thorough evaluation and assessment of the patient's medical condition, history, and response to therapy. Specific reference to medication therapy should, therefore, be incorporated into the standards for assessment, care planning, and treatment. *Effective* pain management and symptom relief also requires the specialized knowledge and expertise of pharmacists with experience in end-of-life care. While consultant pharmacy is required for inpatient hospice settings, we are recommending that medication management care planning by a pharmacist be carried over into all hospice patient care settings, regardless of venue. Finally, to promote compliance with the hospice patient's right to effective pain management and symptom control, we are recommending that pain management be included as an integral element within the standards for quality assurance and quality improvement programs.

3. COMPREHENSIVE ASSESSMENT OF THE PATIENT.

ISSUE: We agree that "[t]he hospice must conduct and document in writing a patient-specific comprehensive assessment that identifies the patient's need for hospice care and services, and the patient's need for medical, nursing, psychosocial, emotional and spiritual care. This care includes, but is not limited to, the palliation and management of the terminal illness and related medical conditions." However, this standard does not go far enough to identify the elements needed to assess medication therapies, a critical aspect of modern hospice treatment.

RECOMMENDATION: We recommend that this requirement be expanded to include a **thorough assessment** of the patient's prior, current, and ongoing pharmacotherapy or medication care plan. Specifically, we recommend that proposed 42 C.F.R. § 418.54(c)(1)(ii) be amended to include the critical elements of medication therapy management. The CMS proposed language and our proposed amendments are depicted in the following table.

Comprehensive Assessment 42 C.F.R § 418.54 (c) (1)(ii)	
CMS proposed language (May 27, 2005)	**excelleRx's recommended revisions**
(ii) *Drug therapy*. A review of the patient's prescription and over-the-counter drug profile, including but not limited to identification of the following – (A) Ineffective drug therapy; (B) Unwanted drug side and toxic effects; and (C) Drug interactions.	(ii) ***Medication therapy***. A **thorough** review **and assessment** of the patient's prescription and over-the-counter **medication** profile, including but not limited to identification of the following – (A) Ineffective **medication** therapy; (B) **Medication therapy deemed unnecessary and/or not consistent with the patient's goals of therapy;** (C) **Medication therapy requiring dosage optimization;** (D) **Therapy that is inappropriate according to evidence-based guidelines;** (E) **Duplicate medication therapy;** (F) **Missing medication therapy necessary to prevent or address a symptom experienced by the patient;** (G) **Medication therapy requiring laboratory monitoring and evidence that the monitoring is being performed (e.g., warfarin and INR);** (H) Unwanted **medication** side and toxic effects; and (I) **Actual or potential medication** interactions.

RATIONALE: Medication-related problems (MRP) are significant in the hospice population, possibly leading to increased morbidity, decreased quality of life, unnecessary hospitalization, and even premature death. In March of 2005, we examined the prevalence of medication-related problems in a sample of 250 hospice patients (excelleRx, Inc.; company data on file). We found that 37% of patients

had been prescribed at least one inappropriate therapy (potential for drug-disease interaction; drug-drug interaction, drug-age interaction, or the medication was not the best choice for other clinical reasons); 30% had one or more indications for therapy without appropriate therapy prescribed; 32% of patients required dose adjustments (prescribed dose was too high or too low); 10% exhibited potential or actual adverse drug reaction; and 5% were receiving a medication with no discernable indication. Based upon our experience in hospice care, we believe that the above eight elements of medication therapy assessment represent the minimum standard that should be applied in the hospice setting to assure the safety and efficacy of medication therapy.

4. INTERDISCIPLINARY GROUP CARE PLANNING AND COORDINATION OF SERVICES

ISSUE 1. – Composition of the interdisciplinary group. The proposed rule at 42 C.F.R § 418.56 omits mention of the important role played by pharmacists in the care planning and coordination process.

RECOMMENDATION: While we are not recommending that the COPs *require* that a pharmacist is included in the interdisciplinary group, we strongly recommend that CMS urge hospices to include in their care planning process a pharmacist who can provide expert medication therapy management in palliative pharmacotherapy.

RATIONALE: As new pharmacotherapy options have become available during the past two decades, hospice clinicians have been challenged to stay abreast of new developments along with myriad other changes in the industry, including applied pharmacogenomics. Pharmacists are a logical and necessary addition to the hospice interdisciplinary team. While pharmacists are not mentioned in the statute pertaining to hospice services, neither is the spiritual counselor, another cornerstone of comprehensive hospice care. CMS has the authority to recognize necessary participation of additional professionals on the hospice interdisciplinary team who will improve patient outcomes. Because of the importance and complexity of appropriate medication care plans in achieving positive outcomes, it is vital to integrate a pharmacist onto the IDG so as to provide pharmaceutical consultative services early in the process, before treatment regimens are finalized.

ISSUE 2. – Plan of Care. We support CMS language in 42 C.F.R § 418.56(c) that "the hospice must develop a written plan of care for each patient that reflects prescribed interventions based on the problems identified in the initial comprehensive and updated comprehensive assessments, and other assessments." As noted below, we recommend specific language change regarding required elements of the care plan.

RECOMMENDATION: The CMS proposed language and our proposed amendments to 42 C.F.R. § 418.56(c)(1) are depicted in the following table.

Interdisciplinary Group Care Planning and Coordination of Services 42 C.F.R. § 418.56(c)(1)	
CMS proposed language (May 27, 2005)	**excelleRx's recommended revisions**
(c)...The plan of care must include, but not be limited to – (1) Interventions to facilitate the management of pain and symptoms.	(c)...The plan of care must include, but not be limited to – (1) Medications **and non-pharmacologic** interventions **necessary for effective pain** management **and symptom relief.**

RATIONALE: This change is consistent with our recommendations to strengthen and clarify care planning requirements to address medication issues, to ensure consistency with the patient's right to effective pain management and symptom relief, and to ensure access to high quality pharmaceutical services for all hospice patients regardless of care setting.

5. QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT (QAPI)

ISSUE: As advocates of evidence-based clinical care, we fully support CMS's expansion of the hospice conditions to include a quality assessment and performance improvement focus. However, we do not believe CMS has gone far enough to identify required elements of an effective QA program.

RECOMMENDATION: We are recommending that hospice track data around certain core elements related to medication therapy and outcomes of that therapy. Specifically, 42 CFR § 418.58 (a) should be amended to read as depicted in the following table.

QAPI 42 CFR § 418.58 (a)	
CMS proposed language (May 27, 2005)	**excelleRx's recommended revisions**
(1) The program must be at least capable of showing measurable improvement in indicators for which there is evidence that improvement in those indicators will improve palliative outcomes and end-of-life support services. (2) The hospice must measure, analyze, and track quality indicators and other aspects of performance that enable the hospice to assess processes of care, hospice services and operations.	(1) The program must be at least capable of showing measurable improvement in indicators for which there is evidence that improvement in those indicators will improve palliative outcomes and end-of-life support services **including, but not limited to, pain relief, and adverse patient events, including adverse medication events such as avoidable medication-related hospitalizations.** (2) The hospice must measure, analyze, and track **such** quality indicators and other aspects of performance that enable the hospice to assess processes of care, hospice services and operations.

RATIONALE: Our recommendation promotes compliance with the patient's right to effective pain management and symptom relief and is consistent with promoting a single, consistent standard for pharmaceutical care across all hospice care settings. Pain relief is recognized within the industry as one of the key measures related to symptom outcomes. While we believe that CMS should require hospices to track pain relief, hospices should have flexibility in choosing the methodology. As one methodology to achieve that standard, we support the CMS *recommendation* that hospices adopt the NHPCO End Result Outcomes measures. Secondly, we believe that hospices should track adverse patient and medication events. Hospice patients as a group are uniquely vulnerable to medication related problems (MRPs) and adverse medication events (also known as adverse drug events, or ADEs), secondary to medication therapies on the one hand, and under-treatment of symptoms that leads to prolongation of unnecessary suffering on the other. With our hospice partners, we have developed and deployed short, easily administered questions and data collection strategies to document patient self-reported outcomes: the gold standard for symptom and quality-of-life assessment. These strategies are being used today to track outcomes for over 50,000 hospice patients per month. By tracking **adverse patient events, including adverse medication events**, we have significantly enhanced patient outcomes, such as time to palliation, and reduced adverse outcomes that can lead to increased suffering and higher costs.

ISSUE 2: The term "adverse patient event" is not defined.

RECOMMENDATION: 42 C.F.R. § 418.3 *Definitions* should be *amended* to include the following definitions:

> *Adverse patient event* means an unanticipated, non-therapeutic response or injury including an adverse medication event.
>
> *Adverse medication event* means a patient injury or avoidable medical intervention resulting from medication therapy

6. CLINICAL RECORDS

ISSUE: In the preamble to the proposed rule, CMS requests comments on the following:

> 1) What are the components of an electronic health record (EHR)? What are the advantages or disadvantages of using EHR in a hospice setting?
> (2) Should an EHR include a personal health record, which is accessible to the patient? What are the positive and negative consequences of personal health records?
> (3) What are the barriers (technical and clinical) to implementing an EHR system in hospice?

CMS expressed interest in knowing about hospice experience thus far and how EHRs have impacted patient care and outcomes.

RESPONSE: excelleRx has developed and has been using an electronic medication record for every hospice patient we have served since 2001. Currently we have over 45 million patient-days worth of data including demographic, diagnosis, pharmacotherapy, and clinical outcomes. These data enable us to both ensure the most appropriate care for individual patients and to track their progress longitudinally. We also mine this data to generate clinical insights and make our Medication Use

Guidelines more robust. All patient records are available via a secure Internet-based platform to our client hospices. excelleRx has also had success in interfacing with other clinical software providers so that clinicians can share data needed to treat and manage the patients we serve. The push for EHR within Medicare is encouraging and consistent with the general direction of the healthcare industry.

In our experience, electronic medication records enable us to reduce errors; provide multiple access points for both data entry and information retrieval (Internet, interactive voice response (IVR) and fax scanning); collect, analyze, and report data at both the patient level and macro-level more easily and cost-effectively; conveniently access records regardless of time or place; and reduce clinical time required for documentation and research.

At the same time, some of the challenges associated with using electronic health records include a cost burden to hospices and access to the data online being constrained by the bandwidth available to the user.

7. SECLUSION AND RESTRAINT

ISSUE: We appreciate that CMS has addressed the critically important issues of seclusion and restraint in the revised COPs. However, we are concerned that the requirements set forth reflect insufficient consideration of the unique patient care issues that are present in hospice care.

