AAHPM American Academy of Hospice and Palliative Medicine

Advancing the Science of Comfort ~ Affirming the Art of Caring

July 25, 2005

BY HAND DELIVERY

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

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

Dear Administrator McClellan:
We at the American Academy of Hospice and Palliative Medicine (AAHPM) appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS'") proposed changes to the Medicare and Medicaid Program proposed rule regarding Hospice Conditions of Participation. The AAHPM consists of nearly 2000 physicians who work in hospice and palliative medicine every day. As such, these rules are of vital importance to our members and to the patients they serve.

II. DEFINITIONS (PROPOSED §418.3)

We believe the **attending physician** should be the physician or nurse-practitioner **designated by the patient**, whether this physician is employed by the hospice or not. Clarification of this point would be helpful.

We are also very concerned about the definition of **drug restraint** as we will discuss below.

VIII. LICENSED PROFESSIONAL SERVICES (PROPOSED §418.62)

And

Proposed §418.100(e) *Standard: Professional management responsibility*

Licensed professionals should certainly **oversee the patient's hospice care**, but there may be other aspects of the patient's care such as dialysis unrelated to the terminal illness, that should remain under the control of others.

XIV. MEDICAL DIRECTOR (PROPOSED §418.102)

The hospice should have the responsibility of designating another physician if the medical director is not available. This would be particularly important if the medical director suddenly became ill or for some other reason was not be able to arrange coverage.

Proposed §418.102(c) Standard: Coordination of medical care.

As stated above, we believe the medical director should be **responsible for overseeing the patient's hospice care.** As hospice extends to care for more patients with non-cancer illnesses that often have other medical problems, it will be even more important to involve other providers in the patient's care.
Likewise, we suggest that the **medical director participate in the quality improvement** efforts but not be held solely responsible this complex new process. Others will need to help to insure the best QA program.

XIX. SECLUSION AND RESTRAINT (PROPOSED §418.110(o))

In some series, over 80% of hospice patients were found to develop delirium in their final days. Expert medical management can reverse some of these episodes of confusion and agitation, but the majority will require sedative medications to reduce the patient's distress. The medications most often used are the major (e.g. chlorpromazine, haloperidol) and minor (e.g. lorazepam, midazolam) tranquilizers. Rarely the barbiturates (e.g. phenobarbital) must be utilized. **The use of these medications for relief of the patient's distress is good medical practice, not drug or chemical restraint**. Clarification of this important point will prevent under treatment of these important symptoms.

Proposed §418.112(d) *Standard: Medical director*

We agree that the medical director or the physician designee should be charged with giving clinical guidance to the development of policies and procedures for nursing home residents, but the **overall responsibility for the patient's medical care should remain with the attending physician.**

We appreciate the opportunity to comment on these important regulations and would be happy to discuss these issues further.

Respectfully submitted,

Bob Arnold

Robert Arnold, MD
President

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JULY 26, 2005

BY HAND DELIVERY

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

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

Dear Administrator McClellan:

On behalf of VistaCare, a national hospice organization operating with 37 provider numbers in 14 states, I am pleased to provide you with our organization's comments on the Centers for Medicare and Medicaid Services' ("CMS"") proposed changes to the Medicare and Medicaid Program proposed rule regarding Hospice Conditions of Participation.

As the nation's third largest hospice provider and an organization dedicated to service excellence and regulatory compliance, VistaCare has greatly appreciated the opportunity to work with our colleagues at the National Hospice and Palliative Care Organization as we reviewed this long-awaited update. We have been actively involved with the NHPCO and our fellow providers throughout this process and fully support the recommendations advanced by the organization.

However, we do have a few additional comments and observations to share and have included those as part of this correspondence. I hope you'll find value in these comments and that you'll consider both these recommendations and the ones advanced by the NHPCO as you finalize the updates to the Hospice Conditions of Participation.

Proposed §418.54(a) *Standard: Initial Assessment*
VistaCare is in agreement with the NHPCO comments and requests for revisions to this proposed standard with one additional comment. We support the intent of this standard

in assuring a quick assessment and initiation of care, especially in light of the high number of short length of stay patients. The proposed language appears to require a physician's order for hospice. The hospice must obtain a physician's certification of the terminal illness (418.22), which is not the same as a physician's order for hospice care. Patients have the right to elect their hospice benefit which does not require a physician order for hospice. We do, however, recognize that there must be physician orders for care. As noted in the preamble of the proposed Hospice Conditions of Participation, hospices do meet with patients and families before the actual hospice care orders are received, and this standard would not prevent this practice. VistaCare requests that CMS clarify in the preamble that this practice would continue to be acceptable. We would also request clarification that a physician's order for care is required but that a physician's admission order to hospice is not.

If you have any questions about these recommendations or if there's anything further that I can do to support this important initiative, please don't hesitate to contact me at (480) 648-4530.

Thanks again for your time and for your valuable work within the hospice industry.

Respectfully submitted,

Richard R. Slager, Chairman and CEO

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July 26, 2005

Via Electronic Mail And Hand Delivery

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 309-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201
Attn: CMS-3844-P

Re: **Comments On Medicare and Medicaid Programs: Hospice Conditions of Participation, 70 Federal Register 30840 (May 27, 2005), CMS-3844-P**

Dear Dr. McClellan:

VITAS appreciates the opportunity to comment on the above-referenced proposed rule, *Medicare and Medicaid Programs: Hospice Conditions of Participation*.

VITAS is the nation's largest and leading provider of hospice services, serving patients from 34 hospice programs in 12 states. For 25 years, VITAS Healthcare Corporation has been a leader in the American hospice movement, helping to define the standards of care for hospice and working to ensure that terminally ill patients and their families have ready access to compassionate and effective end-of-life care through Medicare and Medicaid. On average, VITAS serves almost 9,000 patients each day and employs nearly 7,000 people. More than half of VITAS' patients receive care in their homes, and nearly 40 percent receive care in skilled nursing and assisted living facilities.

VITAS was founded in 1978 as Hospice Care, Inc., one of the nation's first hospice programs. As a hospice pioneer, VITAS was instrumental in leading a bi-partisan effort to add hospice to the health care payment system. As a result of these efforts, Medicare pays for hospice services, many states have established Medicaid

coverage for hospice, and virtually all private insurers and managed care plans provide coverage for hospice care. Today, VITAS is the leading provider of cost effective end-of-life care, working in cooperation with hospitals, physicians, nursing homes, assisted living facilities, insurers and community-based organizations throughout the nation. Given all of these factors, VITAS has a direct interest in the proposed changes to the Medicare and Medicaid conditions of participation.

CMS Proposal: Section 418.52 – Patient's Rights

The proposed rule generally would require that the patient be informed of his or her rights and that the hospice protect and promote the exercise of those rights. The proposal would add a number of specific requirements in this regard.

VITAS Comment

Although most of the proposed requirements reflect VITAS' current practices, we have a few concerns.

First, while we agree that hospices should inform patients and families of the hospice's drug policies and procedures regarding the monitoring and disposing of controlled substances, we do not believe that this should be required as part of the admissions process. Not every patient needs the use of narcotics, and we are concerned that requiring this discussion upon admission has the potential to instill fear in patients and families alike. Hospices have worked hard to dispel the myths associated with narcotic use with terminally ill patients, and such a discussion can only prolong these myths. During the admission visit, extensive and sometimes difficult information must be conveyed. We believe that information on the safe utilization and destruction of narcotics should not occur until such time as narcotics are ordered for a patient. We also suggest using the word "monitoring" in place of "tracking" as it is more consistent with the procedures used in the home setting.

Second, we recommend that CMS insert language into subsection (b) acknowledging that the patient has the right to refuse treatment.

Subsection (b)(4)(i) would require that violations regarding alleged abuse and the like be reported to state and local bodies including the state survey and certification agency. We believe such a requirement to be redundant because we already are legally required to investigate and report these types of incidents to appropriate authorities. If this proposed requirement is retained, we recommend making any reporting time frame more precise by stating that "validated or confirmed significant violations" must be "reported to the appropriate bodies having jurisdiction within at least five business days of the discovery of the incident" (suggested new language underscored).

Finally, while we fully support informing the patient of his or her financial liability, we are concerned that the requirement that the patient be so informed "in a

language that he or she can understand" goes too far, given the existence of multiple languages and dialects. In such situations, we typically employ family members and others as interpreters and use translation services as necessary. We believe that this accomplishes the goal of informing the patient of his or her liability.

CMS Proposal: Section 418.54 – Comprehensive Assessment/Assessment Time Frames

The proposed rule would require a documented patient-specific comprehensive assessment by a registered nurse, identifying the patient's need for hospice care and services. The initial assessment would have to be made within 24 hours after the hospice received a physician's admission order for care. The interdisciplinary group, in consultation with the individual's attending physician, would then need to complete a comprehensive assessment within 4 days. Finally, the comprehensive assessment would have to be updated every 14 days.

VITAS Comment

While we appreciate the concern for efficiency and the need to address patient needs as quickly as possible, we are concerned that the proposed time frames are unrealistically narrow. Given the current national nursing shortage, the fact that some families need to ease into hospice care, the existence of holidays, and other comparable variables, we recommend extending some of the proposed time frames by several days.

First, we believe that 48 hours represents a more reasonable time frame for conducting the initial assessment, depending upon the patient's condition and the family's request, than does the proposed 24 hours. We also support any member of the core interdisciplinary group being able to complete an initial assessment visit, as opposed to CMS' proposal to limit this function to registered nurses. Similarly, we recommend that the interdisciplinary group have 7 days rather than 4 days to complete the comprehensive assessment. As CMS points out in the Preamble, the overall length of stay in hospices is increasing (70 Fed. Reg. at 30845), and for some patients, 7 days represents a reasonable time frame and provides the hospice with needed scheduling flexibility to "triage," and attend to sicker patients first. Finally, it is VITAS' practice to update the patient's plan of care on an ongoing basis depending upon patient needs; hence, we do not believe it necessary or advisable to establish an arbitrary 14 day time frame for updating the assessment.

On a more fundamental level, we are concerned that the proposed regulation appears to require some type of written forms to evidence that assessments have been conducted. We view initial and comprehensive assessments to be *processes,* with care decisions evolving over time. We are concerned that the regulations' prescriptive provisions on documentation may result in hospices' placing more emphasis on rote data entry than on individual care. Such documentation requirements may also result in increasing numbers of arbitrary survey decisions.

In addition, we request that this segment specify that the comprehensive plan of care may be developed without the need for a face-to-face interaction, but can be developed via electronic or telecommunications.

Last, we note that not every hospice patient has an attending physician; thus, subsection (b) should state that the comprehensive assessment is to be conducted by the interdisciplinary group "in consultation with the individual's attending physician, which may be the hospice physician" (suggested new language underscored).

CMS Proposal: Section 418.56 – Plan of Care and Coordination of Services

The proposed rule would require a hospice to designate an interdisciplinary group, as is current practice. In consultation with the patient's attending physician, the group would prepare a written plan of care for each patient, specifying the "care and services necessary to meet the patient and family-specific needs identified in the comprehensive assessment." In the Preamble, CMS notes that "family plays an important role in the care of a hospice patient," and that it is thus "including a reference to the patient's family when establishing the plan of care." 70 Fed. Reg. at 30846. The proposed rule also would require that the medical director or physician designee and the hospice interdisciplinary team review, revise and document the plan of care no less than every 14 calendar days.

VITAS Comment

Although VITAS strives in every case to involve the patient's family in important decisions, it is sometimes difficult in practice to achieve complete agreement with all choices, particularly when dealing with the last stages of a patient's life. Families are often fractured on difficult emotional decisions regarding the end of a loved one's life. We are concerned that the proposed regulations appear to require that the patient and family agree on all decisions, and that the hospice be required to document that consensus. Better terms might include "family awareness, understanding, and involvement in the decision-making process." We are concerned that requiring unanimous patient/family agreement could hinder the development of some patients' plans of care and ultimately affect them negatively.

In addition, we believe that the proposed language regarding the review of the plan of care in subsection (d) could undermine the interdisciplinary group in favor of review of care by a single physician. Because the medical director or physician designee is separated from the rest of the interdisciplinary team at the beginning of the standard, the proposed rule seems to indicate that the physician's influence would be at least equal to that of the entire interdisciplinary group. The purpose of an interdisciplinary group is to receive equal input from professionals in many areas, and this goal could be undermined by the language of the proposed regulation.

As noted previously, we believe that the plan of care should be updated as often as necessary to meet the individual needs of the patient and family as determined by the outcomes of the interventions, rather than within an arbitrary 14 day time period. Each patient has unique needs that are best addressed without a rigid time requirement. The hospice should not be required to specify when the plan of care will be reviewed again, since the interdisciplinary group cannot predict when symptoms will change. Instead, an outcomes approach to care and the evaluation of symptom management should determine when the plan of care should be updated.

Finally, the term "if any" should follow the reference in subsection (b) to the patient's attending physician. This may be the hospice physician because the family and/or the attending physician want the hospice physician to take over. While we concur with CMS' statement in the Preamble that attending physicians often have long relationships with patients, and that their input can be "invaluable" (70 Fed. Reg. at 30847), not all patients have attending physicians, nor do all attending physicians have the expertise effectively to manage symptoms at the end of life.

CMS Proposal: Section 418.58 – Quality Assessment and Performance Improvement (QAPI)

The proposed rule would require the hospice to "develop, implement, and maintain an effective, ongoing, hospice-wide data-driven quality assessment and performance improvement program." In particular, the hospice's governing body would have to ensure that the program: reflected the complexity of its organization and services; involved all hospice services; focused on indicators related to improved palliative outcomes; focused on the end-of-life support services provided; and took actions to demonstrate improvement in hospice performance. Further, the rule would require that the hospice "measure, analyze, and track quality indicators, including adverse patient events and other aspects of performance that enable the hospice to assess processes of care, hospice services, and operations." The rule would place overall responsibility for QAPI on the hospice's governing body.

VITAS Comment

We commend CMS for its recognition that an individual hospice must have the flexibility to "drive its own quality improvement activities and improve its provision of services" (Preamble, 70 Fed. Reg. at 30848). Hospices must necessarily conduct their own quality assessments on an ongoing basis and take whatever unique actions are necessary to implement improvements; hence, the absence of prescriptive, detailed requirements in this section is highly appropriate.

We suggest clarification of a few specific requirements. First, we are unclear as to what CMS believes to constitute an "adverse patient event" under subsection (a)(2). The meaning of this term is different in the context of hospices than other providers, and, while CMS in the Preamble characterizes such events as "occurrences that are harmful or

contrary to the targeted outcomes" (70 Fed. Reg. at 30848), we believe the regulation itself should be clarified.

Second, in subsection (e), we believe that the interdisciplinary group and not the hospice's governing body should be responsible for defining, implementing, and maintaining the QAPI. The governing body should oversee the plan.

CMS Proposal: Section 418.60 – Infection Control

The proposed rule would require the hospice to "maintain and document an effective infection control program that protects patients, families and hospice personnel by preventing and controlling infections and communicable diseases." The rule would further require the hospice to provide infection control education to staff, patients, and family members or other caregivers.

VITAS Comment

Again, we commend CMS for its recognition that hospices must be afforded flexibility in developing infection control plans, recognizing that a hospice cannot reasonably be expected to be directly responsible for maintaining an infection-free environment in a patient's home or inpatient setting. However, we believe that setting standards for education about infection control generally would be unrealistic. We therefore urge CMS to limit this potentially expansive proposed requirement to educating staff, patients, and family members on "significant" and potentially threatening infections only, i.e., we should not have to inform patients and family members of the remote risks of anthrax, SARS, etc.

CMS Proposal: Section 418.64 – Core Services

The proposed rule would require a hospice routinely to provide substantially all core services directly by hospice employees. The rule would only allow a hospice to contract with another Medicare certified hospice under "extraordinary or non-routine circumstances," or with "highly specialized nursing services" that are "provided so infrequently that...[their] provision ...by direct hospice employees would be impracticable and prohibitively expensive...." The rule would provide that such emergency circumstances include: unanticipated periods of high patient loads, staffing shortages due to illness or other short-term temporary situations that interrupt patient care, and temporary travel of a patient outside of the hospice's service area. Outside contracting for continuous care would be prohibited. The proposed rule also would require that a social worker providing medical social services complete a psychological assessment of the patient.

VITAS Comment

While we again commend CMS' effort to allow hospices additional contracting flexibility, VITAS has significant concerns with CMS' proposal to preclude hospices from contracting for continuous care services.

Section 946 of the Medicare Modernization Act did not provide an exhaustive list of the circumstances under which contracting would and would not be appropriate. Rather, it contained the general statement that outside contracting is appropriate in "extraordinary, exigent, or other non-routine circumstances...." It then listed several examples of such circumstances ("such as unanticipated periods of high patient loads, staffing shortages due to illness or other events, or temporary travel of a patient outside a hospice program's service area..."), but this list clearly was not meant to identify the only extraordinary or non-routine circumstances under which contracting world be appropriate. Stated differently, we submit that CMS should not read into the MMA's examples a directive to prohibit arrangements not specifically referenced. Indeed, this provision was included in Title IX of the MMA, and entitled "Administrative Improvements, Regulatory Reduction, and Contracting Reform." Congress clearly intended to provide hospices with additional flexibility.

Outside contracting for continuous care services should be equally justified during periods of high patient loads and during staffing shortages – exigencies which, contrary to CMS' statements in the Preamble, cannot be predicted on a routine basis. We submit that there is no legitimate basis to distinguish these different types of outside contracting needs, and urge that continuous care not be excluded from permissible contracting. We are very concerned that the proposed limitation, given the increasing nursing shortages, could result in continuous care becoming obsolete. This would be a sad consequence considering the fact that most patients would prefer to remain home for their final days even when their care needs are acute. Continuous care frequently is less expensive than a General Inpatient day, as the average number of hours billed each day is between 13 and 17 hours. At VITAS, the primary registered nurse case manager – a VITAS employee -- always retains full management of the case, regardless of the level of care received by the patient. Continuous care, therefore, should be viewed no differently than the General Inpatient level of care. Both are for acute intervention. It would make little sense to permit contracting for supplemental nursing care with General Inpatient care and not at all for continuous care, because in neither case would we abdicate professional management to the contracted staff.

Further, we have concerns that CMS' proposed provision in subsection (a) that "all physician employees and those under contract, must function under the supervision of the hospice medical director." We assume that this provision should not be interpreted to mean that the hospice medical director needs to be involved with every patient's medical care, but we recommend that this be clarified in the final regulations. Specifically, we submit that this section should be amended to read as follows: "all physician employees and those under contract, must function under the general

supervision of the hospice medical director, who shall furnish overall direction for the physician services provided but who shall not be required personally to provide direct physician services to every patient" (suggested new language underscored).