RECOMMENDATION: CMS should convene a task force of experts to examine the issues around chemical restraint in end of life care and provide evidence and consensus-based recommendations to CMS. Given our expertise and experience with the administration and management of medications, including opioid analgesics, in hospice care, we would welcome the opportunity to participate on such a Task Force. We further recommend that guiding principles for this work group should include:

(1) The appropriate selection, use, monitoring, and titration of psychotropic medications to manage symptoms in terminally ill patients should be based on clinical assessment;
(2) Response to therapies must be monitored and adjustments based on clinical assessment;
(3) Criteria should be established for use of palliative sedation for those patients with such severe end-of-life symptoms that conventional interventions (pharmacologic and/or non-pharmacologic) have been exhausted and documented such by the palliative care team.

RATIONALE: Hospice patients are unique in several important ways. First, their illness trajectory is such that, even with optimal symptom management, their symptoms are likely to progress as they approach the end of life. Medications such as opioids and psychotropic medications that might be inappropriately applied to restrict patients' movement or manage their behavior in other settings are regularly and ***appropriately applied, often in escalating doses***, to manage symptoms and increase patient comfort as the end of life approaches. We believe that the proposed regulatory language, including the definition of a medication restraint, does not reflect a sufficient understanding of the appropriate use of sedating and analgesic medications in the hospice setting. We are gravely concerned that if these regulations are finalized, they will negatively impact on patient comfort, increasing their suffering when they are most vulnerable and most dependent on their professional caregivers to ease their pain and symptoms so that they can die comfortably. The proposed regulation will act as a deterrent to appropriate symptom management in much greater proportion to any reduction in

inappropriate patient restraint, as clinicians will hesitate to use medications that have become a mainstay of palliative pharmacotherapy in doses necessary to relieve treatable symptoms.

We believe, therefore, that it is premature to adopt regulatory language that has the risk of increasing patient suffering at the end of life without evidence of a problem that needs improvement. Given the critical role that medications play in pain relief and symptom management in hospice, CMS should await recommendations of an expert Task Force before finalizing these regulations. We understand that CMS has used similar approaches when developing restraint regulations for other care settings such as residential psychiatric settings and nursing homes. Further, we believe that with the recommendations made herein to assure that a pharmacist is involved in the medication care planning process, including the monitoring of adverse events, the risk of an inappropriate therapy for use as a 'restraint' is minimized.

We thank you again for the opportunity to provide you with comments on the proposed hospice COPS. We welcome the opportunity to engage in further discussion and to work collaboratively with CMS to resolve outstanding issues.

Sincerely,

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

Dear Dr. McClellan:

On behalf of the Providence Health System, I want to thank you for the opportunity to provide our comments on the changes proposed by the Centers for Medicare and Medicaid Services (CMS) to the Conditions of Participation for hospice agencies that are certified to provide Medicare or Medicaid services. CMS published these changes as part of its Notice of Proposed Rule Making in the Federal Register on May 27, 2005. The Providence Health System is a faith-based, non-profit health system that operates eight certified hospice agencies in Washington State, Oregon, and California along with hospitals, physician groups, home health agencies, assisted living, senior housing, PACE programs, and a health plan. In 2005 the Providence Health System provided 895,392 hospice and home health visits.

As a Catholic health care system striving to meet the health needs of people as they journey through life, Providence is committed to improving the quality of life for those it serves – including the experience of dying for terminally ill patients. Providence has a longstanding history of providing supportive care to the terminally ill and their families that predates the Medicare program's coverage of hospice as a benefit. For example, Providence Hospice of Seattle is the Northwest's oldest hospice agency having just celebrated its thirtieth year of service and one of Providence's hospice agencies in Portland was among the initial 26 demonstration sites chosen by the Health Care Financing Administration in 1979 to assess the cost effectiveness of hospice care and to help determine what a hospice care should include as a benefit under the Medicare program. As a result of these and similar efforts Providence has been recognized nationally as a leader in hospice care. In 2003 Providence was a recipient of the prestigious Circle of Life Award for its innovative programs in palliative and end-of-life care and Providence is a founding member of "Supportive Care of the Dying: A Coalition

for Compassionate Care;" an organization that has greatly contributed to improved understanding of how best to meet the needs of the terminally ill. It is with this perspective and understanding that Providence provides its comments and recommendations to CMS on the proposed rule.

Before commenting on specific issues, Providence would like to commend CMS for its proposal. While many of the proposed regulations are consistent with current and emerging standards of practice – particularly for those agencies operated by Providence and others that are already accredited by the Community Health Accreditation Program [CHAP] or the Joint Commission for the Accreditation of Healthcare Organizations [JCAHO] – the proposal is a marked improvement over the existing regulatory text and framework. However, because these rules provide the minimum standards for *all* certified hospice agencies Providence believes that the standard of care being advanced in this proposal is worthy of adoption after due consideration of comments that are submitted as part of this rulemaking process. Particularly noteworthy are the provisions that recognize the importance of patient rights (42 CFR §418.52) and the "cycle of care" framework that facilitates continuous integration of the patient assessment, care planning, care delivery, and care evaluation processes (42 CFR §418.54, 418.56, and 418.58).

Once final rules are adopted Providence would note that it is equally important for CMS to modify its survey processes (along with obvious modifications to the interpretative guidelines) to reflect these changes and the expressed regulatory philosophy that underlies the entire proposal: The survey process can either facilitate or frustrate the ability of CMS to achieve its articulated vision of a "patient and family centric" regulatory policy that stresses actual patient outcomes; ***especially if the agency intends to achieve these worthy goals while facilitating "flexibility in how a hospice meets performance expectations."*** Providence is committed to further working with your agency to accomplish this end. However, notwithstanding its overall assessment and support of the direction set forth by CMS, there are a number of areas where Providence believes changes or clarification would serve to improve the proposed revisions. These changes are discussed in the text that follows.

42 CFR §418.52 Patient's Rights

As noted previously, as an organization with a core value of respect Providence agrees that each patient has the right to be informed of their rights and that the hospice must protect and promote the exercise of these rights. With regard to the provision in 42 CFR § 418.52(a) ["Notice of Rights"] Providence believes that the following two clarifications will make the regulatory expectations more coherent:

- As written, the text in 42 CFR § 418.52(a)(1) requires that in addition to receiving verbal notice of their rights each beneficiary has a right to receive *a written copy in a language that the patient understands*. Taken literally, this albeit well-intentioned provision goes beyond the requirements established by the Office of Civil Rights for services provided to those with limited English proficiency and would impose significant cost burdens on many agencies serving a disparate

The regulations found in 42 CFR § 418.52(b) [Exercise of Rights and Respect for Property and Person"] set forth a number of explicit rights for individuals receiving hospice services and create corresponding obligations incumbent upon an agency to respect those rights. While we can find no fault with the proposed text enumerating the rights, Providence is concerned that the language in subsections 42 CFR § 418.52(b)(4)(ii) and (iii) could erroneously suggest that it is within the ability and the responsibility of the agency to immediately investigate and take corrective action in every situation where an alleged violation of rights has occurred. To be sure, hospice beneficiaries are often vulnerable and unable to fully protect their own rights. Thus, it is only reasonable to require that the agency at a minimum report even suspected violations as required by 42 CFR § 418.52(b)(4)(i). However, it has been the experience of our agencies that most situations involving mistreatment, neglect, abuse, and misappropriation of property described in the regulation are often perpetrated by a family member or authorized patient representative. In such cases, beyond establishing the affirmative obligation for an agency to report these concerns to (more) appropriate

investigative agencies, there are very real limits as to what a hospice can do in these situations: Often they are first observed by a home health aide or homemaker aide in the patient's home where the alleged perpetrator is present and there are concerns about the safety of the patient and caregiver alike. Because of the prevalence of these type of fact situations **Providence believes the final regulations must take these instances into consideration and not impose an obligation upon a hospice beyond that of reporting found in 42 CFR § 418.52(b)(4)(i). Of course, distinctions can obviously be made for those unfortunate situations where the individual who may have been involved in violating the rights of a patient is an employee of the agency or acting under arrangement with the hospice.** In these circumstances the additional responsibilities of the agency enumerated in the proposed text are clearly appropriate. We would further note that this recommended approach is consistent with the regulatory expectations of a home health agency under 42 CFR § 484.10(b)(5).

42 CFR §418.54 Comprehensive Assessment

As the first step in the cycle of care a hospice must conduct and document in writing a patient-specific comprehensive assessment that identifies the patient's need for hospice care and services, and the patient's need for medical, nursing, psychosocial, emotional, and spiritual care. This care includes, but is not limited to, the palliation and management of the terminal illness and related medical conditions. The comprehensive assessment is continuously updated and is a critical element that provides the foundation for subsequent care planning, care delivery, and care evaluation processes. As noted previously, Providence is extremely supportive of this overall Condition.

Subsection 42 CFR § 418.54(a) further requires that a registered nurse must make an initial visit within 24 hours of receiving a physician's order for care as part of an "Initial Assessment." Providence would offer the following comments concerning this specific requirement:

- It has been our experience that **the primary presenting needs of the patient should govern the choice of a specific discipline to make this initial visit.** For example, it may be that the most important issue needing resolution is the choice of a residence for the patient. In these cases an initial visit conducted by a social worker may be more responsive to the immediate needs of the patient than a visit conducted by a registered nurse as the proposal is currently drafted. The regulatory text should be amended to permit this flexibility. Of course, the requirements concerning the comprehensive assessment appropriately recognizes the interdisciplinary nature of hospice care planning and delivery.
- **Providence would recommend that the reference to a "physician's admission order for care" as the event that initiates the initial assessment be clarified.** As Providence's administrative and clinical leadership for hospice care reviewed this text it was *presumed* that this order was referencing the physician's certification of the patient's terminally ill status. In any event, given the important time-sensitive actions which are triggered by this event a more appropriate description should be incorporated into the final regulation.

- Finally, as drafted the initial assessment visit must be completed within 24 hours of receiving this order unless ordered otherwise by the physician. Providence supports a requirement for a timely and effective response and the 24-hour standard is appropriate in most circumstances. However, **Providence would recommend that another exception be added to this standard to take into account those situations where additional time is requested by the patient or their Representative.** Often these types of visits are delayed at the patient's request because the patient wants their family to be present. As CMS appropriately moves to create a more patient and family-centric approach to its regulations, this is but one example of where the typical regulatory approach of a single hard and fast standard needs to accommodate the preferences of the patient and their family in order to not frustrate these essential relationships.

Subsection 42 CFR § 418.54(b) establishes the time frame for completion of the comprehensive assessment. As drafted, this assessment must be completed by the hospice interdisciplinary group – in consultation with the patient's attending physician - within four calendar days of when the patient elected the hospice benefit. While the completion of the comprehensive assessment is a key element in the cycle of care and it would be highly desirable to complete it within the proposed time frame. However, notwithstanding our commitment to providing care twenty-four hours a day, seven days a week it is our experience that the proposed four-day requirement is unrealistic. **Providence recommends that a more appropriate standard of seven days be established.** This is especially important for the first comprehensive assessment as it is more important to get a thorough assessment completed rather than a fast one. Providence would note that the first five-day assessment required by Medicare for patients in a Part A stay can extend up to day eight using the concept of "grace days." While Providence is certainly not arguing for an extension of the regulatory framework for skilled nursing facilities to hospice care, this notion of "grace days" may provide a helpful approach to the regulatory requirements for completing the first comprehensive assessment for hospice patients.

While Providence fully supports the continued involvement of the patient's attending physician in the patient's ongoing hospice care unfortunately that is often not the case. For example, many patients first elect the hospice benefit after deciding not to pursue chemotherapy or participate in a clinical trial recommended by their attending physician who is a medical oncologist. Once the hospice benefit is elected the physician may in turn elect not to follow the patient. However, this very common situation appears not to be permitted by subsection 42 CFR § 418.54(b): That text requires the comprehensive assessment to be completed in consultation with the attending physician. It is impractical for CMS to hold the hospice accountable for the performance of the attending physician in these situations. Consequently, **Providence would recommend that the text be changed to require that the hospice seek to promote the continued involvement of the patient's attending physician in the completion of the comprehensive assessment as evidenced by the physician's written approval of the assessment. In situations where this level of involvement is not forthcoming the hospice should document its**

efforts to engage the physician in the patient's assessment. Providence will discuss similar concerns with respect to the language set forth in 42 CFR § 418.56(a).

42 CFR §418.56 Interdisciplinary Group Care Planning and Coordination

As proposed, this Condition would require that the hospice designate an interdisciplinary group which, in consultation with the patient's attending physician, must prepare a written plan of care for each patient. The plan of care must specify the hospice care and services necessary to meet the patient and family-specific needs identified in the comprehensive assessment as it relates to the terminal illness and related conditions. Subsection 42 CFR § 418.56(a) establishes the interdisciplinary approach to service delivery that has been a longstanding characteristic of hospice care. We would particularly commend the agency for its recognition of the need for an increased emphasis on the coordination of care, the continuous assessment of the patient and family's needs, and for ongoing evaluation of the implementation of the care plan. These efforts will be greatly enhanced by the provision calling for the appointment of a licensed health care professional who is designated by the interdisciplinary team as being responsible for these activities. Many of our agencies have had found that their comparable case management models have been an important element to achieving these outcomes.

In describing the composition of the interdisciplinary team charged with the development of the patient's plan of care, the proposed regulation states that the physician serving on that group - typically the hospice medical director - cannot be the patient's attending physician. However, for the reasons noted in our commentary at 42 CFR § 418.54(b), the medical director often becomes the default attending physician for the patient. Consequently, the prohibition proposed in 42 CFR § 418.56(a)(i) will complicate the hospice's ability to engage even their own medical director to serve on the interdisciplinary team. If CMS accepts the revised language Providence recommends in 42 CFR § 418.54(b) and the hospice agency is able to secure the continued engagement of the patient's attending physician then this issue will become moot. However, in the more likely scenario that the hospice medical director becomes the default attending physician for the patient then the prohibition is unworkable. For these reasons **Providence recommends that the phrase "who is not the patient's attending physician" found at 42 CFR § 418.56(a)(i) be deleted.**

In advancing this recommendation Providence would stress that such an outcome is not at odds with the best interests of the patient. Fortunately, many physicians are beginning to recognize the special skills and knowledge held by a doctor who is credentialed in palliative care. Consequently they acknowledge that it is often in the best interest of a patient to be seen by the medical director/attending physician who specializes in this type of care; much in the way a primary care physician appropriately refers a patient with significant cardiac issues to a cardiologist. At the very minimum the regulation should be

amended to at least allow the patient to elect to have the hospice medical director serving on the interdisciplinary group also serve as their attending physician.

Section 42 CFR § 418.56(b) also states that the plan of care must be developed in consultation with the patient's attending physician. Again, as desirable as that standard may sound the proposal is often not workable. Quite frankly, it is Providence's experience that increasingly many physicians are unwilling to see any Medicare patients, much less a patient with the complex medical management needs typical of most hospice beneficiaries. **Providence would recommend that the language already proposed in 42 CFR § 418.56(d) requiring the collaboration of the attending physician in the updating of the care plan only "to the extent possible" be incorporated into the text at 42 CFR § 418.56(b).**

As noted previously, Providence supports a patient-specific comprehensive assessment that identifies the patient's need for hospice care and services, and the patient's need for medical, nursing, psychosocial, emotional, and spiritual care; including care *that is not limited to the palliation and management of the terminal illness and related medical conditions*. A comprehensive assessment should not be narrowly construed. However, the language found in section 42 CFR § 418.56(c) states that the written plan of care must be based upon the problems identified in the comprehensive assessments. As written, the language could have the unintended consequence of broadening the responsibility of the hospice to engage in comprehensive care planning far beyond the condition that gave rise to the patient's decision to elect the benefit. The practical effect of such an interpretation would be to expand the scope of services that a hospice is obligated to provide and even run counter to the longstanding tradition and care philosophy that hospice represents. For these reasons it is essential that clarifying language be added. **Providence would recommend that CMS make explicit in the final rule that while the comprehensive assessment should identify the totality of the patient's and family's needs, the interdisciplinary care plan is not required to address all of these issues but rather focus on those interventions necessary to facilitate the management of pain and symptoms related to the palliation and management of the patient's terminal illness and related medical conditions.**

42 CFR §418.58 Quality Assessment and Performance Improvement

Before offering its comments Providence would note that this area is worthy of commendation as it represents a significant improvement over the current regulations found at 42 CFR §418.66. For agencies that are accredited these new elements are nearly identical to the standards of practice mandated by these accreditation organizations. However, it is worth noting that an unaccredited agency will not be able to demonstrate compliance with a typical effective date of 60 days following publication of the final rule in the Federal Register. **Consequently, without delaying the implementation of these improvements unnecessarily, if CMS elects to move quickly in adopting the proposed regulatory framework at 42 CFR §418.58 then Providence would**

recommend an implementation approach for this specific section that provides additional time for the effective date of this requirement.

Furthermore, as drafted 42 CFR §418.58(a)(2) mandates the tracking of "adverse patient events". Providence fully supports the tracking of certain significant negative events but would note that the inclusion of the word "adverse" may in fact cause unintended confusion. As CMS is well aware that phrase has a specific and well-defined meaning when used by the CHAP program just in the same way that JCAHO has reserved the use of the phrase "sentinel events." Rather than use either term **Providence would recommend that CMS borrow heavily from these definitions and establish a clear threshold delineating the types of events that require special tracking and consideration.**

42 CFR §418.102 Medial Director

Overall responsibility for the direction of the Quality Assessment and Performance Improvement [QAPI] program is affixed with the hospice medical director under language proposed in section (c) of 42 CFR §418.102. **Providence finds no fault with creating a standard requiring the "active involvement" of the medical director in this program but cannot support a mandate that they actually be responsible for directing it.**

In offering this comment Providence would note that oversight and responsibility for ensuring that the QAPI program reflects the complexity of patients served and scope of the services provided by the hospice is properly established at the governance level (see the statement of the Condition at 42 CFR §418.58). Specifying that the program direction must be placed with the medical director may actually distort this intended scope and focus of the QAPI program by reflecting a more medical orientation. **Providence believes that responsibility for direction of the QAPI program should more appropriately be assigned to the interdisciplinary group as this body is more aligned with the desired approach for the QAPI program and can have the greatest impact on actual patient outcomes.**

42 CFR §418.104 Clinical Records

Section (e) of 42 CFR §418.104 requires that a hospice provide a copy of the patient's clinical record and the discharge summary (plan of care, physician orders, any other relevant information to assist in continuity of care) to a facility where the patient is transferred and to the attending physician if the patient revokes their election. Providence has a longstanding commitment to furthering a vision of a continuum of care within the delivery and even financing of health care services. Rather than treating each patient's discharge as an end to our responsibility, we view these events more appropriately as transitions in an ongoing process of care. The benefits of this approach are perhaps best demonstrated in our two PACE programs. Notwithstanding this orientation, we believe that the documentation to be provided to the new provider is excessive in most cases. Instead **Providence would recommend that the hospice be obliged to provide to those**

who need to know for treatment purposes, only that relevant clinical information necessary to promote ongoing continuity of care in a safe and effective manner for the patient.

42 CFR §418.106 Drugs, Controlled Drugs and Biologicals, Medical Supplies, and Durable Medical Equipment

Section (b) of 42 CFR §418.106 requires a hospice to track, collect, and dispose of controlled medications in the home. Further text in the regulatory preamble states that the hospice retains primary responsibility for these controls. While no one can argue with the desirability of maintaining appropriate controls over these medications – especially in the case of controlled substances – there are very real limits to the hospice's ability to control for all of these issues when (1) the medications are owned by the patient and (2) they are most often stored and administered by others in the patient's home environment. The hospice has no standing to track and often we are not able to collect unused medications: While the hospice can and should advise patients and their families on safe disposal there is often no effective way to enforce or monitor this expectation. Obviously this is not to assert that a hospice should not be otherwise responsible for monitoring the patient's medication regimen and Providence has even had to discharge patients from its care when the patient or their family member are knowingly diverting these medications. However, **the current regulatory language found at 42 CFR §418.96(b) ["Controlled Drugs in the Patient's Home"] should be retained in lieu of the proposed text as it represents a more realistic appraisal of what can be expected of the hospice: The hospice should have a policy and notify the patient and the family of their rights and responsibilities under it.**

Finally, Providence would express a concern with the language contained in 42 CFR §418.106(b) concerning the uses and dangers of controlled substances. The comments that follow should not be construed as anything less than a complete appreciation for the importance of informed consent. However, hospices have often struggled to overcome the misconceptions concerning the appropriate role of these medications in the management of pain and other symptoms related to the patient's terminal illness. **Providence would encourage some modification to the text that would acknowledge these pre-existing concerns while recognizing that a proper discussion of these issues would of necessity speak to the beneficial effects of these medications in addressing the needs of the patient and family identified in the comprehensive assessment.** Otherwise the effect of the text as proposed along with the discussion of this issue in the preamble may be to create an unintended barrier for the patient's effective symptom and pain management.