CMS Proposal: Section 418.66 – Statutory Nursing Waiver

The proposed rule would allow a waiver to the requirement that a hospice provide nursing services directly if, among other statutory requirements, the hospice is located in a nonurbanized area.

VITAS Comment

While we appreciate that there can exist differing economic characteristics between urban and nonurban areas, we are concerned that the proposed rule fails to recognize that there currently exists a *national* nursing shortage, and that shortages frequently are the most extensive in large urban areas like Los Angeles, San Francisco and Philadelphia. It is VITAS' experience that nurse recruitment can be just as difficult in these urban areas as in nonurban ones, and we submit that the waiver should apply nationwide. Indeed, the cost to recruit nurses in urban areas has far outstripped the fixed hospice reimbursement rates.

CMS Proposal: Section 418.76 – Home Health Aide and Homemaker Services

The proposed rule enumerates extensive requirements for hospices that provide "home health aide services" and "homemaker services," including provisions relating to aide training, and to supervision and evaluation of aide services.

VITAS Comment

We submit that the proposed requirement of subsection (g)(2) that home health aide services be "ordered by the physician or nurse practitioner" is wholly inconsistent with current practice and with section 418.56(c)(2) of the proposed rule itself. We believe that the interdisciplinary group, and not the physician or nurse practitioner alone, should determine the frequency and scope of services necessary to meet the needs of the patient and family, including home health aide and homemaker services. We request that this section be modified accordingly, and generally urge that CMS permit hospices to be flexible in adapting the scope and frequency of care to respond to patient and family needs. Specifically, we want to make sure that the section allows volunteers to do homemaker chores without having to be certified as aides.

We further urge CMS to eliminate the proposed requirement that "a registered nurse or qualified therapist" make onsite visits to the location where the patient is receiving care, in order to observe and assess each aide while he or she is performing care. At VITAS, we provide extensive orientation and training for our home health aides, including ascertaining their aide skills and competency upon orientation and at least

annually, but more frequently upon request by a member of the interdisciplinary group or, of course, the patient or family. We believe many hospices have the same internal requirements, and we request that CMS not impose arbitrary requirements in this regard.

Finally, we request that language be added to subsection (h) recognizing that information regarding the assessment of a home health aide's competency must be appropriately maintained in the aide's personnel record, rather than the clinical record.

CMS Proposal: Section 418.78(e)

The proposed rule states at subsection (e) that "[v]olunteers must provide day-to-day administrative and/or direct patient care services in an amount that, at a minimum, equals 5 percent of the total patient care hours of all paid hospice employees and contract staff."

VITAS Comment:

We submit that this standard should be revised to specify that calculation of the required 5 percent minimum volunteer hours be based on *routine* home care hours, as opposed to *total* patient hours. With more hospices providing inpatient care directly in hospice facilities having round-the-clock, 24/7 staffing requirements, the total patient care hours provided by paid staff – effectively, the proposed denominator of the volunteer hours calculation -- has increased exponentially. As written, CMS' proposed requirement would provide a disincentive to hospices to provide inpatient care directly.

We also request that CMS clarify what types of volunteer hours appropriately can be included in calculating the 5 percent volunteer requirement. There continues to be confusion in the field about the issue, and the question has been raised in several CMS Open Door Forum calls.

We recommend amending this section as follows:

> (e) *Standard: Level of activity.* Volunteers must provide day-to-day administrative and/or direct patient care services in an amount that, at a minimum, equals 5 percent of the total ~~patient~~ routine home care patient care hours of all paid hospice employees and contract staff. The hospice must maintain records on the use of volunteers for patient care and administrative services, including the type of services and time worked. The volunteer hours that may be used in the calculation of the 5 percent rule may include volunteer travel time, actual time worked as a volunteer, and time spent documenting services provided; however, volunteer training and orientation time may not be included in the calculation.(suggested new language underscored)

CMS Proposal: Section 418.100 – Organization and Administration of Services

The proposed rule would require the hospice to "ensure" that each patient receives hospice care that is "consistent with patient and family needs and desires." It discusses the role of the governing body and the assumption of professional management responsibility. Among other proposed requirements, subsection (e) would require the hospice to be responsible for "supervision of staff and services for all arranged services, to ensure the provision of quality care." Finally, the proposed rule would address satellite locations, stating in subsection (f) that "all hospice satellite locations must be approved by CMS before providing hospice care and services to Medicare patients."

VITAS Comment

As noted, VITAS strives in every case to involve the family and the patient jointly in making care decisions. While we certainly wish to ensure that patients experience hospice care that is consistent with the patient and his or her family's needs and desires, we must acknowledge the reality that families and patients do not always agree on either the needs or "desires" of a patient. We urge CMS to revise the language of subsection (a)(2) to provide that the hospice must "seek to promote hospice care that is consistent with patient and family needs." Thus, we request that CMS replace the word "ensure" with the word "promote" with respect to the patient's and family's needs, and we further request that the word "desires" be eliminated from this proposed subsection.

In addition, we urge CMS to remove the reference in subsection (e) to "supervision of staff" of an agency with which the hospice has a contract. As a technical matter, we supervise service delivery, not the staff itself. Further, we urge eliminating the proposed requirement in subsection (e)(2) that contracted staff have "at least the same qualifications as hospice employees." We submit that this requirement would be difficult to administer at best, and at worst, it may be impossible to meet in certain geographic regions. An example of
this would be the provision of hospice care to a patient who resides in a nursing facility (NF). While the NF aide may bathe the patient once a week and the hospice aide twice a week, the NF aide would be certified as a nursing assistant, whereas the hospice aide would be a certified home health aide. This is due to the different licensing and certification requirements for a NF versus a hospice.

Finally, we appreciate CMS' concern that hospice satellite locations be approved by CMS before they commence hospice care. At the same time, as a practical matter, we would call to CMS' attention the length of time (two years or more) that it is taking satellite locations in some areas, such as California, to receive approval. We urge CMS to take steps to ensure prompt approval of satellite locations, to ensure service to patients located in outlying areas.

CMS Proposal: Section 418.102 – Medical Director

The proposed rule would require that the hospice designate a physician to serve as medical director who would coordinate with other physicians and health care professionals to "ensure that each patient experiences medical care that reflects hospice policy." The rule would further require that before the recertification period for each patient, the medical director or physician designee must review both the patient's clinical information and "the patient's and family's expectations and wishes for the continuation of hospice care." Proposed subsection (c) states that, while the medical director (or designee) and interdisciplinary group are jointly responsible for the coordination of care, the medical director alone is responsible for the hospice's quality assessment and performance improvement.

VITAS Comment

We believe that designating the medical director as responsible for the quality assessment and performance improvement would not be reflective of hospice's interdisciplinary model of care. Often, quite candidly, medical directors do not have the background for such supervision. We urge that the QAPI function be supervised by the specifically designated interdisciplinary group or appropriately qualified individual.

In addition, we request that the phrase "and wishes" be stricken from subsection (b)(2), for reasons discussed earlier on fractured family decisionmaking.

CMS Proposal: Section 418.104 – Clinical Records

The proposed rule would set forth a variety of requirements relating to the maintenance and content of patient clinical records. Subsection (e) would require that, where a patient was transferred to another Medicare/Medicaid approved facility or otherwise discharged (including revoking the hospice election), the hospice would have to forward a copy of the patient's clinical record as well as the hospice discharge summary to that facility or attending physician.

VITAS Comment

VITAS appreciates the concern that a patient's new hospice (or, in the case of a discharge or revocation, attending physician) possess the necessary information to provide effective care. Nevertheless, we submit that the requirement to forward a copy of the entire clinical record along with the discharge summary would be onerous, and may not be operationally feasible, especially for patients who have been on service for some period of time. Furthermore, such a requirement is not likely to contribute to improved quality of care, since the most relevant information would already be contained in the prescribed elements of the discharge summary: a summary of the patient's treatments, symptoms, and pain management; the current plan of care; the physician's order; and "any other documentation that will assist in post-discharge continuity of care." CMS

states in the Preamble its interest in ensuring that attending physicians and new hospices have "the most current clinical information" (70 Fed. Reg. at 30855), and we submit that this information will be contained in the discharge summary alone. Moreover, the clinical record typically contains information regarding the patient's family that we consider to be confidential.

CMS Proposal: Section 418.106 – Drugs, Supplies, and DME

The proposed rule would require that the interdisciplinary group determine the ability of the patient and family to administer medications as a part of the 14-day review of the plan of care that would be required by proposed section 418.54(d). The proposed rule would further require that the hospice have a written policy for tracking, collecting, and disposing of controlled drugs maintained in the patient's home. In addition, during the initial hospice assessment, the rule would require that the use and disposal of controlled substances be discussed with the patient and family to ensure the patient and family are educated regarding the uses and "potential dangers" of controlled substances, with the hospice required to document such discussion. The proposed rule also would require that the hospice ensure that the patient and family receive instruction in the safe use of durable medical equipment (DME) and supplies. Finally, the proposed rule would require that the hospice develop in writing its own repair and routine maintenance policy with respect to DME where there is no manufacturer recommendation for a piece of equipment.

VITAS Comment

As noted in our discussion of proposed section 418.54, we believe that an arbitrary 14-day requirement for the review of the plan of care would be impractical and unnecessary. We submit that the time frame for such review should reflect the patient's personal situation, occurring as often as necessary to meet the needs of the patient and family.

We have a number of comments regarding subsection (b), relating to controlled drugs in the home. First, as noted previously, we do not believe that hospices should be required to discuss drug disposal and the like at the time of admission, but only if or when it is determined that narcotics in fact will be used with a particular patient. We do not use narcotics on every patient, and this conversation has the potential to instill unnecessary fear in patients. Further, we question inclusion of the broad requirement to explain the "potential dangers" of controlled substances, for fear that it would scare our patients. As noted, the hospice industry has worked for years to dispel myths associated with narcotic use with terminally ill patients, and such phrases impede our progress. We do not believe that hospices should be required to document that they have discussed the use and disposal of controlled substances with the patient and family, but, rather, should have a policy that directs staff in the disposal of narcotics within the home. We also request that the word "collecting" be eliminated from subsection (b). "Collecting" implies removal and transporting of narcotics, which could pose safety problems to staff.

Further, the word "tracking" should be replaced with "monitoring" as it is more in line with the industry's practice in the patient's home.

We submit that the word "supplies" in subsection (c)(2) ("use and maintenance of equipment and supplies") is superfluous and should be eliminated. In addition, regarding DME, we submit that it should not be the hospice's responsibility to formulate a repair and routine maintenance policy for a piece of equipment, but rather the vendor's responsibility. Consequently, we request that CMS replace the third sentence of subsection (c)(1) with the phrase "when using an outside vendor for durable medical equipment, the vendor is responsible for obtaining and adhering to manufacturer repair recommendations and maintenance requirements."

CMS Proposal – 418.108 – Short-term Inpatient Care

The proposed rule would require that inpatient care be available for pain control, symptom management, and respite purposes, and be provided in a participating Medicare or Medicaid facility. The rule would eliminate a previous requirement that a registered nurse be available on a 24-hour basis.

VITAS Comment

While we appreciate CMS' concern for providing hospices with staffing flexibility, we believe that registered nurses should in fact be required for all patients receiving the General Inpatient level of care. Such a requirement would not need to apply, however, to patients receiving the Respite level of care. It is an important quality measure to have a registered nurse on site 24-hours per day to meet the potential needs of patients and families. Thus, we request that language be added to subsection (a)(2) that requires the availability of a registered nurse 24 hours per day for General Inpatient stays. In addition, we request that the phrase "crises of a psychosocial/family nature" be added to the first sentence describing the purposes for which inpatient care must be available. Finally, we request that subsection (a)(1) be changed from "A Medicare-approved hospice" to "A Medicare certified hospice."

VITAS requests that CMS clarify that a freestanding hospice inpatient facility operated by a Medicare certified hospice will qualify as a "participating Medicare or Medicaid facility" in this condition.

CMS Proposal – 418.110 – Hospices That Provide Inpatient Care Directly

The proposed rule provides numerous standards with which all hospices furnishing direct inpatient care would have to comply, including adequate staffing, 24-hour nursing services, safe premises, comfortable patient rooms, convenient toilet/bathing facilities, sanitary premises, healthy and appetizing meals, pharmaceutical services, and freedom from restraint/seclusion.

VITAS Comment

We have a variety of miscellaneous comments and recommendations on this section.

First, we request that subsection (c)(1)(ii) provide only that "the hospice must take steps to prevent equipment failure," eliminating the remainder of the sentence requiring the hospice to report such failure to "appropriate State and local bodies."

The patient room space requirements in subsection (f)(3)(iv) should require a patient room to accommodate "no more than two patients and families" (suggested new language underscored), to recognize the important role of ever-present families in the calculation.

We request that CMS add language to subsection (n), specifically to permit a patient to bring previously dispensed drugs into the hospice unit.

Finally, we have several concerns with subsection (o) relating to seclusion and restraint. The subsection as written is inappropriate in light of the fact that hospices use psychotropics in ways that are not "standard treatments" except in the hospice population. In this regard, CMS' references in the Preamble to the Children's Health Act (CHA) as justifying the need for new hospice provisions on seclusion and restraint are inapposite (70 Fed. Reg. at 30857). With respect to patient restraint, we submit that it would be wholly unrealistic to require a physician to evaluate the use of a restraint within the proposed one-hour time frame. In this regard, subsection (o)(3)(ii)(C) should be revised to read "A hospice medical director or physician designee should be consulted to evaluate the continued need for restraint or seclusion in an appropriate timeframe after the initiation of this intervention." We submit that the maximum time frames for seclusion and restraint set forth in proposed subsection (o)(3)(ii)(D), while potentially appropriate for CHA purposes, are wholly inappropriate in a hospice setting; we urge that this subsection be eliminated.

For example, bed rails and Posey vests, which might be considered restraints in other settings, are used in hospice for safety and to assist patients in positioning themselves and maintaining maximum independence. These interventions should be seen in a positive light and not as restrictions imposed on the patient. Finally, we request that subsection (o)(7) be eliminated, as we are already required to report adverse responses, and our patients are expected to die. Furthermore, the requirement to call CMS when a patient dies on, for example, haldol – a drug that might be viewed as restraining in nature, but is frequently used in a hospice setting –would be operationally impossible for both the provider and CMS, and could increase concerns about appropriate drug utilization for the symptom management of hospice patients.

CMS Proposal: Section 418.112 – Residents Residing in a Facility

The proposed rule would provide multiple additional standards with which all hospices that provide hospice care to residents of an SNF/NF, ICF/MR, or other facility must comply, including provisions requiring the medical director to provide overall coordination of the medical care of the hospice resident and further requiring a written agreement that specifies the provision of hospice services in the facility.

VITAS Comment

Our primary and overarching comment is to request that the effective date of this section be delayed until a parallel section is enacted for skilled nursing facilities (SNFs). In our view, this section could not be successfully implemented until the SNF/NF regulations containing a parallel condition conforming these requirements are published. Both entities need to be held to the same requirements at the same time.

To provide some background, we note that, when the Medicare Hospice Benefit was enacted, the primary site of death for Medicare beneficiaries was the hospital. The Hospice Benefit has played an important role in changing that trend, by providing support to terminally ill patients and their families, making it possible for them to die at home in accordance with their wishes. Not only was this a preferable option for many patients/families, it also proved to be cost effective for Medicare.

Today, the demographics have changed, longevity has increased, and people are living longer with multiple chronic illnesses and significant deficits in their ability to perform activities of daily living. As a result, the percentage of Medicare beneficiaries who die while residing in nursing facilities has increased, and VITAS and other hospices have responded by entering into agreements with long-term care facilities to make hospice services available to their residents. Research has indicated that a successful collaboration is beneficial to all concerned: patients, families, and staff of both providers.[1] A study published in the July 13, 2005 issue of the *Journal of the American Medical Association* indicates that simple communication efforts can improve the quality of end-of-life care and increase the use of hospice in nursing homes. A randomized controlled trial evaluated the impact of a "case finding" intervention and found that referrals to hospice were increased and that families' satisfaction ratings with the care their loved ones received at the end of life improved. The study also shows that simple communication interventions about hospice may also decrease the use of acute care resources.[2]

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6 Office of Disability, Aging and Long Term Care Policy, *Use of Medicare's Hospice Benefit by Nursing Facility Residents*,(Washington, D.C., Assistant Secretary for Planning and Evaluation, US DHHS, June 2000).

7 D Casarett, Intervention Increases Hospice Access for Nursing Home Residents and Raises Satisfaction Levels for Patients and Families. *JAMA*, (July 13, 2005).

To the extent that CMS does not delay issuance of these conditions until such time as the SNF conditions are issued, we have the following specific comments in a number of areas:

Title & First Sentence: We suggest revising the title and first sentence of this section to delete an ambiguous reference to "or other facilities." The conditions should apply to hospice services provided "to residents of an SNF/NF or ICF/MR" only – not to services provided in entities that are not subject to federal regulations, such as assisted living facilities. Such entities are regulated at the state level already and, as a practical matter, often do not provide medical services.

(a) Standard: Resident eligibility, election, and duration of benefits: Here too, the phrase "other facility" should be deleted, and a reference to ICF/MR should be added, so that the revised subsection would read:

(a) *Standard: Resident eligibility, election, and duration of benefits.* Medicare patients receiving hospice services and residing in a SNF/~~,~~ NF, or ~~other facility~~ ICF/MR must meet the Medicare hospice eligibility criteria as identified in §418.20 through §418.30.

(b) Standard: Professional management: Proposed section 418.100(e) already requires that hospices assume professional management responsibilities, so we believe this section to be unnecessary and recommend its deletion. We note that the SNF conditions of participation also require the nursing facility to assume professional management responsibility, resulting in occasional conflict between hospice staff (providing palliative care) and nursing staff (providing curative care and rehabilitation services).

(c) Standard: Core services: We also recommend deletion of this subsection, since the content is covered in section 418.64.

(d) Standard: Medical director: We request that subsection (d) reflect that the medical director may not necessarily be the "coordinator of hospice care," and that it therefore may not be appropriate to communicate with the SNF medical director at all. We believe this section might more appropriately be entitled "Physician services," and we believe additional provisions are needed to identify the respective roles of the hospice physician, attending physician, and the facility medical director. We recommend that this section be modified as follows:

(d) *Standard: ~~Medical director~~ Physician services.*

> (1) The medical director or~~and~~ physician designee of the hospice must provide clinical guidance in the development of patient care policies and procedures that meet the needs of terminally ill patients ~~overall coordination of the medical care of the hospice resident that resides in an SNF, NF, or other facility~~.

(2) The attending physician has primary responsibility for the medical care of an individual patient, in collaboration with the interdisciplinary team.