Another area where **this approach should also be incorporated is in the discussion of "drug restraints" as they are defined in 42 CFR 418.3.** As CMS is well aware, hospices quite often appropriately utilize psychotropic medications for the symptom relief of terminal agitation rather than a presenting psychiatric condition. The use of these medications is palliative in nature and not intended as a restraint, yet the regulation

as drafted has incorporated a litany of requirements based upon the presumption of restraint as its intended use. To lose access to these effective interventions - the probable end result – would be a disservice to the patients who could knowingly benefit from this use. This outcome is most likely if the patient is in a facility as that organization will want to avoid the potential liability associated with the use of "drug restraint"' especially given the negative connotations associated with such measures and the real resource requirements to meet the stated standards.

CONCLUDING REMARKS

Notwithstanding the recommended changes noted above, Providence appreciates the efforts of CMS to improve these regulatory provisions and select an approach that fosters improved quality of care and quality of life for those patients electing the hospice benefit. In general, we urge CMS to move forward with many of the proposed changes as modified by the comments Providence has provided. Thank you again for the opportunity to comment on this proposal and for your thoughtful consideration of our remarks. If you have any questions, please contact Chuck Hawley, Vice President of Government Affairs, at (206) 464-4237 or via e-mail at chuck.hawley@providence.org.

Sincerely,

John Koster MD

John Koster, M.D.
President/CEO
Providence Health System

KAISER PERMANENTE®

Kaiser Foundation Health Plan, Inc.

July 25, 2005

Via: Overnight Mail

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

Re: Comments on Proposed Hospice Conditions of Participation
42 CFR Part 418
File Code CMS-3844-P

Dear CMS Hospice Staff:

Kaiser Foundation Hospitals, Inc. ("Kaiser") operates 14 hospices in California and one hospice in Oregon. As such, Kaiser is a key provider of hospice services and is profoundly invested in ensuring a high quality of care for hospice patients. Kaiser hereby submits a summary of its review of and comments on the proposed revisions to the Medicare hospice Conditions of Participation ("CoPs") to the Centers for Medicare & Medicaid Services ("CMS").

General Thoughts on Proposed Rules for Hospice COPs:

In general, Kaiser notes that the proposed revisions to the COPs fit well within the current hospice practice of JCAHO accredited programs. We are encouraged by CMS' emphasis on quality and outcomes for patient care, instead of focusing solely on monitoring of processes that may not result in improved quality of care. Also, we notice that the proposed regulations are moving towards implementing current standards imposed by the industry on itself or using home health agency standards as CMS' model for hospice. In some cases, the regulations propose the same standards as the home health COPs. However, in some cases, the proposed regulations unnecessarily exceed the home health requirements. We are in agreement with the basic philosophy, but believe that CMS must be realistic about the practical application and feasibility of some of these proposed requirements.

Kaiser also believes that the CMS estimates of time and cost to implement these new COPs are too low, especially the requirements under Comprehensive Assessment, QAPI and Care for Facility-Based Residents. These proposed regulations will have a significant financial impact on Hospice.

Comment #1: PATIENT'S RIGHTS – Section 418.52

Walnut Center
Pasadena, CA 91188

Standard (b) – Exercise of Rights and Respect for Property. This standard should include the patient's right to refuse treatment.

Standard (b)(4). The reporting rule for "alleged" violations of abuse seems excessive. This proposed regulation states that hospices must report all alleged violations to the state survey agency within 5 working days "of the incident." Kaiser notes that the timing of this requirement is vague, since the "incident" may have occurred long before it is actually reported to hospice staff. Kaiser further notes that it is unclear whether this requirement applies only to incidents involving hospice staff or whether it applies to any alleged abuse, etc., that may be reported that involves the patient's family or caregivers. Kaiser also notes that some of the alleged incidents are proven to be without basis through internal investigations. Kaiser believes it would be more appropriate to require the investigation of all alleged incidents and the reporting of actual, investigated, actionable violations to the survey agency. In addition, hospices should be required to comply with any other state reporting requirements for elder abuse, etc.

Comment #2: COMPREHENSIVE ASSESSMENT OF PATIENT.

Sections 418.54(a) and (b)

The proposed rule regarding the comprehensive assessment of the patient will drastically increase the administrative requirements of the hospice and set standards that are vague and unrealistic. The proposed rules require that the Initial Assessment be completed within 24 hours of care and that the Comprehensive Assessment be completed within four calendar days (not business days). The Comprehensive Assessment must be updated every 14 days.

The proposed hospice COPs for comprehensive assessment is unnecessarily more onerous that the similar COP for home health agencies. The Home Health COPs, Section 484.55, require an assessment to be completed every 60 days (rather than the 14 days proposed for hospice), or more frequently where there is a beneficiary elected transfer, a significant change in condition resulting in a change in the case-mix assignment, or a discharge and return to the same HHA during the 60-day episode. The initial home health assessment is required to be completed within 48 hours of referral (rather than the 24 hours for hospice) and the comprehensive home health assessment is required to be completed within five days (rather than the four days proposed for hospice). Agency professional staff is also required to promptly alert the physician to any changes that suggest a need to alter the plan of care.

Kaiser is confused with the vagueness and interpretation of the time periods and seeks clarification regarding the time frames as they will be used practically. For the initial assessment, 24 hours is too short a time frame. Many times the physician has ordered the hospice care, but the patient has not accepted the care and the physician has not completed the Certificate of Terminal Illness. It is unclear whether the hospice will be held to 24 hours from the date the physician faxed the order to the hospice, even though the patient has not accepted the order for hospice and/or the hospice has not accepted the patient for hospice care either. The hospice may not be able to be equipped to provide care to that patient and may not be able to accept that patient. As the proposed rules are currently worded, it is not clear when the clock starts ticking and, in any case, 24 hours is too short a time period to finalize this process. In addition, it is

important to note that often the patient and/or family do not wish to have a visit within 24 hours of the time the hospice receives the physician certificate of terminal illness or "order" for hospice services.

Kaiser recommends the following suggestions listed below:

Request for Change of Proposed Rule for Assessments

We agree that there should be timelines on the initial assessment, comprehensive assessment and updates of the comprehensive assessment. However, we do not agree with the timeframes suggested in the proposed rule. We would suggest that the time frames should mimic home health time frames or the standards of practice in the industry, which is longer than 24 hours. We ask to accommodate all the changes and nuances of starting care that the proposed rule for initial care is re-written to state:

a) "A registered nurse will make an initial assessment visit to determine the patient's immediate care and support needs within ~~24~~ **48** hours after the hospice has received the physicians order and the patient and family have signed on or accepted hospice service, or later, as requested by the patient/family or physician."

b) We also ask that the four calendar days to complete the comprehensive assessment be lengthened to seven days, as the Interdisciplinary Group (IDG) meet weekly and this will result in hospices being able to comply with this requirements.

c) We ask that the 14 day comprehensive assessment update be less frequent that every 14 days and be more in-line with the 60 day home health requirement. If the assessment update is required at the end of each certification period, then the assessment results will be more useful for recertification purposes. The rule should include that the assessment update can and should be done more frequently if the patients condition changes. We understand the urgency and more dynamic nature of a hospice patient's health, who is terminally ill, versus a patient under home health requires a more frequent update to care than 60 days. However, we want the patients' needs to be met and not spend unnecessary time and energy on just administrative paperwork. The IDG should be focused on meeting the plan of care needs should they change the rule should include references to require more frequent assessments when there are changes in the patients condition, including psychosocial, emotional, etc.

Comment #3: PLAN OF CARE or COORDINATION OF SERVICES
Section 418.56

Standard (b) Plan of Care – This proposed rule should be changed to clearly state that only one POC is required and that a separate POC is not required for the family.

Standard (C) Content of the plan of care – The proposed regulation should be changed to require that the hospice IDG must document patient and family understanding and involvement with the plan of care. The word **agreement** should be deleted.

During the NAHC Teleconference, Mary Rossi-Coajou and Danielle Shearer (from CMS) presented the concept of the Comprehensive assessment in ways that seemed to indicate it was a combination of Assessment and Plan of Care. This needs to be clarified for all aspects of compliance to the Assessment COP and the Medical Record COP. It is significant as it pertains to content of the POC, versus content of the assessment; the timeframes and the content requirements seem to overlap. Are they one in the same document? There were many questions relating to this, but the answers did not clarify the difference. For example, Section 418.54(e) states the comprehensive assessment must include the data elements. Section 418.56 states the content of the POC must include measurable outcomes, but no reference to the data elements. Section 418.104(a) states the content of the POC must include the data elements. It is unclear where CMS expects the data elements to be documented.

Standard (e)(4). Kaiser requests clarification of the type of "system" CMS is expecting for communication with outpatient settings/contract services. Would this be above and beyond the normal documentation of telephone communication and case conferences? The COP mandating the IDG review the patient care every 14 days would accomplish this. How does CMS expect to see compliance demonstrated to the requirement to have a "system?"

Comment #4: Quality Assessment Performance Improvement (QAPI) - Proposed: Section 418.58 [User Term in Comments: "QAPI"]

The regulation would require that a hospice to create a Quality Assessment Performance Improvement Program ("QAPI"), which include no specific data elements and no requirements for reporting to improve palliative care outcomes and access to end of life supportive services. The hospice is allowed develop their own data elements and measurement process as part of its quality assessment and performance improvement program or could use the suggested NHPCO measures and must focus on high risk, high volume problem areas and track adverse patient events, analyze their causes, and implement preventive actions that include feedback and learning and to demonstrate how staff contribute to the quality improvement program, and must performance improvement projects and to measure and document these projects. The hospice governing body would be responsible for the QAPI program and the specific requirements of monitoring the quality of care. Additionally, in a later part of the proposed rule, under Medical Director, 418.102, it requires the Medical Director or the physician designee to be responsible for the QAPI.

Kaiser has three concerns with the QAPI proposal as described above and in the rule and requests three changes to correspond to these concerns. The concerns are:

a) The future intent of the QAPI for a mandatory assessment tool;
b) The requirement of the Medical Director to be responsible for the AQPI.
c) The vagueness of the QAPI and the application to survey;

General Comment on the QAPI Proposal:

Kaiser extremely concerned about the eventual mandatory implementation of a tool like the Outcome Assessment Information Set (OASIS) for hospice. The OASIS tool has failed the

patient and home health by turning it into an academic tool that is largely unusable for home health care and is instead focused on "getting paid." In hospice, it will harm providers who take patients where they only will get to provide them 2-3 services and then death will result. It will bring down their scores and make it a disincentive to provide care to the very sick seeking hospice care at the end stages of life – which is what most hospice care is for non-home health agency hospices. Also, it is also unclear what would be considered an "adverse event" in Hospice. Without prescribing a defined element, this requirement seems difficult to monitor in a meaningful, consistent method across the industry.

Kaiser also has some concern that there is a requirement to create data sets and collect outcomes without a valid and reliable common set of measures in the industry. This is especially onerous considering the concept that CMS may require specific data measures in the future that may cause Hospices additional burdens of changing systems, documentation and processes to convert to a prescribed system, not mandated now. Kaiser requests that CMS either delete these proposed requirements or specifically define for the hospice industry the standards that CMS will require to measure outcomes-based performance.

Request for Change of Proposed Rule for QAPI:

1) Kaiser requests that CMS either delete these proposed requirements or specifically define for the hospice industry the standards that CMS will require to measure outcomes-based performance. We would ask that the proposed rule indicates that any future discussions of developing a set of measures will occur as a result of industry wide input to come up with outcome management program that is based on compassionate care (rather than developed in an academic setting such as Home Health's OASIS and OBQI) and will include provider stakeholders from across the nation and will outreach to state associations representing home health and hospice to enlist their membership to participate.

2) We would also request that the Medical Director or the physician designee not be responsible for the QAPI, as the proposed rule references in Section 418.102. The proposed rule charges the Hospice Governing Body with oversight. However, the reference to the Medical Director as the responsible entity is in conflict with the proposed rule in the QAPI Section, 418.58 (e), which states that the Governing Body is responsible. Additionally, it is in conflict with current COPs, Section 418.52, indicates: "A Hospice must have a governing body that assumes full legal responsibility for determining, implementing and monitoring policies governing the hospices' total operation. The governing body must designate an individual who is responsible for the day to day management of the hospice program. The governing body must also ensure that all services provided are consistent with accepted standards of practice." Therefore, we recommend that the proposed rules strike the reference to the Medical Director of the Hospice being responsible for the QAPI program, as the governing body will be responsible and, per current regulations, is allowed to select an individual to oversee the body. The hospice should have the option of having the Medical Director review it. However, it should not be required that the staff for this requirement be the Medical Director.

3) We would like to go on record regarding the vagueness of the QAPI program and the application to certification surveys. When an agency is surveyed, it should be written clearly in

the interpretive guidelines that surveyors use to probe that the Hospice should have to show their policy and procedures on the QAPI program, but that it is specific to the hospice, as the indicators are not set. The survey mechanism should be lenient and not stringent, as often occurs in surveys.

Standard (e) - Governing Body – We recommend referring to JCAHO Home Care Standards for Leadership 1.20 elements 1 through 7 in this regulation.

Comment #5: NON-CORE SERVICES – PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND SPEECH-LANGUAGE PATHOLOGY – Proposed Sections 418.72 and 418.74

Kaiser does not believe that it is necessary to have PT, OT and SLP services available on a 24 hour basis. Hospice patients seldom need rehabilitation services and when they are needed, these can be provided on a non-urgent basis. Common patient and family needs are instruction in use of mobility devices (e.g. use of walker) or in assisting with patient transfers. These are basic skills that nurses do or should have. It would be more practical to require that Hospices assure RN competency in these areas and availability of RN intervention in these areas 24 hours/day than to continue with the rehab service (PT, OT, and SLP). Kaiser requests that this standard be changed to waive this requirement for all hospices without requiring a waiver process.

We also recommend adding dieticians to this section as a non-core service

Comment #6: SUPERVISION OF HOME HEALTH AIDES - Proposed: Section 418.76 (h)

Under current Medicare hospice law, Section 418.94 (a) of the Conditions of Participation state, "A registered nurse must visit the home site at least every two weeks when aide services are being provided, and the visit must include an assessment of the aide services." The current hospice requirements do not include a joint visit. Current Medicare home health agency law requires a supervisory non-joint visit every 14 days for patients receiving skilled care and supervisory joint visits every 60 days if the services performed are provided to a person not receiving skilled care. Joint is only required for the skilled care when the home maker/home health aide is getting a performance evaluation.

The proposed rule would expand the rule to require a joint supervisory visit once a month. This would be an entirely new requirement that exceeds the home health joint visit requirement which is every 60 days and/or during performance evaluations.

The proposed rule would require Certified Home Health Aide providing care to a patient receiving no skilled services to be more frequent than 60 days.

*Important Note: The proposed rule background in the paragraph two of the third column on page 30852, indicates that the new 14 day requirement would relieve the requirement of a joint supervisory visit required in Section 484.36(d)(2). A joint visit is currently **not** a requirement for a CHHA. This is only a requirement if they are performing a performance evaluation of the*

CHHA. Therefore this is inaccurate. California Regulations, Title 22, Section 74709, (a) (2) provides even more detail of this federal law as it is modeled after it.

Under current Medicare home health agency law, home health aide supervision for patients receiving skilled care is required every 14 days and is **not a joint visit**, unless part of performance evaluation is occurring. Current law requires that beneficiaries receiving non-skilled care are required to have a joint supervised visit every 60 days.

Request for Change of Proposed Rule for Joint Visits every 28 days:
Current requirements for hospices are nurse visits every two weeks and assessment of the services, but are not joint visits. We agree with the logic that there should be a periodic joint visit, which is not required currently. However, we ask that the hospice COP for joint aide visits mirror the current Federal Home Health COPs, which require a joint visit every 60 days.

Additionally, we ask that CMS clarify that the supervision is not by a specific person, but may be performed by either a nurse or therapist (under the conditions in which they apply). The wording in the proposed regulation is vague regarding supervisor and infers that it can only be done by the aide's immediate supervisor. We would ask that it be clarified and re-worded to say that the supervision may be conducted by either a nurse (if patient is receiving skilled nursing care), or the appropriate therapist, if receiving another skilled service and that it is not required to be performed by a specific supervisor.

Comment #7: Section 418.64 - CORE SERVICES
Standard 418.64(d): Bereavement Services
We do not feel that the hospice should be responsible for services to the employees of a facility as part of our core services.

Comment #8: ORGANIZATION AND ADMINISTRATION - Section 418.100

Standard 418.100(f). The definition of "satellite locations" needs to be clarified. Does the definition include staffing locations or locations where staff pick up supplies and drop off paperwork?

Comment #9: Initial/Recertification Certification of Terminal Illness - Proposed: Section 418.102 – "MEDICAL DIRECTOR".

This proposed regulation would add new requirements for how physicians make decisions on terminal illness and require them to include more information to prove the six month terminal illness qualification and would require the medical director of physician designee to complete a clinical review and a written certification of terminal illness in order to begin hospice care (initial certification). Subsequent certifications would also require review of clinical and the patient and family's expectations and wishes for hospice care on an ongoing basis and before each updated assessment every 14 calendar days **and** at the time of recertification. The rule also makes the medical director of physician designee responsible for the hospice's quality assessment and performance improvement program (which we addressed in the QAPI section and will address below).

Our concerns in this section are as follows:

1) Certification and Recertification Content Requirements
2) Integration of Recertification Content Requirements into new Assessment requirements every 14 days
3) Medical Director or Physician Designee Responsibility for QAPI

General Comment: Current law, 418.22 (a) indicates what hospice personnel can certify the terminal illness, the time periods of certification, as well as the requirement for written certification "content" for terminal illness definitions to qualify for hospice care. The content requires that the prognosis for life expectancy must be 6 months or less. No other content is required to certify the terminal illness. Under the proposed rules, the Medical Director would have to review the clinical information and provide written certification. The proposed rule does not specify what the clinical review entails and what written certification means.

Request for Change of Proposed Rule for Medical Director

1) We request that the current certification and content requirement stay the same for the **initial certification and recertification** of terminal illness diagnosis. Each Medical Director is different in how they make their decision on terminal illness. We do not need to place new burdens on current Medical Directors, but need to examine placing federal requirements on Doctor curriculum that includes classes and rotations on end-of-life care that include understanding how to make a terminal diagnosis and the important questions and methodologies to use to make that important assessment for terminal diagnoses.

2) This new initial and re-certification requirements are included **every 14 days** at the time of each update of the comprehensive assessment (and visa versa with each recertification the assessment is updated). This new rule will have unintended consequences and will likely result in a disincentive for referral to hospice care as the medical director must prove each time when a patient is clearly terminal. Our providers are already experiencing many barriers to getting patients referred to hospice when they need hospice care. We do not want new regulations that create new barriers and disincentives to make it more difficult for the terminally ill to get hospice care. Therefore we request that you leave the initial and recertification process as is and remove it from the proposed 14 day comprehensive assessment update.

We take exception with the timeline of 14 day assessment, as required in 418.24 (d), Home Health COPs, Section 484.18(b) requires an assessment to be completed every 60 days, or more frequently where there is a beneficiary elected transfer, a significant change in condition resulting in a change in the case-mix assignment, or a discharge and return to the same HHA during the 60-day episode. Agency professional staff promptly alerts the physician to any changes that suggest a need to alter the plan of care. We agree that there should be timelines on the initial, comprehensive and update of the comprehensive. However, we do not agree with the timeframes suggested in the proposed rule or all of the content included in the assessment, including the recertification content.

3) We would also request that the Medical Director or the physician designee to not be responsible for the QAPI, as the proposed rule references in Section 418.102. The proposed rule

charges the Hospice Governing Body with oversight. However, the reference to the Medical Director as the responsible entity is in conflict with the proposed rule in the QAPI Section, 418.58 (e), which states that the Governing Body is responsible. Additionally, it is in conflict with current CoPs, Section 418.52, indicates: "A Hospice must have a governing body that assumes full legal responsibility for determining, implementing and monitoring policies governing the hospices' total operation. The governing body must designate an individual who is responsible for the day to day management of the hospice program. The governing body must also ensure that all services provided are consistent with accepted standards of practice." Therefore, we recommend that the proposed rules strike the reference to the Medical Director of the Hospice being responsible for the QAPI program, as the governing body will be responsible and, per current regulations, is allowed to select an individual to oversee the body. The hospice should have the option of having the Medical Director review it. However, it should not be required that the staff for this requirement be the Medical Director. This would be a substantial increase in responsibilities for the medical director. Currently, it is difficult to obtain a medical director. This would make it even more difficult with unrealistic responsibilities being required.

Comment #10: RECERTIFICATION - Section 418.102(b) – It is recommended that the phrase "patient/family expectations and wishes" for hospice care must be reviewed. This should be changed to "hospice goals and POC must be reviewed by patient/family".