(3)The medical director or ~~and~~ physician designee must communicate, as appropriate, with the medical director of the SNF/NF or ICF/MR, the patient's attending physician, and other physicians participating in the provision of care for the terminal and related conditions to ensure quality care for the patient and family.

(e) Standard: Written agreement: We have a number of comments on this proposed subsection. First, we do not believe that CMS intended to require the written contract between the hospice and nursing facility to include the written consent of individual patients in its terms; more likely, CMS intended to specify that the hospice must obtain written consent from nursing facility patients. Providing the hospice election form to the facility, however, would satisfy this requirement.

In subsection (e)(2), we believe the respective roles of the hospice and nursing facility can be more clearly delineated, and we have set forth suggested language for two new subsections below. Subsection (e)(4) should be deleted; nursing facilities should not have to notify hospices if patients develop a "life threatening condition," because hospice patients by definition all have life threatening conditions. Subsections (e)(6) and (e)(7) also should be deleted, as these requirements would be covered in our suggested revisions section 418.112 (1) and (2).

In subsection (e)(8), we suggest clarifying that the hospice's ability to use the facility's nursing personnel to provide certain services will be determined by applicable State law, as well as the facility itself, and to note that the hospice patient's plan of care is to be a coordinated plan. The hospice should be able to have the facility's nursing personnel implement the plan of care to the extent that the hospice would be able to utilize the services of a hospice patient's family, if the patient resided at home. As a practical matter, family members and caregivers of hospice patients often perform skilled nursing care, after having been trained and educated by hospice staff. While nursing services admittedly are a core hospice service, we urge that CMS clarify that nursing facility staff can provide certain nursing services to hospice patients residing in the facility, to the extent that the hospice would have relied on the patient's family to do so in other settings, and to enhance patient safety and comfort. A good example would be the hospice patient who needs to be suctioned in the middle of the night. Hospice staff typically trains family members to provide suctioning so that the patient remains comfortable; in the same way, they would train the nursing home staff to do the suctioning until the hospice nurse is able to visit the patient.

Our suggestions on revising this subsection are set forth below:

(e) *Standard: Written agreement.* The hospice and the facility must have a

written agreement that specifies the provision of hospice services in the facility. The agreement must be signed by authorized representatives of the hospice and the facility before the provision of hospice services. The written agreement must include at least the following:

(1) That the hospice will supply a copy of the written consent of the patient or the patient's representative for each patient stating that hospice services are desired.

~~(2) The services that the hospice will furnish and that the facility will furnish.~~

(2)) Services to be provided by the hospice

(i) A delineation of the hospice's responsibilities, which include, but are not limited to, providing medical direction and management of the patient, nursing, counseling (including spiritual and dietary counseling), social work, bereavement counseling for immediate family members, provision of medical supplies and durable medical equipment, and drugs necessary for the palliation of pain and symptoms associated with the terminal illness, as well as all other hospice services that are necessary for the care of the resident's terminal illness.

(ii) Hospice services would be provided at the same level and to the same extent as would have been provided if the resident were in their own home.

(3) Services to be provided by the nursing facility:

(i) The nursing facility provides 24 hour room and board care, meeting the personal care and nursing needs that would have been provided by a primary caregiver in the home.

(ii) The services provided are at the same level that would have been provided if the resident had not elected to receive hospice services

(4) The manner in which the facility and the hospice are to communicate with each other to ensure that the needs of the patient are addressed and met 24 hours a day.

(5) A provision that the facility immediately notifies the hospice if—

(i) A significant change in the patient's physical, mental, social, or emotional status occurs;

(ii) Clinical complications appear that suggest a need to alter the plan of care;

~~(iii) A life threatening condition appears;~~

~~(iv)~~(iii) A need to transfer the patient from the facility and the hospice makes arrangements for, and remains responsible for, any necessary continuous care or inpatient care necessary related to the terminal illness; or

~~(v)~~(iv) The patient dies.

(6) A provision stating that the hospice assumes responsibility for determining the appropriate course of care, including the determination to change the level of services provided.

~~(6) An agreement that it is the facility's primary responsibility to furnish room and board.~~

~~(7) A delineation of the hospice's responsibilities, which include, but are not limited to, providing medical direction and management of the patient, nursing, counseling (including spiritual and dietary counseling), social work, bereavement counseling for immediate family members, provision of medical supplies and durable medical equipment, and drugs necessary for the palliation of pain and symptoms associated with the terminal illness, as well as all other hospice services that are necessary for the care of the resident's terminal illness.~~

(7) A provision that the hospice may use the facility's nursing personnel where permitted by State law and as specified by the facility to assist in the administration of prescribed therapies included in the coordinated plan of care only to the extent that the hospice would routinely utilize the services of a hospice resident's family in implementing the plan of care.

CMS Proposal: Section 418.114 – Personnel Qualifications for Licensed Professionals

The proposed rule would establish the requisite qualifications for all professionals who furnish services directly, under an individual contract, or under arrangements with a hospice; each would be need to acquire the proper license as required by the particular state in order to perform his or her functions. The proposed rule for social workers would require only a baccalaureate degree from a social work school as opposed to a master's degree in social work. Furthermore, the proposed rule would require the hospice to

perform criminal background checks on each hospice employee and contracted employee before employment at the hospice.

VITAS Comment

While VITAS requires a masters of social work degree for our social workers, we would support the requirement in subsection (c)(7) that a social worker need only have a baccalaureate degree from a school of social work rather than a masters of social work. We recognize that a master's degree in social work is not available in all locations, and therefore urge that CMS allow flexibility here. At the same time, we believe that the proposed requirement to conduct criminal background checks on *all* employees and contactors would be too far reaching and would present a significant financial burden. While patient protection from criminal acts is clearly an important goal, hospices should be permitted to limit such background checks to those providing and supervising patient care. We also believe that contracted agency staff should have their background checks conducted by the agency, as specified in the contract; it would be inappropriate for the hospice to conduct background checks on contracted employees. Language in the contract should require it of the vendor.

CMS Impact Analysis

The Impact Analysis discusses the burdens associated with compliance with each of the proposed rules.

VITAS Comment

We submit that CMS has greatly underestimated the costs related to each of the proposed changes. Many of these changes will present a great burden to providers large and small, and suggest that a more realistic estimation of these costs is in order.

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We appreciate the opportunity to submit comments, and would be pleased to answer questions or provide additional background, operational, or other information.

Sincerely,

Peggy Pettit

Peggy Pettit
Executive Vice President
Chief Operating Officer

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National Hospice and Palliative Care Organization

July 26, 2005

BY HAND DELIVERY

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

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

Dear Administrator McClellan:

The National Hospice and Palliative Care Organization ("NHPCO") appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS'") proposed changes to the Medicare and Medicaid Program proposed rule regarding Hospice Conditions of Participation. NHPCO is the largest nonprofit membership organization representing hospice and palliative care programs and professionals in the United States. The organization is committed to improving end of life care and expanding access to hospice care with the goal of profoundly enhancing quality of life for people dying in America and their loved ones. NHPCO represents 80 percent of the hospices in the United States, and our members care for over 90 percent of the nation's hospice patients.

NHPCO welcomes this long-awaited update of the hospice conditions of participation and has appreciated the opportunity to work with CMS on a number of initiatives that contributed to the development of these proposed rules. We have reviewed these proposed rules carefully and have sought significant input from hospice providers throughout the country. NHPCO is pleased to submit these comments for your consideration.

I. OUTCOME-BASED PERFORMANCE MEASURES

CMS has requested comments on its proposal to require that hospices implement an outcome based internal performance improvement program, and has specifically asked for

examples regarding clinical measures, patient experience of care measures, and systems measures specific to hospice care, including measures in development.

Currently, the Family Evaluation of Hospice Care (FEHC) and the End Result Outcome measures are the NHPCO tools used by many hospices to evaluate outcomes of clinical care. Further, member hospices collect data elements for the National Data Set that is comprised of data on structure and process such as employee retention, average length of stay, and average number of patient visits by discipline. NHPCO has developed a web-based system for submission of data for the NHPCO National Data Set and the FEHC, with an ability to aggregate and provide feedback information to participating hospices. These reports provide participating hospices with national level data to facilitate each program comparing their performance to an industry norm. The End Result Outcome Measures are also web-based; however, NHPCO is currently in the process of recruiting more hospices to collect data for these measures in order to develop a useful report.

Outcome measures regarding patient perception of care and bereavement services are currently in development by NHPCO and its research team. Survey tools should be available in the next two years. NHPCO will continue to identify and develop other outcome measures, and work with other vendors to develop hospice performance measures.

NHPCO is also a member of the National Quality Forum and is represented on the review committee for the Palliative and Hospice Care Quality project. While the first part of this project is to develop a framework and identify best practices in hospice and palliative care, it is anticipated that a second part of the project will focus on performance measures for endorsement. The NHPCO measures that include the FEHC, the End Result Outcome measures and the National Data Set, will be submitted for review and endorsement at that time. Any recommendations for research that result from this project will be explored by NHPCO.

Additional measures need to be identified, as NHPCO is committed to helping its members identify a core set of measures that address the six aims of the Institute of Medicine.[1] We are currently analyzing data from the National Data Set and the FEHC to develop measures of efficiency and equity, the two areas for which NHPCO does not have direct measures. As hospice and palliative care moves forward, adopting new technologies and developing new strategies for caring for people at the end of life, health services researchers in this field will continue to identify areas in practice that will benefit from evaluation with well-specified performance measures.

Like many others providing health care, many hospices find that performance measurement and reporting does pose challenges to organizations that are resource limited and/or are in rural areas where the challenges differ from their urban counterparts. It is not feasible to expect all hospices to be able to collect or submit performance measurement data within the next year (2006). Therefore, a reasonable timeframe for assisting those with the greatest needs is important. The measures currently available from NHPCO have been field tested for reliability,

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[1] Institute of Medicine, *Crossing the Quality Chasm.* (Washington D.C., National Academy of Sciences, 2001)

feasibility and validity. However, not all NHPCO members currently have the infrastructure for collecting all of these measures or the capability of fully analyzing performance measurement data.

II. DEFINITIONS (PROPOSED §418.3)

NHPCO has the following comments and request for changes to the proposed definitions:

Attending Physician – We request that CMS clarify that the hospice medical director or hospice physician, or a nurse practitioner employed by the hospice, may function as a patient's attending physician if so designated by the patient. CMS has stated this in the Medicare Benefit Policy Manual, Chapter 9, section 40.1.3b, but there continues to be confusion around this issue and it would be helpful to have it clarified in the final rule. There is currently no language in this definition that would indicate that option.

Bereavement Counseling – Although hospices typically make bereavement counseling and/or bereavement services available to a broad range of individuals, and certainly to the patient's primary caregiver(s) and those the patient considers to be their "family" (whether or not such individuals are legally so designated), the statutory obligation is limited to the patient's immediate family. The requested change to this definition is consistent with the statutory requirement in Section 1861(dd)(2)(A)(i) of the Social Security Act.

As specified above, we request that this definition be changed to read as follows:

> *Bereavement counseling* means emotional, psychosocial, and spiritual support and services provided to the patient's immediate family after the death of the patient to assist with issues related to grief, loss, and adjusting.

Clinical Note – Hospice care focuses on the patient's psychosocial as well as physical needs, and a change in a patient's spiritual condition is significant and may necessitate a change in a patient's plan of care.

As specified above, we request that this definition be changed to read as follows:

> *Clinical note* means a notation of a contact with the patient and/or the family that is written and dated by any person providing services and that describes signs and symptoms, treatments and medications administered, including the patient's reaction and/or response, and any changes in physical, spiritual, or emotional condition.

Drug Restraint – NHPCO requests that this definition be changed to "Chemical Restraint", which is the more commonly used and accepted term. We are requesting that this change be made throughout the proposed rules. In addition, NHPCO is concerned that confusion may arise

from this proposed definition. In the management and palliation of symptoms related to a patient's terminal illness it is accepted protocol to prescribe medications that, in other settings, might be considered a chemical restraint. This concern is addressed more fully in proposed 418.110(o).

As specified above, we request that the wording of this definition be revised as follows:

> ~~*Drug*~~*Chemical restraint* means a medication used to control behavior or to restrict the patient's freedom of movement, which is not ~~standard~~ an accepted treatment for a hospice patient's medical or psychiatric condition.

Representative – Increasingly patients designate someone to have a "health care power of attorney" to make health-related decisions on behalf of the patient when the patient is unable to do so, or when they are capacitated but choose to have their health care power attorney make those decisions on their behalf. NHPCO feels it is important to recognize this mechanism.

As specified above, we request that the definition be changed to read as follows:

> *Representative* means an individual who has the authority under State law (whether by statute, ~~or~~ pursuant to an appointment by the courts of the State, or designated under a health care power of attorney) to authorize or terminate medical care or to elect or revoke the election of hospice care on behalf of a terminally ill patient. ~~who is mentally or physically incapacitated~~. This may include a legal guardian.

In addition to the requested revisions listed above, NHPCO requests that the following additional definitions be considered for inclusion in the final rule:

Patient's Home – Hospices continue to face confusion among regulators and payers regarding whether various settings can be considered a hospice patient's home. NHPCO requests that CMS clarify that a patient's home is wherever the patient happens to reside, including skilled nursing facilities and a variety of other settings.

As specified above, we request that the following definition be added:

> *Patient's home* means wherever the patient resides, which may include a house, apartment, SNF/NF, ICF/MR, assisted living facility, adult home, shelter, or foster home.

Dietary Counseling – NHPCO requests that a definition of dietary counseling be added. The most common nutritional need is for education of the patient and family regarding patient nutrition expectations as the disease progresses. Alteration in nutritional status is an expected component of the hospice patient's illness course, and related education needs typically can be met by the hospice nurse with support from other team members. In the unusual situation in which a hospice patient requires complex medical nutritional services that are beyond the normal disease process (e.g. complicated feeding tube calculations or mechanical esophageal obstruction), services necessary to meet these needs should not be considered "dietary

counseling" and the hospice should be able to contract with a registered dietitian or other appropriate professional to provide these services.

As specified above, we request that the following definition be added:

> *Dietary counseling* means education and interventions provided to the patient and family regarding appropriate nutritional intake as the patient's condition progresses. Dietary counseling is provided by qualified individuals, which may include registered nurses, dietitians and nutritionists, when identified in the patient's plan of care.

III. PATIENT'S RIGHTS (PROPOSED §418.52)

NHPCO welcomes the addition of a provision specifically addressing patients' rights. The hospice philosophy of care is based on the concept of promoting an individual's right to make decisions about how they want to spend their final days, living and dying in comfort and with dignity. However, we do have concerns about some of the language in the proposed regulation, and also have suggestions for additions.

Proposed §418.52(a) *Standard: Notice of rights*

Proposed §418.52(a)(1), requires that hospices provide patients and their representatives with verbal and written notice of the patient's rights and responsibilities in a language and manner the patient understands. NHPCO is concerned that if this requirement is interpreted literally it could be extremely burdensome for many hospice programs in ethnically diverse areas. In some hospice service areas, there may be patients that speak hundreds of different languages and dialects, and hospices do not have the resources to translate their materials into every language they may encounter. Hospices use a variety of methods to communicate with patients, ensuring that they understand their rights and responsibilities.

Hospices need the flexibility to address this requirement in a way that takes into account the prevalence of a particular language in the hospice's service area, the size of the hospice program and its policies and procedures for addressing communication barriers. We would ask CMS to specify that hospices should develop and adhere to their own policies regarding how they will address the communication needs of patients, and to clarify in the preamble to the final rule or the interpretive guidelines that it may be permissible to ensure that patients understand their rights via an interpreter, family member, or someone else who understands and can communicate these rights to the patient.

As specified above, we request that proposed §418.52(a)(1) be revised as follows:

(a) Standard: Notice of rights.

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

Proposed §418.52(a)(3), requires informing the patient and family of the hospice's drug policies and procedures regarding the tracking and disposal of controlled substances. NHPCO is concerned about the use of the term "tracking" in this standard. As we understand it, the tracking procedure would require that the hospice nurse account for every dosage at every visit and make a record of the count, which would be extremely onerous and likely not well received by patients. NHPCO proposes the use of the term "monitoring," which would allow the hospice to have a policy that is flexible and can be implemented in a way to take into account the particular patient and family circumstances.

There also is confusion regarding the expected time frame for meeting this requirement, since in this section of the proposed regulations the implication is that patients and families would be informed of the hospice's drug policies "during the initial evaluation visit in advance of furnishing care" (consistent with the standard where this provision is placed). However, proposed §418.106(b), requires that the use and disposal of controlled substances must be discussed with the patient and family during the initial hospice assessment. In light of the similar intents of proposed §418.52(a)(3) and §418.106(b), and that the need to inform patients regarding a hospice's drug policies is not something one would typically think of as a "right", NHPCO requests that CMS delete proposed §418.52(a)(3). It is more appropriately placed under the proposed §418.106 condition of participation related to drugs.

While our preference would be to have 418.52(a)(3) deleted to avoid redundancy and potential confusion with 418.106(b), we request, at a minimum, that CMS consider the fragility of patients and their families at the time of admission to hospice care. The admission process includes, by necessity, an overwhelming amount of information that must be conveyed to and understood by patients and their families. Including additional information related to the hospice's drug policies and procedures in this early stage of hospice care (when it may not be immediately relevant) poses an unnecessary burden during an already difficult time. If CMS is unwilling to delete proposed §418.52(a)(3), we request that the language of this provision be revised.

As specified above, we request that proposed §418.52(a)(3) be deleted or, at a minimum, revised as follows:

(a) Standard: Notice of rights.

(3) The hospice must ~~inform~~ provide the patient and family with written information ~~of~~ regarding the hospice's drug policies and procedures, including the

policies and procedures regarding the ~~tracking~~ monitoring and disposing of controlled substances, that can be reviewed with the patient and family during the comprehensive assessment.

Proposed §418.52(a)(4) requires the hospice to maintain documentation that the patient or representative has demonstrated an understanding of their rights. NHPCO requests that CMS change "demonstrated an understanding" to "been informed of". If this change cannot be made, we request that CMS provide guidance on how a hospice would document that a patient or representative has "demonstrated" that they understand the rights addressed in this standard. We would recommend that a patient or representative's signature indicating that they have received their admission packet which includes information about these rights should be sufficient, and we request that the preamble to the final rule and/or the interpretive guidelines address this recommendation.

As specified above, we request that proposed §418.52(a)(4) be revised as follows:

(a) Standard: Notice of rights.

(4) The hospice must maintain documentation showing that it has complied with the requirements of this section and that the patient or representative has ~~demonstrated an understanding~~ been informed of these rights.

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

In proposed §418.52(b)(1), regarding the exercise of rights and respect for property and person, we would ask CMS to include the following additional rights:

- the right to receive information about the services covered under the Medicare Hospice Benefit
- the right to be involved in developing their plan of care, and
- the right to refuse treatment.

In proposed §418.52(b)(3), we would ask that the phrase "and practice" be added after "in accordance with State law", because it is our understanding that there are states in which the law itself may not specify who should be the patient's representative under certain circumstances, but standards or procedures have been developed and/or accepted by the State's courts.

In proposed § 418.52(b)(4), NHPCO is concerned about how this provision may be interpreted and the burdens it may place on hospices. For example, we are concerned about the requirement that hospices report all "alleged" violations involving "mistreatment", and ask that the term "mistreatment" be deleted because it is too vague and subject to varied

interpretation. It is not unusual for patients to feel that a family member or other person is not paying enough attention to them or not treating them as they would like, and they may even complain that they are being "mistreated", but this typically does not involve circumstances that would warrant reporting to state and local authorities.

NHPCO is also concerned about the requirement that all "alleged" violations be reported to state and local bodies, including the state survey and certification agency, even before the hospice has had an opportunity to investigate and determine whether the allegations are substantiated. We are requesting that this be revised to defer to state law. In this same provision we also request that the time frame for reporting be changed to within 5 working days of *becoming aware of* the incident. Hospice personnel are not necessarily in a patient's home every day, and cannot be expected to report an incident until after they have become aware of it.

As specified above, we request that proposed §418.52(b) be revised as follows:

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

(1) The patient has the right—

(i.) To exercise his or her rights as a patient of the hospice;

(ii.) To have his or her property and person treated with respect; ~~and~~

(iii.) To voice grievances regarding treatment or care that is (or fails to be) furnished and the lack of respect for property by anyone who is furnishing services on behalf of the hospice;~~ and~~

(iv.) To not be subjected to discrimination or reprisal for exercising his or her rights.

(v.) To be informed of the full range of services available under the Medicare hospice benefit;

(vi.) To be involved in developing his or her plan of care; and

(vii.) To refuse treatment.

(2) If a patient has been adjudged incompetent under State law by a court of proper jurisdiction, the rights of the patient are exercised by the person appointed pursuant to State law to act on the patient's behalf.

(3) If a State court has not adjudged a patient incompetent, any legal representative designated by the patient in accordance with State law or practice may exercise the patient's rights to the extent allowed by State law.

(4) The hospice must—

(i.) Ensure that all alleged violations involving ~~mistreatment~~, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property are reported to State and local bodies having jurisdiction (including to the State survey and certification agency), to the extent required by State law, within at least 5 working days of becoming aware of the incident, and immediately to the hospice administrator. Investigations and/or documentation of all alleged violations must be conducted in accordance with established procedures.

(ii.) Immediately investigate all alleged violations and immediately

take action to prevent further potential abuse while the alleged violation is being verified;

(iii.) Take appropriate corrective action in accordance with State law if the alleged violation is verified by the hospice administration or an outside body having jurisdiction, such as the State survey agency or local law enforcement agency; and

(iv.) Investigate complaints made by a patient or the patient's family or representative regarding treatment or care that is (or fails to be) furnished, lack of respect for the patient or the patient's property by anyone furnishing services on behalf of the hospice, and document both the existence of the complaint and the steps taken to resolve the complaint.

Proposed §418.52(e) *Standard: Patient liability*

Providers have commented that it would be very difficult to determine the patient's liability at the time of admission. For patients who reside in skilled nursing facilities, the determination of patient liability and responsibility as it relates to Medicaid room and board and the collection of the patient's share of cost is becoming increasingly problematic across the country, as Medicaid programs utilize provider tax programs, various reimbursement mechanisms and managed care. NHPCO recommends that when the patient is in a nursing facility and their room and board is paid by Medicaid, the responsibility for informing the patient of his or her liability should remain with the nursing facility since the facility is directly involved with the Medicaid program and is therefore better able to address payment problems with the patient or responsible party. This could be clarified in the preamble to the final rule.

As for patient liability for services not covered by the hospice, information on what Medicare and Medicaid will cover for hospice services is usually included in the hospice's admission packet. Since it is difficult to anticipate all of the individual's care needs, a hospice program would have difficulty informing the patient of his or her liability "before care is initiated."

Consistent with the concerns outlined above in reference to 418.52(a)(1), NHPCO also requests that in this standard, consideration be given to the difficulty many hospice programs would have meeting the requirement "and in a language that he or she can understand."

As specified above, we request that proposed §418.52(e) be revised as follows:

> (e) *Standard: Patient liability*. ~~Before care is initiated, t~~The patient must be informed, ~~verbally and in writing, and in a language~~ in a manner that he or she can understand, of the extent to which payment may be expected from the patient, Medicare or Medicaid, third-party payers, or other resources of funding known to the hospice.

IV. COMPREHENSIVE ASSESSMENT AND TIME FRAMES (PROPOSED §418.54)

NHPCO welcomes the addition of provisions regarding assessment of the patient, because this is essential to identifying and addressing each patient's specific needs and goals. We agree with the value and importance of completing a comprehensive, interdisciplinary, patient-specific assessment, and we understand the role of this assessment in the development of the patient's plan of care. The observations and recommendations of members of the IDG constitute the comprehensive assessment, and are the basis upon which the plan of care is developed. However, NHPCO and its provider members have major concerns about certain aspects of the proposed requirements.

The introductory provision of proposed §418.54, states that the hospice's assessment of the patient's care needs "includes, but is not limited to, the palliation and management of the terminal illness and related conditions." NHPCO is concerned that hospices would be held responsible for assessing care needs beyond their expertise, which is in the palliation and management of terminal conditions and related illnesses. NHPCO requests that CMS revise this provision to clarify that the hospice's obligation is to identify the patient's care needs as they relate to the patient's terminal illness.

Also in this section, we request that CMS change "terminal illness and related medical conditions" to "terminal condition and related illnesses" since a patient's terminal diagnosis may not be based on a single illness but rather on a combination of factors.

As specified above, we request that the introductory provision of proposed §418.54 be revised as follows:

> *§ 418.54 Condition of participation: Comprehensive assessment of the patient.* The hospice must conduct and document in writing a patient-specific comprehensive assessment that identifies the patient's need for hospice care and services, and the patient's need for medical, nursing, psychosocial, emotional, and spiritual care. This identification of care needs includes, ~~but is not limited to~~, the palliation and management of the terminal ~~illness~~ condition and related illnesses ~~medical conditions~~.

Proposed §418.54(a) *Standard: Initial Assessment*

NHPCO has several comments and requests for revisions to this proposed standard. We request that the standard specify that the initial assessment may be done by a hospice physician as well as a hospice registered nurse. We also request that CMS expand the exception to the 24 hour time frame to include situations when the patient or representative request a longer period before the initial assessment visit is made. Patients sometimes request that the assessment visit be scheduled to accommodate their particular situations or needs. For example, a patient may be waiting for family members to arrive from out of state, and may want them to be present during the assessment visit.

NHPCO also requests that CMS clarify in the preamble that the requirement of this standard is met so long as a hospice registered nurse makes the initial assessment visit within the 24 hour timeframe, but that other members of the interdisciplinary group also may visit the patient, either with the registered nurse or prior to the nurse's visit.

Although we agree that the initial assessment visit should be completed by a registered nurse or physician, we have concerns about the severe nursing shortage in the United States and the impact this requirement could have on hospices. We request that CMS be sensitive to this issue and consider some flexibility in revising the 24 hour time frame should the nursing shortage persist.

As specified above, we request that proposed §418.54(a) be revised as follows:

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

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

NHPCO has serious concerns about the proposed requirement that the comprehensive assessment be completed within 4 calendar days after the patient elects the hospice benefit. While a patient's immediate care and support needs would be identified during the initial assessment visit, and the hospice would begin addressing them before the comprehensive assessment is done, completion of a comprehensive assessment can take up to 7 days, for a variety of reasons. For example, patients electing hospice are often in crisis with severe pain. They do not want and/or are unable to participate in having other needs assessed until their pain is under control, which can take up to several days.

Also, when patients have complicated medical needs and/or multiple caregivers, it can require more than 4 days to gather information and make contact with all of the individuals necessary for the completion of a comprehensive assessment. A longer time frame will help ensure that the vast majority of patients and families receive the benefit of all disciplines, including social work and spiritual care. In rural areas, hospices utilize part time social workers and chaplains, making the completion of an assessment within 4 days not feasible, especially with weekend admissions. Allowing 7 calendar days for completion of the comprehensive assessment is also more manageable for patients and families given the activity attendant to the admission of a patient to hospice. We strongly urge CMS to allow hospices up to 7 days to complete the comprehensive assessment, but certainly no fewer than 5 days. Providers acknowledge that comprehensive assessments should be completed as soon as feasible for patients who are in crisis and/or whose death is imminent, but for most patients, a better comprehensive assessment could be provided if hospices are allowed sufficient time for its completion.

NHPCO also requests that CMS clarify what is required of the various IDG members, since a number of hospice providers and state associations have questioned whether this standard would require all members of the IDG to visit the patient as part of the comprehensive assessment. It is our understanding that this is not the case, and that the comprehensive assessment process will vary from patient to patient depending on the patient's specific circumstances, but may involve in-person meetings and communication, telephone calls, e-mails and team meetings.

To alleviate confusion regarding consultation with the attending physician, NHPCO requests that CMS provide clarification in the preamble to the final rule and/or the interpretive guidelines that the IDG's consultation with the patient's attending physician regarding the comprehensive assessment could occur by telephone.

As specified above, we ask that proposed 418.54(b) be revised as follows:

> (b) *Standard: Time frame for completion of the comprehensive assessment.* The hospice interdisciplinary group in consultation with the individual's attending physician, must complete the comprehensive assessment no later than 4 7 calendar days after the patient elects the hospice benefit.

Proposed §418.54(c) *Standard: Content of the comprehensive assessment*

NHPCO has a number of concerns about the organization of this standard and believes that, as drafted, it places too much emphasis on bereavement and drug therapy, and detracts from the key purpose of the comprehensive assessment, which is to identify the patient's physical, psychosocial, emotional and spiritual needs. We also believe other key elements should be added. For those reasons we are requesting a restructuring of this proposed standard.

In addition to the elements identified by CMS, NHPCO believes the comprehensive assessment should include consideration of: (1) the functional status of the patient, which includes their ability to understand their condition and proposed treatments, their ability to participate in planning their care, and their ability to perform activities of daily living and self-care; (2) the imminence of the patient's death, because so many patients are referred to hospice in the last few days of life, and therefore it is vital to take this into consideration in determining the patient's immediate care needs and prioritizing the care and services that should be provided; and (3) the severity of the patient's symptoms, which also is essential to assist in identifying and prioritizing the patient's and family's most immediate needs.

With respect to the requirement to review the patient's drug profile, we propose changing the proposed requirement to identify "ineffective" drug therapies, to identifying the effectiveness of drug therapies. This would be more comprehensive and would better reflect the reality that most drugs are not either effective or ineffective, but rather fall somewhere along a continuum. Similarly, NHPCO proposes changing "Unwanted drug side and toxic effects" to "drug side effects", which would be more comprehensive and reflect the range of effects that

may be caused by drug therapies. We believe a "toxic" effect would fall within the definition of a "side effect", and therefore is unnecessary.

We also request that CMS acknowledge that while hospices can evaluate a patient's drug profile and identify those drug therapies they believe to be less effective and those that have potentially problematic side effects, hospices have a limited ability to dictate what drugs a patient takes. Hospices can control what drugs are included in the hospice plan of care, and therefore are paid for by hospice, but they often cannot control what drugs a patient may choose to take, or be prescribed, particularly for reasons unrelated to the terminal illness. And certainly we would like for it to be clear that identification of a patient's drug therapies as part of the comprehensive assessment does not require that those drugs be included in the hospice plan of care and provided by hospice, unless the IDG and the attending physician so determine. The statute makes clear that payment with respect to hospice care is not made for items or services that are not reasonable and necessary for the palliation and management of the terminal condition, but there have been problems with hospices being held financially responsible for any drug identified on the plan of care.

As specified above, we request that proposed 418.54(c) be revised as follows:

> (c) *Standard: Content of the comprehensive assessment.* The comprehensive assessment must identify the physical, psychosocial, emotional, and spiritual needs related to the terminal illness that must be addressed in order to promote the hospice patient's well-being, comfort, and dignity throughout the dying process. The comprehensive assessment ~~describes~~ must take into consideration the following factors:
>
> (1) The nature and condition causing admission (including the presence or lack of objective data and subjective complaints);
> (2) Complications and risk factors that affect care planning,
> (3) Functional status, including the individual's ability to understand and participate in their own care;
> (4) Imminence of death;
> (5) Severity of symptoms;
> (6) ~~*Drug therapy.*~~ Drug profile. A review of the patient's prescription and over-the-counter drug profile, including but not limited to identification of the following—
> (i.) ~~Ineffective~~ Effectiveness of drug therapy;
> (ii) ~~Unwanted~~ Drug side ~~and toxic~~ effects; and
> (iii) Drug interactions.
> (7) *Bereavement.* An initial bereavement assessment of the needs of the patient's immediate family ~~and other individuals~~ focusing on the social, spiritual, and cultural factors that may impact their ability to cope with the patient's death. Information gathered from the initial bereavement assessment must be incorporated into the bereavement plan of care.
> (8) The need for referrals and further evaluation by appropriate health professionals.

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

NHPCO is concerned about timing issues under the proposed rule because the update of the comprehensive assessment would have to be accomplished at least every 14 days, and at the time of recertification. NHPCO requests that CMS change the 14 day time frame to 15 days. Although most hospices would still update the comprehensive assessment every 14 days, the additional day would allow for flexibility to accommodate holidays. For example, if the update of the comprehensive assessment typically is accomplished at the meeting of the interdisciplinary team every other Monday, the team should be allowed to meet on a Tuesday one week if there is a Monday holiday. We also request that the requirement to update the comprehensive assessment at the time of each recertification be deleted. The update would be done as needed, but at least every 14 days, so there is no need to mandate that it also be done prior to each recertification, which in some cases will require that updates be done within just a few days of one another.

As specified above, we request that proposed 418.54(d) be revised as follows:

> (d) *Standard: Update of the comprehensive assessment.* The update of the comprehensive assessment must be accomplished by the hospice interdisciplinary group and must consider changes that have taken place since the initial assessment. It must include information on the patient's progress toward desired outcomes, as well as a reassessment of the patient's response to care. The assessment update must be accomplished—
>
> (1) As frequently as the condition of the patient requires, but no less frequently than every ~~14~~ 15 days; and
>
> ~~(2) At the time of each recertification.~~

Outcome Measures (proposed §418.54(e))

NHPCO appreciates the flexibility provided by CMS on how the data elements will be determined and how they will be integrated into the comprehensive assessment. Providers have expressed concerns that this requirement will be burdensome on small hospices, and that many hospices will need to make major changes to be able to use the data collected. For many providers in different parts of the country, data collection is in its infancy. Many hospices and state hospice associations commented that smaller hospices have difficulty understanding the value and return on investment of this requirement, especially when faced with finite resources – time, people and money. Another concern expressed is that patient outcome measures may take some time to develop and that currently, not many outcome measures are in place.

Other providers suggested that a list of possible outcome measures be provided as examples so that providers would have a clearer understanding of the intention of CMS. A possible list might include pain management, fall risk and prevention, adverse drug reactions, medication reconciliation, life closure, device-related urinary tract infections, management of

documentation, national patient safety goals implementation, wound management, adequacy of communication with the attending physician, home health aide supervision, client response to pain management strategies and medication compliance, documentation of level of care changes, and quality of care at the time of death. With a list of possible outcome measures, CMS could also provide some guidance to give hospice programs a basic foundation in what is expected under this proposed new standard.

NHPCO is able to assist the hospice industry with standardizing data elements so that they can be benchmarked between providers. Providers can also be assured that much of the data is already collected in the patient's clinical record.

NHPCO is not requesting any changes to this proposed standard.

V. PLAN OF CARE OR COORDINATION OF SERVICES (PROPOSED §418.56)

Proposed §418.56(a) ***Standard: Approach to service delivery***

In proposed §418.56(a)(1)(i) we request that CMS delete the limitation that the physician member of the IDG may not be the patient's attending physician, since the hospice medical director or other hospice physician may serve as the patient's attending physician. There are many scenarios in which this could cause unnecessary distress to the patient and family. Examples include: the physician who has been caring for the patient prior to the patient's election of the hospice benefit does not wish to act as the patient's attending physician once the patient elects hospice; the hospice medical director was already the patient's attending physician before the patient elected hospice; the patient chooses to designate a hospice physician as their attending physician rather than the physician previously overseeing their care; or, patients electing the hospice benefit do not have a relationship with a physician who can function as the attending physician, and therefore the hospice medical director or other hospice physician functions in that role.

The language in proposed §418.56(a)(1)(iv) specifying that the IDG must include a "pastoral, clergy or other spiritual counselor" is inconsistent with the statute (Social Security Act §1861(dd)(2)(B)(i)) and would unduly limit the types of counselors who could serve on the IDG. We are requesting that this be revised as noted below.

Proposed §418.56(a)(2), regarding designation of a single interdisciplinary group to establish policies governing the day-to-day provision of hospice care and services, is inconsistent with current practice and is overly prescriptive. Typically, hospices designate one of their IDGs to also establish these policies, or appoint a separate interdisciplinary group that is tasked with establishing policies and overseeing day-to-day provision of hospice care and services. Therefore, we are requesting revisions to this provision, as noted below, to allow the hospice to select and designate the individuals best suited to this role, whether or not they otherwise all serve on the same IDG.

As specified above, we request that proposed 418.56(a) be revised as follows:

(a) *Standard: Approach to service delivery.*

(1) The hospice must designate an interdisciplinary group or groups composed of individuals who work together to meet the physical, medical, social, emotional, and spiritual needs of the hospice patients and families facing terminal illness and bereavement. Interdisciplinary group members must provide the care and services offered by the hospice, and the group in its entirety must supervise the care and services. The hospice must designate a qualified health care professional that is a member of the interdisciplinary group to provide coordination of care and to ensure continuous assessment of each patient's and family's needs and implementation of the interdisciplinary plan of care. The interdisciplinary group must include, but is not limited to, individuals who are qualified and competent to practice in the following professional roles:

(i) A doctor of medicine or osteopathy ~~(who is not the patient's attending physician)~~.

(ii) A registered nurse.

(iii) A social worker.

(iv) A pastoral~~, clergy,~~ or other ~~spiritual~~ counselor.

(2) If the hospice has more than one interdisciplinary group, it must ~~designate~~ identify in advance a specifically designated interdisciplinary group ~~only one of those groups~~ to establish policies governing the day-to-day provision of hospice care and services.