Comment #11: CLINICAL RECORDS – Section 418.104

Standard (b) Authentication - The proposed regulation states that "All entries must be signed and the hospice must be able to authenticate each handwritten…signature…". This is not realistic. Examples that would present compliance problem include contracted nursing home and facility staff and infusion vendors who provide hospices with progress notes.

Standard (e): Discharge or transfer of care

We do not feel that a complete record should be sent to another hospice or to a physician. This is a time intensive and expensive process that does not add value for the patient nor will the physician or hospice use this on a regular basis. A discharge summary should be sufficient.

Comment #12: CONTROLLED DRUGS IN PATIENT HOME – Proposed Section 418.106 (b) – [DRUGS, SUPPLIES, and DME]

This proposed regulation adds a new requirement for a hospice to track, collect and dispose of controlled substances.

General Concern: Hospice agencies have no responsibility for and control over the medication when they are not in the home and this requires the hospice to take on a responsibility that they can not feasibly be responsible over in a person's home. Also, the medications are the property of the patient, not the hospice. Making a hospice responsible for this care will put them at risk for scenarios and situations that they can not control. CMS can not require a hospice agency to pick up the medications for the patients and not all hospices dispose of controlled substances. It is also dangerous for staff to carry controlled substances anywhere for disposal. Also, if the family refuses to dispose of them at the time of death, hospices do not want staff in a position of being required to take them from the home and dispose of them.

It would be helpful to have the intent of the drug control standard specified in the COPS. This is an area of conflict between local medical examiners and hospice's. It should be clearly defined what Hospice's are and are not responsible for. For example we are responsible for patient/family/caregiver education regarding drug disposal and safety but not disposal of the drugs or control of the drug inventory in the home. The words "tracking" and "collecting" suggest more of an enforcement role than an educational one by the hospice. The drugs are the property of the patient and family and we feel that the role of the hospice is education, not enforcement.

Additionally, the CMS discussion of this item states, "During the initial assessment, the hospice policy regarding the use and disposal of controlled drugs would be required to be discussed with the patient and family." We take exception to the hospice having to cover this during the initial assessment with the family and the patient. The patient is in pain and until the patient has an order for drugs, then it should not be necessary to review a policy and procedure that is not relevant to the patient and family. During the initial assessment, the family and patient should not be overwhelmed with technical details that are not relevant.

Request for Change of Proposed Rule for Drugs Supplies and DME

1) We would like the entire section requiring a hospice to be responsible for tracking, collecting and disposing of controlled substances to be deleted from the proposed regulation.
2) The hospice must discuss the use of controlled drugs with the patient and family, but it should not be required to collect, track or dispose. It should only have this discussion once the patient has an order for drugs and not before that time.

Comment #13 – DME MANAGEMENT REPAIR – Proposed 418.106 (c) – DME Management Repair

The new regulation requires a hospice to be responsible for the maintenance of equipment and supplies, and to ensure adequate training and instruction ("the how and when") to family regarding the equipment and supplies.

Concerns: This proposed rule does not take into consideration the differences between states. This regulation implies that hospices have their own equipment. In California, home health agencies and hospices do not oversee the use of the DME and, in fact, can not bill for DME or supplies. They contract with licensed DMEs to supply the product and service. DMEs are required to be licensed through Department of Health Services, Food and Drug Department and are required to get Medical Device Retailers License, which have strict requirements. The hospice doesn't have anything to do with the DME. Therefore, it does not make sense to make hospices responsible for this care as they are not supplying the DME. Requiring this will only result in problems and confusion for California hospice providers.

Request for Change of Proposed Rule for DME Management Repair

The proposed rule indicates that "the hospice may carry out this responsibility through a contractual arrangement with others, but would continue to maintain primary responsibility." We ask that this section is changed to adequately deal with states where hospices do not own and/or

provide the DME equipment to the state and rely on professional DME companies. We suggest that the sentence is clarified as such: "The hospice may use persons under contract and those persons would maintain primary responsibility for the services and the care.

Comment #14: SHORT TERM INPATIENT CARE – Section 418.108. This Condition should be rewritten to also allow this level of care for psychosocial/family crisis.

Comment #15 – Hospice Care in a Facility – Proposed 418.112 - "RESIDENTS RESIDING IN A FACILITY"

The new regulation expands the role of the Hospice Medical Director and expects them to play an expanded role in providing medical supervision to the hospice interdisciplinary group and overall coordination of the patient's plan of care. The medical director must now also communicate with all facility physicians and the attending physician for the patient. This would result in a barrier to patients receiving care and could result in a delay of services or no services because of a lack of compliance, and therefore, hospices **not taking patients who need facility level care.** This does not take into consideration that, most of the time, the Medical Director of the Hospice is the attending physician, and that the Medical Director of the SNF is different from SNF to SNF. This requirement takes only into consideration the SNF approach. The Hospice approach is that the Hospice has the professional judgment of the Hospice. The proposed rule seems to suggest that CMS is requesting the Hospice to take on more and more of the SNF role, when the hospice is not on site for 24 hours a day. By making the Medical Director of the Hospice responsible to consult with

The proposed rule indicated the following, "We are preparing a separate regulatory document to address long-term care facility obligations regarding residents receiving hospice services." We suggest that the Hospice CoPs do not include regulations regarding residents residing in a facility UNTIL the report regarding long-term care facility obligations regarding hospice services is complete. This will allow us to adequately respond to this section of the proposed rules which include added new requirements for hospices in SNFs, because we will know what CMS will be requiring of SNFs.

Concern:
With more hospice recipients needing hospice services in the community and not in the home, this added requirement on the Medical Director could lead to major issues and disincentives to getting a patient in one of these types of institutional settings. Part of the proposed rule, which states, "The medical director of the must communicate with all facility physicians and the attending physician and other professionals involved in developing and/or implementing the patient's plan of care" is of great concern for hospices. The concern is specifically related to the reality of the request. Currently, hospices also provide care to the hospice patient. Asking the Hospice Medical Director to consult with all Doctors is unrealistic because, often times, the Medical Director of the SNF is the attending physician for the patient.

Request for Change of Proposed Rule for Residents Residing in a Facility
We would suggest that the proposed rule is changed to require notification of the Medical Director of the SNF regarding the update of the plan of care. However, it should not be

mandatory to talk with all physicians at the SNF and require it in order to do a plan of care. It should be optional and encouraged, especially when there is a development. With the plan of care being required, under the ASSESSMENT TIME FRAMES, Proposed Rule 418.54, for every 14 days, this requirement is impractical and unfeasible for real world scenarios. While CMS is hoping to encourage a lively and thorough discussion for the patient to help them achieve the best outcomes, it will result in the opposite. It will result in either non-compliance or physicians of hospices and nursing homes developing a quick check off ability. We should ensure that physicians are encouraged to communicate with each other periodically at important time points to examine important outcomes for the patient.

As this proposed rule is shifting much of the burden and responsibility onto a hospice to deliver care, even though the SNF or facility has responsibility for non-terminal care as well, it becomes more illogical to require the Hospice Medical Director to consult even more frequently with a SNF as they are to provide less care than before under this proposal..

We would also agree with language that stated, The Hospice Medical Director shall notify in writing or verbally the SNF facility physicians regarding the POC every 30 days to confer regarding the patients overall coordination of care.

Needing a written agreement per patient with consent and specific clarification per care plan for which services the hospice will provide, and which the facility will provide will increase the amount of time needed to admit, document, and provide oversight for facility residents. Especially significant is that the hospice may only use the facility nursing personnel for those tasks which would ordinarily have been done by a resident's family in implementing a care plan. How does that impact SNF licensed caregivers needing to provide care as needed?

Comment #16 – HOSPICES THAT PROVIDE INPATIENT CARE DIRECTLY – Section 418.110.

Standard (f) Patient rooms – **Agree** that patient rooms must provide at least 80 square feet with no more than 2 beds to a room requirement.

Comment #17 - PERSONNEL QUALIFICATIONS – Section 418.114

The proposed rule asked for comments on the issue of changing the current requirement of a bachelor's degree for a social worker under Hospice to a Masters level. We would advise that this not occur. Currently, our state and federal requirements for a social worker in a home health setting requires a Master's Degree from a school of social work accredited by the Council of Social Work Education, with one year of social work experience in a health care setting. This has limited provider's abilities to be able to find social workers. A Masters in Social Work should be required OR a baccalaureate degree from a school of social work accredited by the Council of Social Work AND a least one year experience in a health care setting.

Request for Change of Proposed Rule for Social Work Definition
We would advise that CMS keep the Bachelor's degree requirement and additionally add a social work assistant as a type of social worker in a hospice. Adding the social work assistant to the

rules would open up the opportunity for a hospice to attract caring candidates who are suitable for hospice care services who have studied related disciplines (psychology; sociology; other social work related field) without penalizing potential employees who have already finished their bachelor's degree. Additionally, we would also ask that the regulations pattern the assistant social worker for persons with doctorates in fields that are not social work, such as psychology. We have heard of providers who could not hire a PhD in Psychology who was interested in the social worker position at a hospice because he had changed his focus in life and wanted to work in hospice, but could not because of the current regulations. The regulations need to be flexible to allow for PhDs in other fields, as well.

Standard (d) – Criminal background checks – **Strongly recommend keeping this new standard.**

Comment #18 - ELECTRONIC RECORDS

Regarding CMS's request for comments regarding electronic records we can add the following:

Benefits

- Facilitates improved coordination of care, especially with nurses on different shifts
- There are numerous challenges/limitations in Hospice's ability to make changes in software to meet regulatory requirements and quality initiatives. Paper records are more flexible, easier to adapt to changes.

Disadvantages

- Cost
- Often decreases in staff productive adding to cost and reducing time spent with patients
- When computers fail (hardware or software) information is not accessible. Patient care and business processes revolve around the information system, if the computer is not accessible patient care, intake and referral can become paralyzed

Patients should be able to access at least some parts of their records (e.g. medication list, test results, plan of care). Ideally, this would occur through a secure internet site.

It is concerning to think that it might be mandated in future regulations. The cost may be prohibitive for smaller hospices.

Sincerely,

Gina M. Reese

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Senior Counsel

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July 14, 2005

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Attn: File Code CMS-3844-P

***Re:* Comments on Medicare and Medicaid Programs: Hospice Conditions of Participation, Federal Register Volume 70, No. 102, Friday May 27, 2005, CMS Reference #CMS-3844-P**

Dear Dr. McClellan:

AseraCare, Inc. has hospice locations in sixteen (16) states. All AseraCare agencies are Medicare/Medicaid certified. We are pleased to offer comments on CMS' proposed changes to 42 CFR 418.