Proposed §418.56(b) *Standard: Plan of care*

NHPCO requests that this standard be revised to accommodate the fact that the responsibilities assumed by patients, families and caregivers in providing care and services varies, and the hospice's responsibility to provide education and training to these individuals should vary accordingly. For example, a family member may be involved in making decisions but not in the actual provision of certain types of care. In that situation the hospice should not be responsible for training that person to provide the care to the patient. As set forth below, we are proposing a revision that would allow the hospice to tailor their education and training of individuals to their assumed and expected responsibilities for providing care.

As specified above, we request that proposed 418.56(b) be revised as follows:

(b) *Standard: Plan of care*. All hospice care and services furnished to patients and their families must follow a written plan of care established by the hospice interdisciplinary group in collaboration with the attending physician. The hospice must ensure that each patient and family and primary caregiver(s) receive education and training provided by the hospice as appropriate to their

responsibilities for the care and services identified in the plan of care.

Proposed §418.56(c) *Standard: Content of the plan of care*

We have a number of requested revisions regarding the content of the plan of care, which we believe will better serve the needs of patients and provide hospices with greater flexibility to meet patient needs. We believe the introductory section could be interpreted too broadly, and therefore we propose specifying that the plan of care is focused on services necessary for the palliation or management of the terminal condition. We believe this change is necessary because the Medicare statute defines "hospice care" to include any item or service specified in the plan of care and for which payment may otherwise be made under Medicare. This change would clarify that the hospice is not responsible for care planning related to treatment of the patient's health problems that are unrelated to the palliation and management of the terminal condition.

NHPCO believes proposed §418.56(c)(2) requiring a detailed statement of the scope and frequency of services is overly prescriptive and inconsistent with CMS' intended shift to an outcome-oriented and patient-centered approach. Many patients have very short lengths of stay in hospice, and because of the acuity of the condition of many patients, their needs with respect to the scope and frequency of services may change often and unexpectedly. We are proposing revisions that would give hospices more flexibility to adapt to patients' changing needs and desires without being held to specific requirements and timeframes that may no longer be appropriate after a short period of time.

We are requesting changes to §418.56(c)(6) to acknowledge that even when patients agree with the plan of care, some or all of their family may not, and the level of understanding and agreement among these individuals regarding the plan of care may vary. We believe the hospice should be able to document the patient's understanding, involvement and agreement with the plan of care, and to document discussions about the plan of care with the family, and the hospice's perceptions regarding the level to which the family understands and/or agrees with the plan of care. However, the hospice cannot assure that all family members will understand or agree with the hospice patient's plan of care.

As specified above, we request that proposed 418.56(c) be revised as follows:

> (c) *Standard: Content of the plan of care*. The hospice must develop a written plan of care for each patient that reflects prescribed interventions based on the problems identified in the initial comprehensive and updated comprehensive assessments, and other assessments. The plan of care must ~~include~~ address services for the palliation and management of the terminal condition, including ~~but not be limited to —~~
>
> (1) Interventions to facilitate the management of pain and symptoms;
> (2) A ~~detailed~~ statement of the anticipated scope and frequency of services necessary to meet the ~~specific~~ changing patient and family needs;

(3) Measurable targeted outcomes anticipated from implementing and coordinating the plan of care;
(4) Drugs and treatment necessary to meet the needs of the patient;
(5) Medical supplies and appliances necessary to meet the needs of the patient; and
(6) The interdisciplinary group's documentation of the patient's understanding, involvement, and agreement, and the family's level of understanding, involvement, and agreement with the plan of care, in accordance with the hospice's own policies, in the clinical record.

VI. QAPI (PROPOSED §418.58)

Comments that NHPCO received from providers on this condition of participation and its related standards support CMS' commitment to significantly strengthen the current quality assurance requirement. Concerns that were noted include the financial impact on small programs, and a potential for a redirection of limited resources to be used for non-patient care activities. Several providers also suggested that having domains defined in the standards would help focus outcome measurement accordingly.

Proposed §418.58(a) *Standard: Program scope.*

The hospice industry is in the early stages of development in identifying and measuring data for performance improvement purposes. It is NHPCO's hope that CMS would recognize and ensure leniency in this area.

Proposed §418.58(d) *Standard: Performance improvement projects.*

Providers had questions about the number and complexity of quality improvement projects. NHPCO would recommend some discussion in the preamble of the final rule that would answer the following questions: How is CMS going to determine measures of "complexity" for the hospice's performance improvement project? How would the complexity and scope be judged? What is an adequate number of quality improvement projects? If a hospice participates in a national quality improvement project pertaining to an issue consistent across the majority of hospices, would that satisfy this standard?

NHPCO would suggest that language in the preamble encourage hospice providers to participate in national quality improvement projects. It provides an opportunity for the whole industry to adopt and work on specific performance improvement areas that may apply to a majority of hospices in the country. A good example of a national performance improvement project would be the measurement and improvement of pain management. The appropriate management of pain is a priority for Medicare beneficiaries and is one of the national priorities in the Institute of Medicine report *Crossing the Quality Chasm*[2]. Hospices should

[2] Institute of Medicine, *Crossing the Quality Chasm*,(Washington, D.C., National Academy of Sciences, 2001

participate in developing a national response.

As specified above, we request that proposed §418.58(d) be revised as follows:

(1) The number and scope of distinct performance improvement projects conducted annually, based on the needs of the hospice's population and internal organizational needs, must reflect the scope, complexity, and past performance of the hospice's services and operations.

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

VII. INFECTION CONTROL (PROPOSED §418.60)

We believe this proposed regulation reflects current standards of practice in health care. NHPCO has no comments.

VIII. LICENSED PROFESSIONAL SERVICES (PROPOSED §418.62)

NHPCO requests that the requirement that licensed professionals actively participate in the coordination of all aspects of the patient's care be limited to the patient's hospice care, since hospices cannot control other aspects of their patients' care.

As specified above, we request that proposed §418.62(b) be revised as follows:

(b) Licensed professionals must actively participate in the coordination of all aspects of the patient's hospice care, in accordance with current professional standards and practice, including participating in ongoing interdisciplinary comprehensive assessments, developing and evaluating the plan of care, and contributing to patient and family counseling and education; and

IX. CORE SERVICES (PROPOSED §418.64)

NHPCO is concerned that the revised core services provision, as drafted, could be interpreted to limit the flexibility that always has been available to hospices to use contracted staff, if necessary, to supplement hospice employees in order to meet the needs of patients during periods of peak patient loads or under extraordinary circumstances. In proposed §418.64 CMS has added a sentence to address the changes made by section 946 of the Medicare Modernization Act, which specifies that a hospice may enter into arrangements with another Medicare-certified

hospice to obtain core hospice services under certain circumstances, such as when a hospice patient travels outside the hospice's service area for a limited period of time. We request that CMS clarify that this provision does not limit hospices to contracting only with another hospice, and that hospices also may use contracted staff from a nursing registry, home health agency or other entity under extraordinary circumstances, as is currently permitted. In some areas, contracting with another hospice may not be possible, either because there are no other hospices nearby, or for competitive or other reasons the hospice may not be willing or able to provide staffing to another hospice, therefore it is essential that hospices continue to have the flexibility to use contracted staff from other sources in order to meet patient needs when extraordinary circumstances arise.

As specified above, we request that proposed §418.64 be revised as follows:

> A hospice must routinely provide substantially all core services directly by hospice employees. These services must be provided in a manner consistent with acceptable standards of practice. These services include nursing services, medical social services, and counseling. The hospice may contract for physician services as specified in § 418.64(a). A hospice may, under extraordinary or other non-routine circumstances, use contracted staff if necessary to supplement hospice employees in order to meet the needs of patients during periods of peak patient loads or under extraordinary circumstances. A hospice may also enter into a written arrangement with another Medicare certified hospice program for the provision of core services to supplement hospice employee/staff to meet the needs of patients. Circumstances under which a hospice may enter into a written arrangement for the provision of core services include: Unanticipated periods of high patient loads, staffing shortages due to illness or other short-term temporary situations that interrupt patient care; and temporary travel of a patient. If contracting is used, the hospice must maintain professional, financial, and administrative responsibility for the services and must assure that the qualifications of staff and services provided meet the requirements specified in this subpart.

Proposed §418.64(b) Standard: Nursing services

Although continuous care is not mentioned in CMS' proposed rule regarding core services, NHPCO wishes to comment on our continued concerns that hospices are not permitted to contract for continuous care staffing on a routine basis, even with appropriate training and communication systems in place. In all levels of hospice care, the core IDG maintains professional management responsibility for the care provided. Many hospice programs are not able to provide the level of nursing services required for continuous care due to the great fluctuation in the number of hours and the number of patients that may need continuous care at any given time. Nurses who will work PRN are less and less available, and there can be greater consistency in being able to offer this important level of care if hospices were permitted to contract with an agency. We request that a formal dialogue with CMS staff begin on this issue and its possible solutions.

Proposed §418.64(d) *Standard: Counseling services*

The requirement proposed in §418.64(d)(1)(ii) regarding the provision of bereavement counseling to residents and employees of a SNF/NF and ICF/MR or other facility exceeds the statutory authority, which requires only that hospices provide bereavement counseling "for the immediate family of terminally ill individuals." (Social Security Act section 1861(dd)(2)(A)(i)). Although hospices typically define who constitutes a patient's "family" broadly, and certainly might provide bereavement counseling to a hospice patient's roommate, friends and caregivers in a SNF/NF or ICF/MR, when appropriate, the statute does not require them to do so. In addition, hospices typically provide a broad range of bereavement-related services, including services provided to members of the community who may have had no involvement with the hospice, but these services are not required by the statute.

With respect to spiritual counseling, we request that CMS clarify in the final rule that hospices are only required to facilitate visits by local clergy or others who can support the patient's spiritual needs, and that the hospice is not required to arrange visits by out-of-town spiritual counselors.

As specified above, we request that proposed 418.64(d)(1) be revised as follows:

(d) *Standard: Counseling services.* Counseling services for adjustment to death and dying must be available to both the patient and the immediate family. Counseling services must include but are not limited to the following:

(1) *Bereavement counseling.* The hospice must:

(i) Have an organized program for the provision of bereavement services furnished under the supervision of a qualified professional with experience in grief/loss counseling.

(ii) Make bereavement services available to the immediate family and other individuals identified in the bereavement plan of care up to one year following the death of the patient. Bereavement ~~counseling~~ services ~~also~~ may extends to residents and employees of a SNF/NF~~,~~ or ICF/MR~~, or other facility~~ when appropriate and identified in the bereavement plan of care.

(iii) Ensure that bereavement services reflect the needs of the bereaved.

(iv) Develop a bereavement plan of care that notes the kind of bereavement services to be provided and the frequency of service delivery. A special coverage provision for bereavement counseling is specified in § 418.204(c).

X. STATUTORY NURSING WAIVER (PROPOSED §418.66)

We understand that the requirements for obtaining the nursing waiver addressed in proposed §418.66 are set forth in the Social Security Act, and we agree that this provision may be obsolete since it applies only to hospices that were in operation on or before January 1, 1983, and are located in an area that is not urbanized. However, CMS also has used its discretion to determine that the current nursing shortage constitutes an "extraordinary circumstance" and has allowed hospices affected by the shortage to obtain a waiver and contract for nursing services if certain conditions are met. A number of hospice providers reported there have been problems in accessing this nursing waiver throughout the country. CMS regional offices do not understand the process when hospices try to apply for the nursing waiver, and have limited hospices access to hospices for this reason. We would like the process to be more user-friendly. We also request clarification as to who is eligible for the waiver. With the nursing shortage, there is a need for the waiver in many urban areas as well as rural, since hospices serving inner city areas have problems similar to rural areas in employing nurses.

XI. NON-CORE SERVICES - PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND SPEECH-LANGUAGE PATHOLOGY, AND WAIVER OF REQUIREMENTS (PROPOSED §§418.70, 418.72 AND 418.74)

We have no comments on these conditions.

XII. HOME HEALTH AIDE AND HOMEMAKER SERVICES (PROPOSED §418.76)

Proposed §418.76(c) ***Standard: Competency Evaluation***

We request that this standard be revised to clarify that it applies to home health aide services.

As specified above, we request that proposed 418.76(c) be revised as follows:

> (c) *Standard: Competency evaluation.* An individual may furnish home health aide services on behalf of a hospice only after that individual has successfully completed a competency evaluation program as described in this section.

Proposed §418.76(e) ***Standard: Qualifications for instructors conducting classroom supervised practical training, competency evaluations and in-service training***

We request that this provision be revised to specify that a registered nurse performing or supervising the classroom training must have experience in hospice or home health care.

As specified above, we request that proposed 418.76(e) be revised as follows:

> (e) Classroom supervised practical training must be performed by or under the supervision of a registered nurse who possesses a minimum of two years nursing experience, at least one year of which must be in hospice or home health care. Other individuals may provide instruction under the general supervision of a registered nurse.

Proposed §418.76(f) *Standard: Eligible training organizations*

We request that the exception regarding who is permitted to offer home health aide training programs should be changed from a home health agency to a hospice, since this is a hospice standard.

As specified above, we request that proposed 418.76(f) be revised as follows:

> (f) A home health aide training program may be offered by any organization except by a ~~home health agency~~ hospice that, within the previous 2 years— ...

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

We request that this standard be more flexible regarding the ordering of services, and defer to state law. A physician or nurse practitioner's order is not necessarily required for home health aide services, and in many cases the IDG could be more responsive and would appropriately determine a patient's need for such services.

We also are requesting that CMS provide clarification regarding the role of a home health aide in assisting with administration of medications that are ordinarily self-administered. In particular, we would like guidance on how this would be determined, and what assistance the home health aide may provide.

As specified above, we request that proposed §418.76(g) be revised as follows:

> (g) A registered nurse or the appropriate qualified therapist that is a member of the interdisciplinary team makes home health aide assignments.
>
> (1) Home health aides are assigned to a specific patient by a registered nurse or the appropriate qualified therapist. Written patient care instructions for a home health aide must be prepared by a registered nurse or other appropriate skilled professional (*i.e.*, a physical therapist, speech-language pathologist, or occupational therapist) who is responsible for the supervision of a home health aide as specified

under paragraph (h) of this section.

(2) A home health aide provides services that are:

(i) Ordered, as required by state law ~~by the physician or nurse practitioner~~;

(ii) Included in the plan of care;

(iii) Permitted to be performed under State law by such home health aide; and

(iv) Consistent with the home health aide training.

Proposed §418.76(h) *Standard: Supervision of home health aides*

NHPCO appreciates the importance of assuring the competence of home health aides, and the quality of services they provide. However, we have serious concerns about the requirements of this standard. We believe they would be extremely burdensome and would not offer any greater assurance of the quality of hospice services provided.

We do not have concerns with the requirement in §418.76(h)(1) that an evaluation visit by a registered nurse or qualified therapist to each individual patient's home be made at least every 14 days to assess the home health aide's services. We agree that this evaluation can provide helpful information that would allow the nurse or therapist to update the plan of care and/or provide the aide with additional information or instruction. However, we find the second section of this standard confusing. It requires that a nurse or qualified therapist make an "onsite visit to the location where the patient is receiving care in order to observe and assess each aide while he or she is performing care no less frequently than every 28 days." This could be interpreted to require that every aide be evaluated while providing care to every one of his/her patients every 28 days. However, for purposes of this comment, we are assuming that it requires that each aide be evaluated while providing care to any one patient every 28 days, and that the results of the evaluation would be documented in the home health aide's personnel record. Nonetheless, we strongly object to this requirement.

In a June 2005 presentation on these proposed regulations, a CMS staff member suggested that this requirement was related to the short length of stay for hospice patients; however we see no logical connection between that observation and the proposed requirement since the intent is to assess the aide's services and competency in general, not necessarily the home health aide services received by a particular patient.

While home health aides are paraprofessionals who are called upon to work independently, a requirement that would mandate mini-competency assessments 13 times a year is excessive. Home health aides are trained to deliver a very specific set of clearly defined services; approved training programs focus on assuring competency in these duties. Home health aides work from a patient-specific plan of care prepared by the registered nurse or qualified therapist. They receive a minimum of 12 hours of inservice training annually and periodic competency assessments. The services they provide are evaluated every 14 days to assure quality and competence and that care is being provided in accordance with the patient's plan of care.

We believe that a requirement that would find optimal balance between promoting safe, high quality patient care and wise use of resources would be to: (1) continue to require that the registered nurse or the qualified therapist complete an on-site evaluation visit to the residence of each patient when the patient's plan of care includes home health aide services (the aide would not have to be present for this visit); and (2) on a quarterly basis, require the registered nurse or qualified therapist to conduct an observation visit in order to observe and assess each aide while he/she is performing care.

As specified above, we request that proposed 418.76(h)(1) be revised as follows:

Proposed 418.76(h)(1) *Standard: Supervision of home health aides.*

(1) A registered nurse or qualified therapist must make an onsite visit to the patient's home no less frequently than every 14 days to assess the home health aide's services. The home health aide does not have to be present during this visit. A registered nurse or qualified therapist must make an onsite observational visit to the location where ~~the~~a patient is receiving care in order to observe and assess each aide while he or she is performing care no less frequently than every ~~28 days~~ quarter.

Proposed 418.76(i) ***Standard: Individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit***

Patients who have been receiving personal care aide services under a Medicaid waiver program, and who are eligible for hospice care, often have to choose between the aide services and hospice care because the State Medicaid agency has interpreted the current home health aide requirements in the conditions of participation to be duplicative of the waiver program services. The wording that has been questioned is in the current Conditions of Participation, §418.94 Home Health Aide Services, which states "Home health aide and homemaker services must be available and adequate in frequency to meet the needs of the patients." CMS has also tried to clarify this issue through regional office Program Memoranda. NHPCO requests that CMS clarify that the primary caregiver function is not a service provided by hospice. Many Medicaid waiver programs are providing the equivalent of primary caregiver or attendant care services, not a service provided by hospice.

This standard references only the qualifications of the home health aide. We would request language that would address the option of personal care services and hospice services being provided concurrently.

As specified above, we request that a sentence be added at the end of proposed 418.76(i) as follows:

(i) *Standard: Individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit.* An individual may furnish personal care services, as defined in § 440.167 of the Code of Federal Regulations, on behalf of a hospice or home health agency. Before the individual may furnish personal care services, the individual must be found competent by the State to furnish those services. The individual only needs to demonstrate competency in the services the individual is required to furnish. Personal care aide only services are not considered to be duplicative of home health aide services provided by the hospice and can be coordinated between the hospice and the personal care aide services provider.