Initially, AseraCare would express our support of and assent to, the comments to be provided by the National Association for Home Care (NAHC). AseraCare is an active member of both NAHC and the National Hospice and Palliative Care Assocation (NHPCO). AseraCare participated in the recent CMS/NAHC conference call and have joined with NAHC in preparing the comments they will be presenting on behalf of the hospice industry. We would encourage you to give careful consideration to the comments of these organizations.

In addition to supporting NAHC comments on the proposed regulations, we would offer the following comments and specific observations by AseraCare staff in hopes they are helpful to you in analyzing the impact the proposed regulations would have on hospices operating across the country. Our comments are organized by reference to the regulations amended under the Federal Register notice, followed by the comments of AseraCare, noted in bold type below the particular regulation being amended. We would be glad to further explain or discuss the comments, and to answer any questions you may have. Thank you for your attention to the concerns of AseraCare, Inc.

42 CFR §418.3 Definitions

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

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AseraCare would support NAHC's recommendation that the language "within a hospice program" be added after the words "psychiatric condition" in the proposed definition above, to recognize the use of drugs in hospice for specific symptoms not commonly used as treatment for the same symptoms by other healthcare providers.

42 CFR §418.52 Patient Rights

The hospice must provide the patient or representative with verbal and written notice of the patient's rights and responsibilities in a language and manner that the patient understands during the initial evaluation visit in advance of furnishing care.

AseraCare would support NAHC's recommendation that it be permissible to ensure the patient understands his/her rights through an interpreter (family member or other).

42 CFR §418.54(a) Initial assessment

The hospice registered nurse must make an initial assessment visit within 24 hours after the hospice receives a physician's admission order for care (unless ordered otherwise by the physician), to determine the patient's immediate care and support needs.

AseraCare supports NAHC's recommendation that the assessment visit be made within 24 hours of receipt of the Medicare certification, as opposed to the physician's order. We would further suggest that CMS give consideration to permitting other disciplines, such as social workers, to perform the initial assessment.

42 CFR §418.54(b) Time frame for completion of the initial assessment

The hospice interdisciplinary group in consultation with the attending physician, must complete the comprehensive assessment no later than 4 calendar days after the patient elects the hospice benefit.

AseraCare supports an expansion of the requirement, and that the comprehensive assessment be completed no later than 7 calendar days after election, and supports NAHC's additional comments to this requirement adding language that the attending physician be included if he or she desires.

CFR §418.54(e)(1) Patient outcome measures

The comprehensive assessment must include data elements that allow for measurement of outcomes. The hospice must measure and document data in the same way for all patients. The data elements must take into consideration aspects of care related to hospice and palliation.

AseraCare supports the development of standard patient outcome measures to improve the delivery of hospice care and services. AseraCare utilizes NHPCO

quality measures, and other internal data collection tools for benchmarking in our quality improvement program.

CFR §418.56(b)(6) Plan of care
The interdisciplinary group's documentation of patient and family understanding, involvement, and agreement with the plan of care, in accordance with the hospice's own policy, in the clinical record.

AseraCare supports NAHC's comments that the word "agreement" in this context could be problematic if the patient and/or family disagreed on what was appropriate for the plan of care. This could be especially difficult to administer in light of the myriad of existing advance directive and substituted decision making laws in the various states.

CFR §418.56(d) Review of the plan of care
The medical director or physician designee and the hospice interdisciplinary team (in collaboration with the individual's attending physician to the extent possible) must review, revise, and document the plan as necessary at intervals specified in the plan but no less than every 14 calendar days. . .

AseraCare suggests that the specific reference to the medical director or physician designee is unnecessary and repetitive, since this individual is already a member of the interdisciplinary team.

CFR §418.58(b)(1) Program data
The program must utilize quality indicator data, including patient care, and other relevant data, in the design of its program.

As stated earlier, AseraCare supports the movement toward national standards for benchmarking quality indicator data. We suggest that this process be implemented in phases, first with the implementation of QA/QI outcomes, then in the future, once a recognized standard system is selected, that hospices move to begin more defined adverse event tracking and reporting. We would further recommend that at that point, CMS specify what would be the acceptable data source and benchmark as the outcomes standards are further defined. This approach would allow hospice programs to first install the quality data initiative while benchmarking is being further identified and standardized for the industry.

CFR §418.58(c)(2) Program activities
Performance improvement activities must track adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospice.

AseraCare would assert that hospices are not prepared at this time to meet this requirement. We suggest that CMS first begin to implement QA/QI processes, before moving toward collection of adverse event data. We suggest that this process

be implemented in phases, first with the implementation of QA/QI outcomes, then in the future, once a recognized standard system is selected, that hospices move to begin more defined adverse event tracking and reporting. We would further recommend that at that point, CMS specify what would be the acceptable data source and benchmark as the outcomes standards are further defined. This approach would allow hospice programs to first install the quality data initiative while benchmarking is being further identified and standardized for the industry.

CFR §418.58(d)(2) Performance improvement projects

The hospice must document what quality improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.

AseraCare recommends that CMS adopt a phased-in approach to implementing this requirement. This will permit CMS to achieve its goal of understanding more about hospice quality improvement projects, while not placing an undue burden on the agency staff and the delivery of hospice services. We suggest that this process be implemented in phases, first with the implementation of QA/QI outcomes, then in the future, once a recognized standard system is selected, that hospices move to begin more defined adverse event tracking and reporting. We would further recommend that at that point, CMS specify what would be the acceptable data source and benchmark as the outcomes standards are further defined. This approach would allow hospice programs to first install the quality data initiative while benchmarking is being further identified and standardized for the industry. If this provision is retained, consideration is needed to allow the hospice to first install the addition to the QA/QI outcome data gathering and adverse event collection. This will create a burden on the hospice if a phased in approach is not allowed for implementation.

CFR §418.58(e)(2) Executive responsibilities

The hospice's governing body is responsible for ensuring . . . [T]hat the hospice-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety, and that all improvement actions are evaluated for effectiveness. . .

AseraCare would point out that this will require a significant commitment of time by the governing body to accomplish this task. The governing body is comprised of hospice staff members with significant additional responsibilities in addition to serving on the governing body. We understand the importance of QA standards, but suggest that the governing body already has overall responsibility for everything in the program, and this specific focus on QAPI is not necessary.

42 CFR §418.64(d)(2) Nutritional counseling

Nutritional counseling, when identified in the plan of care must be performed by a qualified individual, which include dietitians as well as nurses and other individuals who are able to address and assure that the dietary needs of the patients are met.

AseraCare supports NAHC's comments to this provision, and believe that it provides flexibility to the hospice without compromising care of its patients.

42 CFR §418.76(j) Homemaker qualifications
A qualified homemaker is a home health aide as described in §418.76 or an individual who meets the standards in §418.202(g) and has successfully completed hospice orientation addressing the needs of and concerns of patients and families coping with a terminal illness.

AseraCare supports this clarification of homemaker qualifications with regard to their completion of hospice orientation.

42 CFR §418.76(g)(2) Home health aide assignments and duties
A home health aide provides services that are (i) ordered by the physician or nurse practitioner. . .

AseraCare supports NAHC's comments that as the aide's services are included in the IDG plan of care, there should not be a need for a separate physician's order for this care. Such language is redundant could become confusing.

42 CFR §418.76(h)(1) Supervision of home health aides
. . . A registered nurse or qualified therapist must make an onsite visit to the location where the patient is receiving care in order to observe and assess each aide while he or she is performing care no less frequently than every 28 days.

AseraCare would suggest that the supervisory requirement frequency be extended from every 28 days to every 60 days. We believe that this would fit in more easily with existing staffing patterns in hospices while not compromising patient care.

42 CFR §418.100(a)(2) Serving the hospice patient and family
The hospice must ensure . . . that each patient experience hospice care that is consistent with patient and family needs and desires.

AseraCare agrees with NAHC's recommendation that the language "desires" is inappropriate in this setting. Rather, AseraCare would suggest that the hospice be required to provide care that is consistent with patient and family needs "as set out in the plan of care". The family participates in the plan of care, and tying this standard back to the plan of care ensures that hospices and surveyors are not confused by implementing care patient consistent with vague language such as "desires".

42 CFR §418.100(e) Professional management responsibility
A hospice that has a written agreement with another agency, individual, or organization to furnish any services under arrangement, must retain administrative and financial management, and supervision of staff and services to ensure the provision of quality care.

Arranged services must be . . . (2) furnished in a safe and effective manner by personnel having at least the same qualifications as hospice employees.

AseraCare and NAHC would suggest that the word "supervision" be replaced with "oversight" as the supervision would be conducted by the actual contracted employee. Also the language "at least the same qualifications as hospice employees" could be problematic and should be replaced with "by qualified personnel".

42 CFR §418.100(f)(1) Hospice satellite locations

(1) All hospice satellite locations must be approved by CMS before providing hospice care and services to Medicare patients. The determination that a satellite location does or does not meet the definition of a satellite location, as set forth in this part, is an initial determination, as set forth in §498.3. (2) The hospice must continually monitor and manage all services provided at all of its locations to ensure that services are delivered in a safe and effective manner and to ensure that each patient and family receives the necessary care and services outlined in the plan of care.

AseraCare joins NAHC in their praise of CMS' efforts to clarify this issue. We have no problem with the language proposed in this standard, but would ask for additional clarification of the distinction between "satellite locations" and "alternate sites". These terms are used in the industry, and clarification from CMS of the different standards applied to each would clear up some confusion among the various states.

42 CFR §418.102(b) Recertification of the terminal illness

Before the recertification period for each patient, as described in §418.21(a), the medical director or physician designee must review. . . (2) the patient's and family's expectations for the continuation of hospice care.

AseraCare would assert that it is unclear what is meant by patient/family "expectations" for care. Retaining such vague language sets the hospice up for failure both in determining and meeting those "expectations". Rather, AseraCare would suggest that the medical director review information provided by the IDG, including the patient and family's response to the hospice plan of care on a ongoing basis and before each updated assessment

42 CFR §418.102(c) Coordination of medical care

The medical director or physician designee is also responsible for directing the hospice quality assessment and performance improvement program.