Proposed 418.76(j) *Standard: Homemaker qualifications*

A number of providers commented that in some rural areas, home health aides are very difficult to find, and clarification on the qualifications for a homemaker would be helpful. NHPCO is requesting that CMS clarify that homemaker services could be provided by employees or volunteers who do not meet the training requirements of a home health aide.

As specified above, we request that proposed 418.76(j) be revised as follows:

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

XIII. VOLUNTEERS (PROPOSED § 418.78)

Proposed §418.78(e) *Standard: Level of activity*

NHPCO is requesting a revision to this standard to specify that the total patient care hours from which the 5 percent volunteer requirement is calculated is routine home care hours. With more and more hospice patients utilizing short term inpatient care in a hospice facility, the total patient care hours provided by paid staff has increased with the 24/7 staffing requirements in these facilities. In addition, some hospices find it difficult to find sufficient volunteers to meet the requirement, due to more working volunteers and the aging population.

We also request that CMS further clarify what types of volunteer hours can be used in the calculation of the 5 percent volunteer requirement. There continues to be confusion in the field about the issue, and the question has been raised in several CMS Open Door Forum calls. We are proposing the addition of a sentence at the end of 418.78(e) to address that clarification.

As specified above, we request that §418.78(e) be revised as follows:

(e) *Standard: Level of activity.* Volunteers must provide day-to-day administrative and/or direct patient care services in an amount that, at a minimum, equals 5 percent of the total ~~patient~~ routine home care patient care hours of all paid hospice employees and contract staff. The hospice must maintain records on the use of volunteers for patient care and administrative services, including the type of services and time worked. The volunteer hours that may be used in the calculation of the 5 percent requirement may include volunteer travel time, actual time worked as a volunteer, and time spent documenting services provided. Training and orientation time may not be counted for purposes of meeting the 5 percent requirement.

XIV. ORGANIZATION AND ADMINISTRATION (PROPOSED §418.100)

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

While the goal of hospice is to serve the needs of dying patients and their families, NHPCO is concerned about the language in §418.100(a) requiring that the hospice "must ensure" that the patient experiences hospice care that optimizes comfort and dignity, and "must ensure" that hospice care is consistent with the patient's and family's "desires". The hospice should be responsible for ensuring that the patient receives hospice care that is included in the plan of care and intended to optimize the patient's comfort and dignity, but the hospice cannot ensure how patients will experience the care they receive. Similarly, hospices should ensure that the hospice care provided is consistent with the patient's and family's needs, as identified in the plan of care, but hospices should not be held responsible for all of the patient's and family's desires, particularly to the extent that the family's desires are not consistent with the patient's.

As specified above, we request that proposed §418.100(a) be revised as follows:

(a) *Standard: Serving the hospice patient and family.* The hospice must ~~ensure~~provide—

(1) ~~That each patient receives and experiences~~ Hospice care that optimizes comfort and dignity; and

(2) ~~That each patient experience~~ Hospice care that is consistent with patient and family needs ~~and desires.~~ as identified in the comprehensive assessment and included in the patient's plan of care.

Proposed §418.100(e) *Standard: Professional management responsibility*

NHPCO is quite concerned about the use of the word "supervision" in this standard as it relates to the relationship between the hospice and a contracted provider or service. While we agree that hospices have professional management responsibility for services provided under contract, we would recommend the use of the word "oversight" to more accurately reflect the relationship, and we request that the responsibility extend only to the services provided, not to the contracted staff themselves. We believe this is consistent with the statutory requirement in section 1861(dd)(2)(A)(ii)(II) which requires that when a hospice does not provide a service directly, it "must maintain professional management responsibility for all such services". It is our understanding that requiring hospices to supervise the staff of an independent contractor could be considered to create a "joint employer" relationship that could, in turn, lead to unintended liability for the hospice, including potential liability for the employment actions of the independent contractor company.

We are also concerned about the requirement in §418.100(e)(2) that staff furnishing arranged services have the "same qualifications" as hospice employees. Under normal circumstances, hospices would be contracting for services that complement hospice staff's expertise and services. Two individuals can both be qualified by training and/or experience to provide a service, but they may not have the "same qualifications". An example of this would be hospice care provided to a patient who resides in a nursing facility. While the NF aide may bathe the patient once a week and the hospice aide twice a week, the NF aide would be certified as a nursing assistant, whereas the hospice aide would be a certified home health aide. This is due to the different licensing and certification requirements for a NF versus a hospice. We would recommend that the language "qualified personnel" be used to better reflect the intention of this standard.

As specified above, we request that proposed §418.100(e) be revised as follows:

(e) *Standard: Professional management responsibility*

A hospice that has a written agreement with another agency, individual, or organization to furnish any services under arrangement, must retain administrative and financial management, and ~~supervision of staff and services~~ oversight for all arranged services, to ensure the provision of quality care. Arranged services must be supported by written agreements that require that all services be --...

(1) Authorized by the hospice;
(2) Furnished in a safe and effective manner by ~~personnel having at least the same qualifications as hospice employees;~~ qualified personnel; and
(3) Delivered in accordance with the patient's plan of care.

Proposed §418.100*(f) Standard: Hospice satellite locations*

There have been recurring problems with inconsistent standards regarding hospice satellite locations, and we are requesting that CMS establish a consistent policy across CMS Regions for defining and approving satellite locations. CMS regional offices in some areas of the country have limited satellite locations with a specific minutes/miles drive time limitation, while in other areas satellites have been approved at great distance from the main office. In some areas, the limitation on a satellite location has been imposed because of geographic barriers (mountains), and in other areas that has not been a factor. We would also like to express concern about the length of time for approval of satellite locations – in some parts of country it currently takes up to two years for a satellite location to be approved.

XV. MEDICAL DIRECTOR (PROPOSED §418.102)

A hospice must be in an employment or contractual relationship with a physician designated to serve in the place of the medical director when the medical director is not available. In practice, often the medical director will identify another physician to provide medical director services in his/her absence. This responsibility may even be specified in the medical director's job description, developed by the hospice. Ultimately, however, it is the hospice that has the responsibility for assuring that the medical director duties are covered on an ongoing basis. Consequently, NHPCO believes that this proposed condition of participation needs to be revised to include language that provides for collaboration between the hospice and the medical director in meeting the responsibility of designating a physician to serve in the place of the medical director.

As specified above, we request that the introduction to proposed §418.102 be revised as follows:

> When the medical director is not available, the hospice assures the designation of another physician to assume the same responsibilities as the medical director. ~~a physician designated by the medical director assumes the same responsibilities and obligations as the medical director.~~

Proposed §418.102(b) *Standard: Recertification of the terminal illness*

NHPCO has concerns about the requirement that the medical director or physician designee must review "the patient's and family's expectations and wishes for the continuation of hospice care?" It is unclear what the physician would be expected to do under this standard. It is also likely to be upsetting and cause undue stress for the patient and family if the physician questions whether they want to continue receiving hospice care. Patients always have the option of revoking the hospice benefit, but if the physician questions whether they want to continue, the patient may wonder if there is a reason why they should not continue in hospice, or if they may no longer be able to continue. Since the IDG review of the patient's comprehensive assessment

and plan of care prior to the patient's recertification includes a discussion of the patient and family's expectations and wishes for the continuation of hospice care, we suggest that this provision be deleted.

As specified above, we request that proposed §418.102(b) be revised as follows:

(b) Before the recertification period for each patient, as described in Sec.418.21(a), the medical director or physician designee must review the patient's clinical information.
~~(1) The patient's clinical information; and~~
~~(2) The patient's and family's expectations and wishes for the continuation of hospice care.~~

Proposed §418.102(c) ***Standard: Coordination of medical care.***

NHPCO feels very strongly that this standard should be revised regarding the statement that the hospice physicians and IDG are responsible for the coordination of the patient's "medical" care in its entirety. This is a particularly problematic requirement, especially when viewed in conjunction with the language in the preamble that states that the hospice physician and IDG are responsible "…for coordinating a patient's medical care in all settings, even when multiple physicians are participating in the care." This requirement would exceed a hospice's professional management responsibilities that extend only to coordinating services provided related to the patient's hospice plan of care . In addition, this requirement would be particularly problematic when the hospice medical director is working with physicians in other settings. Such a standard is likely to alienate other physicians involved in the patient's care, particularly in a SNF/NF setting where the SNF/NF medical director continues to have responsibilities for the patient pursuant to that facility's conditions of participation. While assuming responsibility for the patient's hospice care, hospice physicians need to work collaboratively with other physicians and staff involved in the care of hospice patients.

We also have serious concerns about CMS' requirement that the hospice medical director or physician designee be "responsible for directing" the hospice's QAPI program. In light of the scope of the QAPI requirements, which are broad and extend beyond purely medical issues, and the fact that many medical directors are part time or volunteers, we are requesting a revision to require the medical director or physician designee "participate" in the hospice's QAPI program, but not that they direct it. Particularly in smaller hospice programs, the medical director may be a volunteer or work part-time, and may be neither willing nor qualified to assume this responsibility. In addition, this requirement appears to conflict with §418.58(e) that requires the hospice's governing body to assume executive responsibility for the hospice's QAPI program. As part of that responsibility, it would be appropriate for the governing body to appoint the most qualified individual to direct the hospice's QAPI program. In some hospices that individual might be the hospice's medical director but for the large majority, it would not.

As specified above, we request that proposed §418.102(c) be revised as follows:

> (c) *Standard: Coordination of medical care.* The medical director or physician designee, and the other members of the interdisciplinary group are jointly responsible for the coordination of the patient's ~~medical~~ hospice care ~~in its entirety~~. The medical director or physician designee ~~is also responsible for directing~~ should participate in the hospice's quality assessment and performance improvement program.

XVI. CLINICAL RECORDS (PROPOSED §418.104)

In response to CMS' query, a number of providers commented to NHPCO on the use of the Electronic Health Record ("EHR") in the hospice setting. Providers stated that the advantage of EHR is that it is accessible from any computer anywhere in the world at any time of the day or night, and is easily portable, with a clean copy that is legible if notes are typed versus scanned. The disadvantages are that the provider must have very computer literate clinical staff, often unavailable in today's environment; staff must carry a laptop from house to house, giving the appearance of a "cold machine"; theft; and risk of cross contamination between households. In addition, there are significantly increased costs for infrastructure, software, maintenance, training, and data entry. EHRs have been used successfully in facilities and physician offices, due to the nature of care and location. They also work efficiently and appropriately in those settings for billing. However, hospice uses four billing codes, one of which is used 90 percent of the time, and consequently hospices gain no billing efficiency by implementing an EHR system. The system would be more appropriately used for team communication. If only nurses are supplied with laptops, and all other disciplines use handwritten notes then there is a lag time between the note being written, transcribed, and being available in the EHR, which could be problematic for continuity of care.

A number of small and rural providers commented that they do not expect to be able to use EHRs in the near future due to cost, training of staff, hiring technical staff and need.

If a hospice uses electronic medical records, sharing of the discharge summary and/or medical record through an electronic format is possible and facilitates communication between providers. It should be possible for electronic sharing of records to include access to the record through secure internet access or other electronic access available through transferable data storage media.

Proposed §418.104(a) *Standard: Content*

We have questions about the "authorization" referred to in §418.104(a)(2) regarding the content of the patient's clinical record. Authorization has a specific meaning in the

context of the HIPAA privacy regulations, but such authorizations are required in limited circumstances and would not typically be part of a hospice patient's clinical record. Please clarify what "authorizations" CMS is referring to in this standard.

Proposed §418.104(b) *Standard: Authentication*

NHPCO has serious concerns about the proposed requirement that all entries in the clinical record must be authenticated and that the hospice must be able to authenticate each handwritten and electronic signature of a primary author who reviewed and approved the entry. Our concern is that hospice home care is so broad, (unlike other health care settings, such as hospitals, for which this standard is more appropriate) and can involve so many health professionals in so many different settings, that it may not be feasible to completely comply with the authentication standard for attending physicians, consulting physicians and other care providers throughout a hospice's service area.

NHPCO is concerned about the application of the term "primary author" and how it would apply in hospice. Those providing care are widely dispersed and hospices may receive records from dozens, hundreds or more referring or attending physicians, some of whom may refer only one patient a year to the hospice. Electronic signatures are not yet in widespread use, and it would be extremely burdensome for hospices to be required to authenticate the handwritten signatures of every one of these physicians. In addition, the environment is different for a hospice than for a hospital. It is practiced in the community setting, not in a controlled environment, such as a hospital. We would request that you take these factors into account when writing the final rule.

As specified above, we request that proposed §418.104(b) be revised as follows:

> (b) *Standard: Authentication.* All entries must be legible, clear, complete, and appropriately authenticated and dated for all hospice employees. ~~All entries must be signed, and the hospice must be able to authenticate each handwritten and electronic signature of a primary author who has reviewed and approved the entry~~.
>
> (i) The author of each entry must be identified and must authenticate his or her entry.
>
> (ii) Authentication may include signatures, written initials or computer entry.

Proposed §418.104(d) *Standard: Retention of records*

The HIPAA privacy regulations require record retention for 6 years, unless state law stipulates a longer period of time. We recommend following the HIPAA requirement as the minimum for this standard.

As specified above, we request that proposed §418.104(d) be revised as follows:

> (d) *Standard: Retention of records.* Patient clinical records must be retained for ~~5~~ 6 years after the death or discharge of the patient, unless State law stipulates a longer period of time. If the hospice discontinues operation, hospice policies must provide for retention and storage of clinical records. The hospice must inform its State agency and its CMS Regional office where such clinical records will be stored and how they may be accessed.

Proposed §418.104(e) *Standard: Discharge or transfer of care*

We are requesting that CMS change the phrase "Medicare/Medicaid-approved" to "Medicare/Medicaid-certified" or clarify the difference between the two. "Medicare-certified" is the commonly accepted term and utilization of the term "Medicare-approved" may cause unnecessary confusion.

Requiring hospices to send a copy of the patient's entire clinical record if the patient transfers, revokes or is discharged is particularly onerous, and is not necessary since the discharge summary requirements are comprehensive, and receipt of the entire printed clinical record (sometimes hundreds of pages) is not likely to be welcomed by facilities or attending physicians. In addition, such a release often would not be in compliance with the minimum necessary disclosure standard in the HIPAA privacy regulations.

Because hospice care includes care of the patient and family, hospice records often include sensitive, personal information about individuals other than the patient, such as family members or caregivers. For example, the records could include notations regarding substance abuse by a family member, which is relevant to their role as a hospice caregiver. The discharge summary is very thorough and would be disclosing the minimum amount of protected health information needed to achieve the purpose of the disclosure which, in this case, would be to ensure continuity of care with another provider. As always, additional records would be available from the hospice if needed.

As specified above, we request that proposed §418.104(e) be revised as follows:

> (e) *Standard: Discharge or transfer of care.*
> (1) If the care of a patient is transferred to another Medicare/ Medicaid-~~approved~~ certified facility, the hospice must forward a copy of the patient's ~~clinical record and the~~ hospice discharge summary to that facility.
> (2) If a patient revokes the election of hospice care, or is discharged from hospice because eligibility criteria are no longer met, the hospice must provide a copy of the ~~clinical record and the~~ hospice discharge summary ~~of this section~~ to the patient's attending physician.
> (3) The hospice discharge summary must include—

(i) A summary of the patient's stay including treatments, symptoms and pain management;
(ii) The patient's current plan of care;
(iii) The patient's latest physician orders; and
(iv) Any other documentation that will assist in post-discharge continuity of care.

XVII. DRUGS, SUPPLIES, AND DURABLE MEDICAL EQUIPMENT (PROPOSED §418.106)

Proposed §418.106(b) ***Standard: Controlled drugs in the patient's home.***

NHPCO has significant concerns regarding this standard and the chilling effect that it may have on patients accepting and receiving medications adequate to control their pain. It has been well documented that untreated or under-treated pain is a major problem[3,4] and this is particularly true for patients with terminal illnesses. Patients themselves are often one of the impediments to achieving pain control, and hospices often struggle to convince patients to take the medications they need to address their pain. If hospices are required to talk to patients about the "dangers" of controlled substances during the initial assessment, this could potentially frighten patients and families and may undermine the hospice's efforts to bring the patient's pain under control. While we appreciate CMS' concerns regarding diversion of controlled substances, and the potential dangers if they are not appropriately safeguarded, we are requesting that the hospice instead be required to discuss the safe uses of controlled substances, and we believe such discussions also would address the risks of misuse or diversion of such drugs.

NHPCO also is concerned about the use of the term "tracking" in this standard. As we understand it, the tracking procedure would require that the hospice nurse account for every dosage at every visit and make a record of the count. While we believe this procedure may be warranted in some instances, the procedure could be covered in the hospice's policies and procedures. The use of the word "monitoring" would allow the hospice to have a policy that is flexible, and to take into account the specific patient and family circumstances. We also are requesting that CMS clarify that the requirement is that the hospice develop a policy regarding tracking and disposing of controlled drugs, but such drugs are the property of the patient, and the hospice cannot dictate that patients dispose of them. In addition, state laws regarding controlled substances vary, including recently passed state laws restricting the disposal of controlled substances in the sewer system in order to protect water quality.

We specifically request that CMS delete the requirement that the hospice have a policy for "collecting" controlled drugs. A hospice would not "collect" such drugs in a patient's

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3 "Hospitals and clinicians confront a new imperative: PAIN MANAGEMENT," *Hospitals and Health Networks*, (April 1, 2005): 54

4 DE Joranson, R Payne, "Will my pain be managed?" ed. WAD Edmondson. *Improving End-of-Life Care: The Role of Attorneys General.* (Washington, DC: National Association of Attorneys General, 2003): 27-34.

home except for the purpose of disposing of them, and then only with the consent of the patient. In addition, requiring hospice personnel to collect and transport controlled substances could put them at risk.

We also feel that requiring a hospice to discuss its drug use and disposal policy during the initial assessment (the first 24 hours of care) would be counter-productive, because so much information is being shared at that time, and the patient may not even be taking any controlled drugs. As stated in our comments regarding proposed §418.52(a)(3), we would recommend that the information concerning the hospice's drug use and disposal policy be a part of the hospice's admission packet, and that this information be discussed during the comprehensive assessment period rather than the initial assessment.

As specified above, we request that proposed §418.106(b) be revised as follows:

> (b) *Standard: Controlled drugs in the patient's home.* The hospice must have a written policy for ~~tracking,~~ monitoring, ~~collecting,~~ and disposing of controlled drugs maintained in the patient's home. During the ~~initial~~ comprehensive hospice assessment, the hospice will inform patients and families of their policies ~~the use and disposal of controlled substances must be discussed with the patient and family to ensure the patient and family are educated~~ regarding the safe uses and appropriate safeguards for the use ~~and potential dangers~~ of controlled substances. The hospice nurse must document that the patient and family have received this information. ~~policy was discussed with the patient and family.~~

Proposed §418.106(c) *Standard: Use and maintenance of equipment and supplies.*

This is not a core service, and almost all hospices contract for durable medical equipment ("DME") services. Adding the words "either directly or through contractual agreement" clarifies the responsibilities of the hospice and of the contractors they use to supply medical equipment. While the hospice is responsible for ensuring that the patient has safe, working equipment, contractors have the expertise in this area and should be responsible for writing repair and routine maintenance policies for equipment.