Asseracare suggests that this requirement would be very difficult and may not be appropriate. The day to day duties of the QAPI program can and should be assigned the appropriate hospice leadership such as the Director of Clinical Services, as in other programs (i.e., nursing facilities, home health), with the medical director maintaining oversight. The Medical Director is active participant on the

team, but can't be responsible for directing the day to day responsibilities for the QAPI program. Retaining this requirement could affect ability of hospices to recruit medical directors. In addition, the hospice should designate an alternate medical director, because of the vital nature of this role.

42 CFR §418.104 Clinical records
. . . The clinical record may be maintained electronically.

EHRs would improve coordination of care, however, one barrier that we currently have in hospice is lack of standardized plans of care, and certifications of terminal illness. The ability of multiple providers to access EHRs would require additional technology and effort. Hospice today has no standardized system for documentation of the plan of care. Everyone uses different forms. AseraCare suggests that we move slowly to implement such a requirement.

42 CFR §418.104(b) Authentication
All entries must be legible, clear, complete, and appropriately authenticated and dated All entries must be signed, and the hospice must be able to authenticate each handwritten and electronic signature of a primary author who has reviewed and approved the entry.

AseraCare and NAHC agree that the origin of this requirement is from hospital COPs, and the nature of hospice care is much broader than that provided in an acute care setting. The application of this standard is unclear with respect to certain individuals and classes of provider, e.g., all consulting or covering physicians, all contracted nursing home and facility staff who care for hospice patients, and contracted infusion vendors who provide hospices with progress notes.

42 CFR §418.104(d) Retention of records
Patient clinical records must be maintained for 5 years after the death or discharge of a patient, unless State law stipulates a longer period of time.

We suggest that the retention be changed to 6 years to mirror the requirement under HIPAA.

42 CFR 418.104(e)(1) Discharge or transfer of care
If the care of a patient is transferred to another Medicare/Medicaid approved facility, the hospice must forward a copy of the patient's clinical record and the hospice discharge summary to that facility.

Like NAHC, AseraCare suggests that other providers will not want the complete clinical record, and a copy of the discharge summary will be adequate coupled with the option for the receiving facility or MD to be able to request additional information from the hospice. This change will enable appropriate documentation and information to follow the hospice patient upon discharge, without unreasonably burdening either the transferring facility or the facility accepting the patient.

42 CFR 418.106(b) Controlled drugs in the patient's home
The hospice must have a written policy for tracking, collecting, and disposing of controlled drugs maintained in the patient's home. During the initial hospice assessment, the use and disposal of controlled substances must be discussed with the patient and family to ensure the patient and family are educated regarding the uses and potential dangers of controlled substances. The hospice nurse must document that the policy was discussed with the patient and family.

The word "collecting" in this standard is problematic. A better substitute would be the word "monitoring". Further, use of the words, "potential dangers of controlled substances" could influence acceptance of narcotics necessary to make the patient comfortable. The hospice patient's family's focus is and should be on the control of the patient's pain. While it is important to educate the patient and family members, the language of these regulations must be sensitive to this focus. We believe that deletion of the words "and potential dangers" would balance the need to educate the family on the safe delivery, disposal, and appropriate use of controlled substances in the patient's home with the focus remaining on the control of pain.

42 CFR §418.106(c) Use and maintenance of equipment and supplies
(1) The hospice must follow manufacturer recommendations for performing routine and preventive maintenance on durable medical equipment. The equipment must be safe and work as intended for use in the patient's environment. Where there is no manufacturer recommendation for a piece of equipment, the hospice must develop in writing its own repair and routine maintenance policy. The hospice may use persons under contract to ensure the maintenance and repair of durable medical equipment. (2) The hospice must ensure that the patient, where appropriate, as well as the family and/or other caregiver(s) receive instruction in the safe use of durable medical equipment and supplies. The patient, family, and/or caregiver must be able to demonstrate the appropriate use of durable medical equipment to the satisfaction of the hospice staff.

AseraCare and NAHC agree that this provision should be rewritten to state that when DME is provided under contract, the vendor is responsible. This maintains the appropriate focus on the role of the hospice to provide "professional management" for oversight of contracted services. Hospices do not have the expertise to do what the medical equipment experts are trained to do. The DME company must be held primarily responsible for delivering safe and appropriate equipment and supplies.

42 CFR §418.108 Short term inpatient care
This proposed regulation would eliminate existing requirements at §418.100(a)(2) requiring RN to provide direct patient care on each shift.

Due to the anticipated timeline for implementing the new hospice COPs, we request consideration from CMS to issue a specific memorandum to give immediate relief to the existing standard for 24 hour RN coverage, similar to earlier memorandums providing relief for staffing contracting with extenuating circumstances. AseraCare

applauds CMS for recognizing the staffing shortages giving rise to the necessity of providing relief to the 24 hour RN requirement. However, we would emphasize the need for immediate relief from this requirement, and would state that we do not believe patient care would be threatened by isolating this requirement by making the relief it would provide immediately available to hospice providers.

42 CFR §418.110(l) Meal service and menu planning

The hospice must furnish meals to each patient that are – (1) Consistent with the patient's plan of care, nutritional needs, and therapeutic diet; (2) Palatable, attractive, and served at the proper temperature; and (3) Obtained, stored, prepared, distributed, and served under sanitary conditions.

AseraCare joins NAHC is applauding CMS for this language, which is significant for what it omits. We support removing language requiring the hospice to serve 3 meals at regular times with no more than 14 hours between the breakfast and evening meals. Doing so respects the needs of the patient, rather than forcing the patient to adhere to rigid and artificially established meal times.

42 CFR §418.110(o)(1) Seclusion and restraints

. . . A drug used as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard treatment for a patient's medical or psychiatric condition. . .

AseraCare would join NAHC in calling CMS' attention to the fact that hospice programs commonly use drugs for treatment of terminal restlessness which are viewed in other settings as chemical restraints. We would urge CMS to confine the definition of drug restraint to medication used to control behavior or restrict patient's freedom of movement and which are not a standard treatment for a medical or psychiatric condition within a hospice program.

42 CFR §418.112(d) Medical director

The medical director and physician designee of the hospice must provide overall coordination of the medical care of the hospice resident that resides in an SNF, NF, or other facility. The medical director and physician designee must communicate with the medical director of the SNF/NF, the patient's attending physician, and other physicians participating in the provision of care for the terminal and related conditions to ensure quality care for the patient and family.

AseraCare joins NAHC in suggesting it would be best for the IDG to be responsible for this function and continue the current practice of assigning a registered nurse to coordinate the care. If the facility medical director is also the hospice patient's attending physician, it would then be appropriate to communicate with the facility medical director.

42 CFR §418.114(c)(7) Social worker
A person who has a baccalaureate degree from a school of social work accredited by the Council on Social Work Education.

AseraCare strongly believes that a BSW should continue as the standard for social work qualification for hospice social workers. BSWs have the needed skills for providing for the needs of hospice patients. Imposing a requirement for MSWs will increase hospice staffing difficulties without providing significant benefit to the patient.

42 CFR §418.114(d) Criminal background checks
The hospice must obtain a criminal background check on each hospice employee and contracted employee before employment at the hospice.

AseraCare agrees with the need for obtaining background checks on hospice employees prior to employment, but disagrees with a requirement that this process be followed for contracted employees. Hospices should be required to ensure that background checks on contracted employees have been obtained, but should be able to accomplish this through a written agreement rather than maintaining primary responsibility for doing so directly.

Sincerely,

Chris Roussos

Chris Roussos
President
AseraCare

HPNA
Hospice and Palliative Nurses Association

Penn Center West One, Suite 229 • Pittsburgh, Pennsylvania 15276

July 22, 2005

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

Dear Sirs:

The Hospice and Palliative Nurses Association (HPNA) is submitting their comments in response to the Federal Registry Part II 42 CFR Part 418 Medicare and Medicaid Programs: Hospice Conditions of Participation; Proposed Rule.

HPNA represents nearly 8,000 nurses throughout the United States who deliver hospice and palliative care to Medicare and Medicaid recipients. Our comments reflect our desire to assure the delivery of nursing care meets expectations of the Department of Health and Human Services.

We thank DHHS for allowing us the opportunity to provide documentation for the need for clarification and expansion in the roles of the nursing team in providing hospice care as we move forward to the future.

Sincerely,

Judy Lentz, RN, MSN, NHA
Chief Executive Officer

(412) 787-9301 • fax (412) 787-9305 • email: HPNA@hpna.org
http://www.HPNA.org

HOSPICE AND PALLIATIVE NURSES ASSOCIATION

RECOMMENDATIONS IN RESPONSE TO THE RECENTLY PUBLISHED

CONDITIONS OF PARTICIPATION

FEDERAL REGISTRY VOL. 7 NUMBER 10

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

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

	comprehensive assessment. The hospice interdisciplinary group in consultation with the individual's attending physician must complete the comprehensive assessment no later than 4 calendar days after the patient elects the hospice benefit.	**maximum of 3 days. The role of the attending physician should be at the discretion of the attending physician.**
418.64	**Core services.** A hospice must routinely provide substantially all core services directly by hospice employees. These services must be provided in a manner consistent with acceptable standards of practice. These services include nursing services, medical social services, and counseling. The hospice may contract for physician services as specified in § 418.64(a). A hospice may, under extraordinary or other non-routine circumstances, enter into a written arrangement with another Medicare certified hospice program for the provision of core services to supplement hospice employee/staff to meet the needs of patients. Circumstances under which a hospice may enter into a written arrangement for the provision of core services include: Unanticipated periods of high patient loads, staffing shortages due to illness or other short-term temporary situations that interrupt patient care; and temporary travel of a patient outside of the hospice's service area.	
	(a) *Standard: Physician services.* The hospice medical director, physician employees, and contracted physician(s) of the hospice, in conjunction with the patient's attending physician, are responsible for the palliation and management of the terminal illness, conditions related to the terminal illness, and the general medical needs of the patient. (1) All physician employees and those under contract, must function under the supervision of the hospice medical director. (2) All physician employees and those under contract shall meet this requirement by either providing the services directly or through coordinating patient care with the attending physician. (3) If the attending physician is unavailable, the medical director, contracted physician, and/or hospice physician employee is responsible for meeting the medical needs of the patient.	
	(b) *Standard: Nursing services.* (1) The hospice must provide nursing care and services by or under the supervision of a registered nurse. Nursing services must ensure that the nursing needs of the patient are met as identified in the patient's initial comprehensive assessment and updated assessments. (2) If State law permits nurse practitioners (NPs) to see, treat and write orders for patients, then NPs may provide services to beneficiaries receiving hospice care. The role and scope of the services provided by a NP that is not the	**Request this is changed to read Advanced Practice Nurse instead of NPs.**

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

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

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

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

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

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

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

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

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