As specified above, we request that proposed §418.106(c) be revised as follows:

> (c) *Standard: Use and maintenance of equipment and supplies.*
>
> ~~(1) The hospice must follow manufacturer recommendations for performing routine and preventive maintenance on durable medical equipment. The equipment must be safe and work as intended for use in the patient's environment. Where there is no manufacturer recommendation for a piece of equipment, the hospice must develop in writing its own repair and routine maintenance policy. The hospice may use persons under contract to ensure the maintenance and repair of durable medical equipment.~~

(1) The hospice ensures, either directly or through contractual agreement, that there is a process for providing routine and preventive maintenance and repair of equipment, and that the equipment is safe and works as intended for use in the patient's environment.

XVIII. SHORT TERM INPATIENT CARE (PROPOSED §418.108)

NHPCO believes it should be clear that inpatient care must also be available for crises of a psychosocial nature as well as pain control, symptom management and respite. CMS manual provisions allow for a psychosocial crisis as a basis for admission for inpatient care, as stated in Medicare Benefits Policy Manual, Ch. 9, §40.1.5: "General inpatient care may be required for procedures necessary for pain control or acute or chronic symptom management, which cannot feasibly be provided in other settings. Skilled nursing care may be needed by a patient whose home support has broken down if this breakdown makes it no longer feasible to furnish needed care in the home setting…Other examples of appropriate general inpatient care include a patient in need of medication adjustment, observation, or other stabilizing treatment, such as psycho-social monitoring, or a patient whose family is unwilling to permit needed care to be furnished in the home." We request that CMS clarify the circumstances under which inpatient care is appropriate because there has been confusion among providers and intermediaries about the possible reasons for short term inpatient care.

NHPCO requests that CMS add to the introduction that short-term inpatient care may be provided in a hospice inpatient facility.

As specified above, we request that the introduction to proposed §418.108 be revised as follows:

> *Condition of participation: Short-term inpatient care.*
> Inpatient care must be available for pain control, symptom management, psychosocial crises and respite purposes, and must be provided in a participating Medicare or Medicaid facility, or a Medicare-certified hospice that meets the conditions of participation for providing inpatient care directly.

Proposed §418.108(a) ***Standard: Inpatient care for symptom management and pain control.***

NHPCO is requesting that this standard also include the provision of inpatient care for crises of a psychosocial nature. We are also requesting that CMS change the phrase "Medicare-approved" to "Medicare-certified" because we believe this is the correct terminology.

As specified above, we request that proposed §418.108(a) be revised as follows:

> (a) *Standard: Inpatient care for symptom management, ~~and~~ pain control and psychosocial crises.* Inpatient care for pain control, ~~and~~ symptom management and psychosocial crises must be provided in one of the following:
>
> (1) A Medicare-certified hospice that meets the conditions of participation for providing inpatient care directly as specified in Sec. 418.110.

Proposed §418.108(b) *Standard: Inpatient care for respite purposes*

We are requesting that CMS change the phrase "Medicare-approved" to "Medicare-certified", and that CMS provide an exception to the requirements referred to in §418.110(f) to allow rooms used for inpatient respite care to accommodate up to four patients. We believe this change is appropriate because patients receiving respite care typically are not actively dying patients, which would be the most compelling reason for limiting the number of patients per room to two. Eliminating this requirement would provide better access for hospices to contract with some nursing homes for respite care.

As specified above, we request that proposed §418.108(b) be revised as follows:

> (b) *Standard: Inpatient care for respite purposes.* Inpatient care for respite purposes must be provided by one of the following:
> (1) A provider specified in paragraph (a) of this section.
> (2) A Medicare/Medicaid ~~approved~~ participating nursing facility that also meets the standards specified in § 418.110(b) and (f), except that patient care rooms used for respite purposes may accommodate up to four patients.

Proposed §418.108(c) *Standard: Inpatient care provided under arrangements*

NHPCO has two comments related to provisions in this standard at proposed §418.108(c)(3) and §418.108(c)(5). First, similar to the concern expressed regarding proposed §418.104(e), hospices do not need a copy of the inpatient clinical record since the inpatient discharge summary would provide the necessary information to ensure continuity of care, and additional information would be available upon request. We are concerned that the wording in the proposed standard, requiring that a copy of the inpatient clinical record is "available" to the hospice at the time of discharge, may be misinterpreted to mean that a hospice must obtain a copy of the entire inpatient clinical record for each patient that receives care at an inpatient facility. This would pose an inordinate burden on inpatient facilities and risk their compliance with the minimum necessary disclosure requirement of the HIPAA privacy regulations. It would also risk the hospice's compliance with the minimum necessary request requirements of the

HIPAA privacy regulations.

With regard to proposed §418.108(c)(5), NHPCO is concerned that inpatient facilities that contract with several hospice programs to provide the inpatient level of hospice care may be inundated with obligations to receive similar training from multiple hospice

providers. This risks placing an unnecessary strain on relationships between hospices and the inpatient facilities with which they contract.

As specified above, we request that proposed §418.108(c)(3) and 418.108(c)(5) be revised as follows:

(c) *Standard: Inpatient care provided under arrangements.* If the hospice has an arrangement with a facility to provide for short-term inpatient care, the arrangement is described in a legally binding written agreement that at a minimum specifies --

(3) That the hospice patient's inpatient clinical record includes a record of all inpatient services furnished, events regarding care that occurred at the facility, and that a copy of the inpatient clinical record be provided if requested by the hospice, and a discharge summary is ~~available~~ provided to the hospice at the time of discharge.

(5) That the hospice retains responsibility for ~~arranging~~ ensuring that the training of personnel who will be providing the patient's care in the inpatient facility has been provided, and that a description of the training and the names of those giving the training is documented; and

XIX. HOSPICES THAT PROVIDE INPATIENT CARE DIRECTLY (PROPOSED §418.110)

While we appreciate CMS' effort to make inpatient care more accessible by making the requirement for 24 hour nurse staffing more flexible, we are recommending that a clear distinction be made between staffing for short term inpatient care for symptom management and pain control (§418.108(a)), and short term inpatient care for respite purposes (§418.108(b)). While we believe that the standard for nursing services in a facility providing respite care to a hospice patient should be in accordance with the patient's plan of care, which might not require 24 hour nursing care, hospice patients receiving inpatient care for pain control or symptom management typically have acute needs, and we believe a registered nurse who can provide direct patient care should be included on each shift of a facility in which such care is provided.

As specified above, we request that proposed §418.110(b) be revised as follows:

> (b) *Standard: Twenty-four hour nursing services*. The hospice facility must provide 24-hour nursing services that meet the nursing needs of all patients and are furnished in accordance with each patient's plan of care. Each patient must receive all nursing services as prescribed and must be kept comfortable, clean, well groomed, and protected from accident, injury, and infection.
>
> (1) For inpatient care provided for pain control or symptom management, as described in §418.108(a), each shift must include a registered nurse who can provide direct patient care.
> (2) For inpatient care provided for respite purposes, as described in §418.108 (b), nursing services must be provided to meet the needs of the patient as specified in the patient's plan of care.

Proposed §418.110(c) *Standard: Physical environment*

NHPCO has concerns regarding the safety management requirements in proposed §418.110(c)(1)(i) and §418.110(c)(1)(ii). While our concerns may not require a rewording of these provisions, we request that in the final rule and/or the interpretive guidelines, CMS provide further clarification of reporting requirements and how these requirements are consistent with or exceed the requirements of the Safe Medical Device Act. NHPCO also requests that CMS provide some examples of the "equipment failures" referred to in §418.110(c)(1)(i), and describe under what circumstances such failures would be required to be reported to appropriate State and local bodies, if this provision exceeds the reporting requirements of the Safe Medical Device Act.

Proposed §418.110(d) *Standard: Fire protection*

We had many providers comment that the most current edition of the Life Safety Code was published in 2003. It is currently used in every U.S. state and adopted for statewide use in 35 states. There is confusion that this standard still requires the 2000 edition and we request that the updated version be referenced throughout this section. In addition, the standard includes a number of incorrect citations.

Specifically, the language in proposed §418.100(d)(4) states "beginning March 13, 2006, a hospice must be in compliance with Chapter 9.2.6 Emergency Lighting." The highest section in that chapter is 9.2.4. Chapter 9 is titled "Building Service and Fire Protection Equipment" and 9.2 is titled "Heating, Ventilating and Air Conditioning." Emergency lighting is actually in Chapter 7, and is titled "Means of Egress", and Emergency Lighting is actually in Section 7.9

Another reference appears to be incorrect in proposed §418.100(d)(6)(iv). The standard states "dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code." However, Chapter 18.3.2.7 actually states

"Buildings housing health care occupancies as indicated in 18.1.1.1.2 that have rooftop heliports shall be protected in accordance with NFPA 418, Standard for Heliports." Chapter 19.3.2.7 does not exist; the highest provision in this chapter is 19.3.2.6.

Proposed §418.110(f) *Standard: Patient rooms*

In the event of hurricanes, tornadoes and other community disasters, we would like to have the flexibility for some variance in this standard, including the number of patients per room in proposed §418.110(f)(3)(iv). We are not requesting a change to the standard, but some recognition of extraordinary circumstances could be made in the preamble to the final rule and in the interpretive guidelines.

Proposed §418.110*(l) Standard: Meal service and menu planning*

NHPCO appreciates CMS' revision of this standard to be in keeping with the needs and desires of hospice patients, rather than requiring the provision of meals that may be inappropriate for dying patients.

Proposed §418.110(n) *Standard: Pharmacist*

We request that the phrase "if required by law" be added to the requirement in §418.110(n)(4)(iii) that a written account of the hospice's investigation of any discrepancies in the acquisition, storage, use, disposal, or return of controlled drugs be made available to State and Federal officials. If not required by law, it would be unclear to whom such an account should be provided.

As specified above, we request that proposed §418.110(n) be revised as follows:

(n) *Pharmacist.*
(4) *Drug management procedures.*
(iii) Any discrepancies in the acquisition, storage, use, disposal, or return of controlled drugs must be investigated immediately by the pharmacist and hospice administrator and where required reported to the appropriate State agency. A written account of the investigation must be made available to State and Federal officials, if required by law.

XX. SECLUSION AND RESTRAINT (PROPOSED §418.110(o))

NHPCO would like to comment on the use of seclusion and restraints in hospice care. Many providers commented that the entire issue of restraints, both physical and drug, needs further examination. Major components of what hospices do for both symptom

management and safety includes medications and practices that may be considered restraints in other settings. For instance, in hospice, haloperidol (Haldol) is used as an anti-emetic, as well as for restlessness and anxiety, not for a restraint. Some providers suggested that the condition use the phrase "accepted hospice and palliative care standards of practice" and list classes of drugs, such as anti-emetics and psychotropics, rather than specific drugs such as lorazepam and haloperidol. Others suggested language such as: "A drug is not considered a chemical restraint when used to palliate symptoms." The key is intent. Hospices' intent is to palliate a symptom, not to restrain. NHPCO received many requests for CMS to clearly distinguish how medications being used as chemical restraints in other settings are medically appropriate when used in hospice and palliative care. The plan of care should include specific indications for pharmacotherapy, obviating misunderstanding of intent.

Here are some specific examples (not meant to be all inclusive):

Hiccups: Haloperidol (Haldol), Chlorpromazine (Thorazine) – note that this works in 80% of hiccup cases when nothing else has.

Itching (pruritus): Hydroxyzine (Atarax, Vistaril), doxepin (Sinequan, Adapin), both at bedtime.

Delirium: Haloperidol (Haldol), oxazepam (Serax), midazolam (Versed).

Anxiety and panic (including anxiety associated with dyspnea): Lorazepam (Ativan), oxazepam (Serax), diazepam (Valium).

Terminal restlessness: Chlorpromazine (Thorazine), midazolam (Versed), oxazepam (Serax), phenobarbital.

Some providers commented that they hoped that "restraint" did not include bed rails or positional devices such as posey vests, since bed rails are often used to ensure the patient's safety or to assist the patient in positioning and independent functioning, and posey vests in a hospice setting would be used to help a patient sit up.

Our concerns about the appropriate use of bedrails, and nursing facilities' concerns that use of them will be considered a "restraint", is highlighted in a report issued by AARP's Public Policy Institute in November 2004, which describes end-of-life care in nursing homes from the perspective of bereaved family members or others close to the decedents in order to identify policy issues and to make recommendations for policy change and educational initiatives. A case study from this report is included below:

> **Case III**: The nursing home sent 89-year-old Mrs. X to the hospital on numerous occasions. These visits involved long waits in the emergency room while Mrs. X's daughter agonized over the burden that repeated emergency room visits and hospitalizations created for her mother. Despite the daughter's insistence that Mrs. X be treated in the nursing home, the nursing home staff continued to urge hospitalization. Mrs. X's mattress was placed on the floor of her room in the nursing home to prevent

injuries from falling, an action her daughter considered demeaning. Increasingly vigilant about her mother's care, Mrs. X's daughter was dismayed by inadequate staffing, medication errors, insensitive staff, inadequate facility responses to her complaints, and inadequate information from the staff and doctors. One doctor mistakenly talked with her about a different person's care. When ownership of the nursing home changed, hospice care was added, and, according to the respondent, conditions improved.[5]

As specified above, we request that proposed §418.110(o)(1) be revised as follows:

(1) The patient has the right to be free from seclusion and restraint, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. The term restraint includes either a physical restraint or a drug that is being used as a restraint. A physical restraint is any manual method or physical or mechanical device, material or equipment attached or adjacent to the patient's body that he or she cannot easily remove, that restricts free movement of, normal function of, or normal access to one's body. Bed rails and positional devices are not included in this definition of restraint if used for the safety or support of the patient or to assist the patient in independent functioning. A ~~drug~~ chemical used as a restraint is a medication used to control behavior or to restrict the hospice patient's freedom of movement and is not a standard treatment for a patient's hospice medical or psychiatric condition. Seclusion is the confinement of a person alone in a room or an area where a person is physically prevented from leaving.

Proposed 418.110 (o) Standard: Seclusion and restraint. Time frames and reporting

NHPCO had many provider comments on the time frames mentioned in 418.110(o)(3)(ii)(d). The time frames listed are not feasible if the medical director or physician designee must see the patient and evaluate the need for restraint within 1 hour after the initiation of this intervention. Medical directors are not on site at inpatient facilities and would not be able to evaluate the patient within that time frame. Some providers suggested that a nurse must see the patient and evaluate the need hourly when any restraint is utilized.

NHPCO also received a number of comments on the provision in 418.110(o)(7) that requires a report to the CMS regional office of any death that occurs. Because of the nature of the patient population served by hospices and their impending death from their disease process, we would recommend a change that would add the word "unexpected" to this provision in the standard.

[5] T Wetle, J Teno, R Shield, L Welch, and S Miller, S. *End of Life in Nursing Homes: Experiences and Policy Recommendations* (Washington, D.C., AARP Public Policy Institute, 2004)

As specified above, we request that proposed §418.110(o)(7) be revised as follows:

(7) The hospice must report to the CMS regional office any unexpected death that occurs while the patient is restrained or in seclusion, within 24 hours after a patient has been removed from restraint or seclusion.

XXI. RESIDENTS RESIDING IN A FACILITY (PROPOSED §418.112)

When the Medicare Hospice Benefit was enacted, the primary site of death for Medicare beneficiaries was the hospital. The Hospice Benefit has played a role in changing that trend, by providing support to terminally ill patients and their families, making it possible for them to die at home in accordance with their wishes. This was not only a preferable option for many patients/families, but also proved to be cost effective for Medicare.

Now, the demographics have changed, longevity has increased, and people are living longer with multiple chronic illnesses and significant deficits in their ability to perform activities of daily living. As a result, the percentage of Medicare beneficiaries who die while residing in nursing facilities has increased, and hospices have responded by entering into agreements with nursing facilities to make hospice services available to their residents. Research has indicated that a successful collaboration is beneficial to all concerned: patients, families, and staff of both providers.[6] A study published in the July 13, 2005 issue of the *Journal of the American Medical Association* indicates that simple communication efforts can improve the quality of end-of-life care and increase the use of hospice in nursing homes. A randomized controlled trial evaluated the impact of a "case finding" intervention and found that referrals to hospice were increased and that families' satisfaction ratings with the care their loved ones received at the end of life improved. The study also shows that simple communication interventions about hospice may also decrease the use of acute care resources.[7]

Over the past several years, NHPCO has developed educational tools and provided educational workshops to address issues important to forming partnerships between hospices and nursing facilities. While we feel that the addition of this provision to the hospice conditions of participation is appropriate, we are concerned about the incongruence between the proposed hospice conditions and the existing nursing facility conditions of participation. We understand that CMS is aware of these problems, and that the nursing facility conditions of participation are in the process of being updated, but we are concerned that these hospice provisions will become effective before the nursing facility conditions are updated, and hospice providers will be unable to comply with some of the standards in this condition.

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[6] Office of Disability, Aging and Long Term Care Policy, *Use of Medicare's Hospice Benefit by Nursing Facility Residents*,(Washington, D.C., Assistant Secretary for Planning and Evaluation, US DHHS, June 2000).

[7] D Casarett, Intervention Increases Hospice Access for Nursing Home Residents and Raises Satisfaction Levels for Patients and Families. *JAMA*, (July 13, 2005).

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

NHPCO requests that the title of this condition be revised to remove the reference to "other facilities" because the term is too vague, and the proposed standards themselves clearly contemplate a SNF/NF or ICF/MR setting. In the absence of federal regulations applicable to "other facilities" such as assisted living facilities, personal care homes, foster homes, and board and care facilities, the standards in this provision would not be applicable. For example, not all such "facilities" provide medical services, have care plans for their residents, or employ medical directors. State regulations of these types of facilities also vary widely. Therefore, throughout proposed §418.112 we request that CMS delete the references to "other facilities", so that the remaining references to "facility" or "facilities" will apply to SNF/NFs and ICF/MRs.

As specified above, we request that title and introductory provisions of proposed §418.112 be revised as follows:

> §418.112 *Condition of Participation: Hospices that provide hospice care to residents of a SNF/NF, or ICF/MR~~, or other facilities~~*
>
> In addition to meeting the conditions of participation at §418.10 through §418.116, a hospice that provides hospice care to residents of a SNF/NF~~,~~ or ICF/MR~~, or other residential facility~~ must ~~abide by~~ comply with the following additional standards.

Proposed §418.112(a) *Standard: Resident eligibility, election, and duration of benefits*

Consistent with the rationale discussed above, we are proposing that the reference to other facilities be deleted and a reference to ICF/MR be added.

As specified above, we request that proposed §418.112(a) be revised as follows:

> (a) *Standard: Resident eligibility, election, and duration of benefits.* Medicare patients receiving hospice services and residing in a SNF/~~,~~NF, or ~~other facility~~ ICF/MR must meet the Medicare hospice eligibility criteria as identified in §418.20 through §418.30.

Proposed §418.112(b) *Standard: Professional management*

Hospices' professional management responsibility is already addressed in proposed §418.100(e) and is duplicative in this section. We also note that this is often an area of conflict between the hospice and nursing facility staff, because the nursing facility conditions of participation also require the nursing facility to maintain professional responsibility. This issue is further complicated because the protocols in nursing facilities are oriented toward cure and

rehabilitation, where hospice protocols are focused on palliative care. We are concerned about the words "full responsibility" for it may cause greater conflict between the two staffs and would recommend the deletion of the word "full."

As specified above, we request that proposed §418.112(b) be revised as follows:

> (b) *Standard: Professional management.* The hospice must assume ~~full~~ responsibility for professional management of the resident's hospice care, in accordance with the hospice conditions of participation and make any arrangements necessary for inpatient care in a participating Medicare/Medicaid facility according to § 418.100.

Proposed §418.112(c) *Standard: Core services*

NHPCO is requesting that this standard be removed in its entirety from this condition of participation since hospices' core services obligations are already addressed in proposed §418.64. The proposed language in this standard does not offer any additional clarification for core services when the service is provided in a nursing facility, and therefore the standard is redundant.

As specified above, we request that proposed §418.112(c) be deleted:

> ~~(c) *Standard: Core services*. A hospice must routinely provide all core services. These services include nursing services, medical social services, and counseling services. The hospice may contract for physician services as stated in § 418.64(a). A hospice may use contracted staff provided by another Medicare certified hospice to furnish core services, if necessary, to supplement hospice employees in order to meet the needs of patients under extraordinary or other non-routine circumstances, as described in § 418.64.~~

Proposed §418.112(d) *Standard: Medical director*

We are proposing that the title of this standard be changed to "physician services". This more accurately reflects its contents, which refer to the role of the medical director and physician designee. We also are proposing that the content of this standard be revised and formatted to better reflect the roles of the hospice physician, the attending physician, and the facility medical director, and their need to communicate regarding the patient's care. We also are requesting that CMS clarify that the required "communication" between the hospice medical director or physician designee and the other physicians involved in the patient's care may include telephone calls, faxes and e-mail communication, and does not require face-to-face interaction.

As specified above, we request that proposed §418.112(d) be revised as follows:

(d) *Standard: ~~Medical director~~ Physician services.*

(1) The medical director or~~and~~ physician designee of the hospice must provide ~~overall coordination of the medical care of the hospice resident that resides in an SNF, NF, or other facility~~ clinical guidance in the development of patient care policies and procedures that meet the needs of terminally ill patients.

(2) The attending physician has primary responsibility for the medical care of an individual patient, in collaboration with the interdisciplinary team.

(3)The medical director or ~~and~~ physician designee must communicate with the medical director of the SNF/NF or ICF/MR, the patient's attending physician, and other physicians participating in the provision of care for the terminal and related conditions to ensure quality care for the patient and family.

Proposed §418.112(e) *Standard: Written agreement*

We are proposing a number of changes to this standard, which we hope will better clarify the roles and responsibilities of hospices and nursing facilities providing care to the same patient. We continue to have concerns about nursing facilities' acceptance of some of these provisions due to their obligations to comply with the nursing facility conditions of participation, and we urge CMS to work with and educate state surveyors of nursing facilities regarding these requirements.

We are requesting that CMS clarify what is meant in §418.112(e)(1), requiring that the written consent of the patient for hospice services be included in the written agreement between the hospice and facility. If the requirement is that a written and signed consent document be provided by the hospice to the nursing facility for all patients, we would agree. If, however, an individual patient's consent agreement is required to be included in the written agreement between the hospice and nursing facility, we would not agree. The patient consent is a part of the individual patient's medical record and should not be a part of the agreement between the hospice and nursing facility, which typically applies to all of the hospice's patients residing in the facility, and not to a specific patient. There was a great deal of confusion about the language in this standard. We are requesting that CMS clarify that the requirement in §418.112(e)(1) would be fulfilled by the hospice providing the facility with the patient's hospice election form, which would include the patient's or representative's signature.

We are requesting that CMS significantly restructure proposed §418.112(e)(2) to separately identify the roles and responsibilities of the hospice and the nursing facility. Traditionally this has been an area of confusion and conflict, and we believe separating these into

two subsections would better clarify the issues. Most of the services to be provided by the hospice currently are set forth in proposed §418.112(e)(7), but we are requesting that they be moved. The language we are proposing regarding services to be provided by the nursing facility is adapted from State Operations Manual §2082A.

We are requesting that CMS delete proposed §418.112(e)(4) requiring that the written agreement include a provision that the nursing facility must notify the hospice immediately if a life-threatening condition appears. All hospice patients have life-threatening conditions or they would not be eligible for the hospice benefit, and unexpected events or changes are already addressed in proposed §418.112(4)(i).

We request that CMS delete proposed §418.112(e)(6) and (7) since these provisions would now be addressed in the language we are proposing to add to §418.112(1) and (2).

We are requesting several changes to proposed §418.112(e)(8). We want to clarify that the hospice's ability to use the facility's nursing personnel to provide certain services will be determined by applicable State law, as well as the facility, and to note that the hospice patient's plan of care is to be a coordinated plan. We also want to clarify that the hospice may use the facility's nursing personnel to implement the plan of care to the extent that the hospice would utilize the services of a hospice patient's family if the patient resided with them. The reality is that many family members and caregivers of hospice patients perform skilled nursing care, after having been trained and educated by hospice staff. While nursing services are a core hospice service, it is important to clarify that nursing facility staff can provide certain nursing services to hospice patients residing in the facility, to the extent that the hospice would have relied on the patient's family to do so in other settings, and to enhance patient safety and comfort. A good example would be the hospice patient who needs to be suctioned in the middle of the night. Hospice staff would have trained the family to provide suctioning so that the patient remains comfortable; in the same way, they would train the nursing home staff to do the suctioning until the hospice nurse is able to visit the patient.

As specified above, we request that proposed §418.112(e) be revised as follows:

> (e) *Standard: Written agreement.* The hospice and the facility must have a written agreement that specifies the provision of hospice services in the facility. The agreement must be signed by authorized representatives of the hospice and the facility before the provision of hospice services. The written agreement must include at least the following:
>
> (1) That the hospice will supply a copy of the written consent of the patient or the patient's representative for each patient stating that hospice services are desired.
>
> ~~(2) The services that the hospice will furnish and that the facility will furnish.~~
>
> (2)) Services to be provided by the hospice

(i) A delineation of the hospice's responsibilities, which include, but are not limited to, providing medical direction and management of the patient, nursing, counseling (including spiritual and dietary counseling), social work, bereavement counseling for immediate family members, provision of medical supplies and durable medical equipment, and drugs necessary for the palliation of pain and symptoms associated with the terminal illness, as well as all other hospice services that are necessary for the care of the resident's terminal illness.

(ii) Hospice services would be provided at the same level and to the same extent as would have been provided if the resident were in their own home.

(3) Services to be provided by the nursing facility:

(i) The nursing facility provides 24 hour room and board care, meeting the personal care and nursing needs that would have been provided by a primary caregiver in the home.

(ii) The services provided are at the same level that would have been provided if the resident had not elected to receive hospice services.

(4) The manner in which the facility and the hospice are to communicate with each other to ensure that the needs of the patient are addressed and met 24 hours a day.

(5) A provision that the facility immediately notifies the hospice if—

(i) A significant change in the patient's physical, mental, social, or emotional status occurs;

(ii) Clinical complications appear that suggest a need to alter the plan of care;

~~(iii) A life threatening condition appears;~~

~~(iv)~~(iii) A need to transfer the patient from the facility and the hospice makes arrangements for, and remains responsible for, any necessary continuous care or inpatient care necessary related to the terminal illness; or

~~(v)~~(iv) The patient dies.

(6) A provision stating that the hospice assumes responsibility for determining the appropriate course of care, including the determination to change the level of services provided.

~~(6) An agreement that it is the facility's primary responsibility to furnish room and board.~~

~~(7) A delineation of the hospice's responsibilities, which include, but are~~

~~not limited to, providing medical direction and management of the patient, nursing, counseling (including spiritual and dietary counseling), social work, bereavement counseling for immediate family members, provision of medical supplies and durable medical equipment, and drugs necessary for the palliation of pain and symptoms associated with the terminal illness, as well as all other hospice services that are necessary for the care of the resident's terminal illness.~~

(7) A provision that the hospice may use the facility's nursing personnel where permitted by state law and as specified by the facility to assist in the administration of prescribed therapies included in the coordinated plan of care only to the extent that the hospice would routinely utilize the services of a hospice resident's family in implementing the plan of care.

Proposed §418.112(f) *Standard: Hospice plan of care*

Developing a coordinated care plan is a challenging task in the nursing facility. It is extremely difficult because the nursing facility's Resident Assessment Instrument is so prescriptive regarding the completion of the assessment and care plan, which is focused on attaining "highest practicable functioning". Nursing facility staff are reluctant to abide by a care plan that deviates from the norm and focuses on comfort, rather than cure. Changes need to be made in the nursing facility regulations and guidelines applicable to hospice patients before it is realistic for hospices to comply with this standard. However, NHPCO appreciates the flexibility allowed in this standard by not specifying the number of care plans, but rather the need for coordination. We are suggesting a modification to this standard to refer to a comprehensive assessment of the patient's needs and unique living situation in the facility.

NHPCO is requesting the deletion of proposed §418.112(f)(3), requiring that the plan of care be reviewed at least every 14 days, "in conjunction with representatives of the facility". Pursuant to other provisions of the proposed rules, the hospice is required to perform a comprehensive assessment and review the plan of care for every patient, including those residing in a nursing facility, at least every 14 days. The nursing facility conditions of participation only require review of the plan of care every three months, and therefore we are concerned that the nursing facility staff will consider this requirement to be extremely burdensome. In performing the comprehensive assessment, the hospice would communicate and confer with nursing facility staff, and we are proposing changes to subsection (4) to make clear that any changes in the plan of care must be communicated with the nursing facility.

We also request that CMS clarify that the requirement to "discuss" changes in the plan of care can include fax, email, and other forms of communication.

As specified above, we request that proposed §418.112(f) be revised as follows:

(f) *Standard: Hospice plan of care.* A written plan of care must be established and maintained for each facility patient and must be developed by and coordinated with the hospice interdisciplinary group in consultation with facility representatives and in collaboration with the attending physician. All care provided must be in accordance with this plan. The plan must reflect the hospice's policies and procedures in all aspects and be based on ~~an~~ comprehensive assessment of the patient's needs and unique living situation in the facility. It must include the patient's current medical, physical, social, emotional, and spiritual needs. Directives for management of pain and other symptoms must be addressed and updated as necessary to reflect the patient's status.

(1) The plan of care must identify the care and services that are needed and specifically identify which provider is responsible for performing the respective functions that have been agreed upon and included in the plan of care.
(2) The plan of care reflects the participation of the hospice, the facility, and the patient and family to the extent possible.
~~(3) The plan of care must be reviewed at intervals specified in the plan but no less often than every 14 calendar days.~~
(43) Any changes in the plan of care must be discussed ~~among all caregivers~~ between both providers and must be approved by the hospice before implementation.

Proposed §418.112(g) *Standard: Coordination of services*

NHPCO considers this standard to have the greatest potential for strengthening the partnerships between hospices and nursing facilities, and improving patient care and outcomes. We particularly urge CMS to accept our request to add a requirement that the hospice have a system of communication with the facility to assure integration of hospice and SNF/NF or ICF/MR care and services. We also are proposing to re-order the list of information that the hospice must provide to the facility, to better correspond with the order in which the documents are normally gathered.

As specified above, we request that proposed §418.112(g) be revised as follows:

(g) *Standard: Coordination of services.* The hospice must designate a member of its interdisciplinary group to coordinate services ~~the implementation of the plan of care~~ with the representatives of the ~~facility~~ SNF/NF or ICF/MR. The hospice must have a system of communication with the facility to assure integration of hospice and SNF/NF or ICF/MR care and services. The hospice must provide the facility with the following information:

(21) Patient's or patient's representative hospice informed consent form,

election form and any advance directives.
(2) Physician certification and recertification of terminal illness.
(~~1~~3) Hospice p~~P~~lan ~~of~~ for palliative care.
(~~3~~4) Names and contact information for hospice personnel involved in hospice care of the patient.
(45) Instructions on how to access the hospice's 24-hour on-call system.
(~~5~~6) Medication information ~~specific to the patient~~
(~~6~~7) Physician orders.

Proposed §418.112(h) ***Standard: Transfer, revocation, or discharge from hospice care***

NHPCO requests that CMS delete the second sentence in this standard. Hospices are not in a position to influence the eligibility of patients to continue to reside in a SNF/NF or ICF/MR.

As specified above, we request that proposed §418.112(h) be revised as follows:

(h) Standard: Transfer, revocation or discharge from hospice care. Requirements for discharge or revocation from hospice care, § 418.104(e), apply. ~~Discharge from or revocation of hospice care does not directly impact the eligibility to continue to reside in an SNF, NF, ICF/ MR, or other facility.~~

Proposed §418.112(i) ***Standard: Orientation and training of staff***

We are proposing changes to this standard to require that hospices ensure that nursing facility staff have been oriented and trained in the hospice philosophy and hospice practices, but not require redundant training. Some nursing facilities have agreements with several hospices, and each hospice should not be required to orient all nursing facility staff in hospice concepts and practices if, for example, another contracted hospice has recently conducted an orientation. As written, proposed §418.112(i) could be quite burdensome for both hospice and nursing facility staff, and is not necessary to achieve the goals of the standard.

As specified above, we request that proposed §418.112(i) be revised as follows:

(i) *Standard: Orientation and training of staff.* Hospice staff must ~~orient~~ ensure facility staff furnishing care to hospice patients have been oriented in the hospice philosophy, including hospice ~~policies and procedures~~ protocols and practices regarding methods of comfort, pain control, symptom management, as well as principles about death and dying, individual responses to death, patient rights, appropriate forms, and record keeping requirements.

XXII. PERSONNEL QUALIFICATIONS (PROPOSED §418.114)

CMS has proposed significant revisions to the personnel qualifications for hospice employees, and in particular is proposing that where personnel qualifications are not statutory or do not relate to a specific payment provision, CMS would simply require personnel to meet State licensure or certification requirements. This proposed change has particular relevance in the case of social workers. The current hospice regulations require that social workers have at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education; however, some states allow licensure of social workers who do not meet this qualification. As requested by CMS, NHPCO solicited comments from the field on the issue of social work qualifications, and received a high volume of responses.

Although we received a wide range of comments, overwhelming provider consensus was to continue to require that personnel functioning as hospice social workers have at least a bachelor's degree in social work. NHPCO recommends that the requirement for social work remain at the current level, requiring that social workers be licensed and have a bachelor's degree from a school accredited or approved by the Council on Social Work Education.

As specified above, we request that proposed §418.114(b) be revised as follows:

(b) Personnel qualifications for physicians, speech-language pathologists, social workers, and home health aides.
The following qualifications must be met:

(1) *Physicians.* Physicians must meet the qualifications and conditions as defined in section 1861(r) of the Act and implemented at § 410.20 of this chapter.

(2) *Speech language pathologists.* Speech language pathologists must meet the qualifications specified in section 1861(ll)(1) of the Act. The individual must have a master's or doctoral degree in speech-language pathology and must—

(i) Be licensed as a speech-language pathologist by the State in which the individual furnishes such services, or,

(ii) In the case of an individual who furnishes services in a State which does not license speech-language pathologists, must:

(a) Have successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating such supervised clinical experience),

(b) Have performed not less than 9 months of supervised full-time speech language pathology services after obtaining a master's or doctoral degree in speech-language pathology or a related field, and successfully completed the Praxis National Examination in Speech-Language Pathology.

(3) *Social workers.* Social workers must have at least a bachelor's degree from a school accredited or approved by the Council on Social Work

Education, and be licensed by the State in which the individual furnishes services, if such licensure is required.

(~~3~~)(4) *Home health aides.* Home health aides must meet the qualifications required by section 1891(a)(3) of the Act and implemented at § 484.75.

XXIII. CRIMINAL BACKGROUND CHECKS (PROPOSED §418.114(d))

Most states and many liability insurers now require hospices to obtain criminal background checks on employees. Providers who commented perform these checks currently, and do not object to this practice due to potential liability issues. However, NHPCO has concerns with the proposed requirement that hospices obtain a criminal background check on EACH employee. Many programs require background checks only for those employees involved with patient care, or who have contact with financial information. There was also a concern raised about the language in the preamble stating that such background checks would be required "before employment".

NHPCO is uncertain of CMS' intent in this standard. Would hospices be prohibited from hiring individuals with certain backgrounds; could they be hired conditionally; could they be hired provided they had no patient care or financial contacts? Many companies that provide background checks have a response time of 30 days; it is common practice in many hospices to conditionally hire the employee until the criminal background check results are in, and use that time for orientation and non-patient care related training activities. Some hospices commented that it should be sufficient for the hospice to obtain background checks in accordance with state law.

There was a concern raised about current volunteers and employees. One provider commented, "we do object to having to check employees and volunteers who were working with us prior to our initiating this practice years ago. We will lose volunteers who will take it as a personal affront." We request that in the final rule CMS address the issue of hospices' responsibility regarding current employees and volunteers.

As specified above, we request that proposed §418.114(d) be revised as follows:

d) *Standard: Criminal background checks.* The hospice must obtain a criminal background check on ~~each~~ hospice employees ~~and contracted employee before employment at the hospice.~~ in accordance with state law. Hospice contracts must require that all contracted entities obtain criminal background checks on contracted employees in accordance with State law.

Conclusion

NHPCO conducted extensive outreach to the hospice community during the comment period and incorporated many comments from the field in this comment letter. We are pleased to provide our thoughts and recommendations on the proposed Hospice Conditions of

Participation, and look forward to working with CMS and with hospice providers to prepare for the implementation of the final rule.

Should you have any questions or wish to discuss any of these issues with us, we would be happy to work with you.

Respectfully submitted,

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President and CEO