Comments for CMS-3844-P

Medicare and Medicaid Programs:
Hospice Conditions of Participation

July 8, 2005

Patient's Rights – Proposed §418.52

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

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

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

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

418.80 reads as follows:

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

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

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

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

Page 30850 of the proposed conditions of participation state:

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

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

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

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

Page 30874 states:

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

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

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

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

Sec. 418.64 Condition of participation: Core services.

A hospice must routinely provide substantially all core services directly by hospice employees. These services must be provided in a manner consistent with acceptable standards of practice. These services include nursing services, medical social services, and counseling. The hospice may contract for physician services as specified in Sec. 418.64(a). **A hospice may, under extraordinary or other non-routine circumstances, enter into a written arrangement with another Medicare certified hospice program for the provision of core services to supplement hospice employee/staff to meet the needs of patients. Circumstances under which a hospice may enter into a written arrangement for the provision of core services include: Unanticipated periods of high patient loads, staffing shortages due to illness or other short-term temporary situations that interrupt patient care; and temporary travel of a patient outside of the hospice's service area.**

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

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

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

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

(1) Authorized by the hospice;

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

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

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

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

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

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

We implore CMS to consider the needs of the patient to include the utilization of qualified staff wherever they may originate from. We would gladly offer ourselves as available for scrutiny if CMS would like to appoint some form of inspection/survey on our own program. We want to offer only care that meets standards of quality the terminally ill patient deserves, and have spent many, many hours refining policies, orientation, and training that generally far exceeds that of the host hospice themselves. We welcome the survey process perhaps as part of the survey on the host hospice, and indeed many times surveyors have requested quite specific items related to our services in continuous care. If we are deficient, we expect to be held accountable, and would earnestly endeavor to improve when necessary. As patient advocates, we strongly urge CMS to grant us (and other qualified agencies) the opportunity to prove the value of such a service as ours, and not simply dismiss this program without first giving us an honest prospect of proving the benefits we offer the patient and the hospice.

S Stone

July 22, 2005

Response to New Cops for Hospice Care

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

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

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

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

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

Thank you,

Sandra E. Miller, RN

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July 18, 2005

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

Dear CMS Representative,

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

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

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

Respectfully Submitted,

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

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

CMS introductory statements paraphrased and numbered for reference in comments:

1. "…focus on the care delivered to patients and their families."
2. "…reflect an interdisciplinary view of patient care and allow hospices flexibility in meeting patient standards."
3. "…efforts to achieve broad-based improvements in the quality of health care."
4. "…to focus on a patient-centered, outcome oriented process that promotes patient care foremost, rather than penalizing unproductive providers."
5. "…to achieve a balanced regulatory approach by ensuring that hospice furnishes health care that meets essential health and quality standards."
6. "All of the revised requirements are directed towards improving patient outcomes of care and satisfaction."
7. "…this problem focused approach has inherent limits. Ensuring quality through the enforcement of prescriptive health and safety standards, rather than improving the quality of care for all patients, has resulted in our expending much of our resources on dealing with marginal providers, rather than on stimulating broad-based improvements in quality care."
8. "…adequate to protect the health and safety of individuals under hospice care and to promote the effective and efficient use of Medicare funds."
9. "Use a patient-centered, interdisciplinary approach that recognizes the contributions of various skilled professionals and other support personnel and their interaction with each other to meet the patient's needs."
10. "Use performance measurement systems to evaluate and improve care."

418.54 COMPREHENSIVE ASSESSMENT OF THE PATIENT

(a) A "within 24 hours" requirement is made in disrespect of patient rights. Many patients, after their physician requests hospice services, do not want a visit from hospice within 24 hours due to a number of reasons, from simple convenience to wanting other family members present (who otherwise cannot be present within that time frame) during the initial hospice visit. In the latter example, having family members present helps the patient garner needed support and helps the hospice do a comprehensive assessment, the basis for formulating an adequate care plan and thereby meeting the patient's and family's needs. Also, many hospices, due to practicalities, may not be able to adequately meet this requirement (i.e. a small rural hospice with one RN who has received 2 or more orders for hospice on one day. It does happen). **Alternative:** Have hospices monitor a quality standard around timeliness in meeting patient needs at the start of care, with the expectation that hospices having problems in these areas be able to demonstrate improvement in providing hospice services to beneficiaries in a timely fashion. Refer to CMS introductory statements 4, 6, 7 and 10.

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

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

(d)(1) The 14-day requirement is again a digression from a CMS stated goal to move away from "Enforcing structure and process requirements," that have "...been inadequate to meet the growing challenges associated with the changing hospice care environment." For practical reasons, the ultimate effect of this requirement would be a detriment to our highly valued and effective team functions in the care of hospice patients. It would likely result in rubberstamping of assessments by team members and the fragmenting of team processes. If CMS is going to realistically move toward ..."outcome-oriented standards," they are going to have to rely on quality measures and provide reasonable time frames that support rather than detract from team processes and patient-centered care. **Alternative:** Require that hospices maintain ongoing documentation of comprehensive assessments at frequencies based on patient needs and in respect of patient rights, that care planning be based on ongoing comprehensive assessment, and that care plans are reviewed by the IDT within 7 days of a change in condition warranting changes in the plan of care and no less than every 30 days. This allows for adequate interdisciplinary processing and leeway for holidays that can bump IDT meetings by a day or two. Refer to introductory statements 2, 4, 6, 7, 8, 9 and 10.

418.56 IDG PLANNING AND COORDINATION OF SERVICES

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

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

418.58 QUALITY ASSESSMENT AND IMPROVEMENT PROCESS

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

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

418.76 HOME HEALTH AIDE AND HOMEMAKER SERVICES

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

(h)(i) The CMS is moving toward quality measurement and improvement. If Home Health Aide quality indicators for a hospice are favorable, the hospice is assessing Home Health Aide competency, and the patient is satisfied with Home Health Aide services, why would point of care assessments of aides be necessary much less have a time frame associated with them? The CMS appears to once again be drifting from its vision of moving from structure to quality measurement in regards to this standard. **Alternative:** Require hospices to measure home health aide outcomes and patient satisfaction, and demonstrate improvement when there are substandard results. See introductory statements 1, 3, 4, 5, 6, 7, 8 and 10.

418.100 ORGANIZATION AND ADMINISTRATION OF SERVICES

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

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

418.102 MEDICAL DIRECTOR

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

418.104 CLINICAL RECORDS

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

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

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

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

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

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

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

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

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

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

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

418.114 PERSONNEL QUALIFICATIONS FOR LICENSED PROFESSIONALS

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

Comments for CMS-3844-P

Medicare and Medicaid Programs: Hospice Conditions of Participation

June 27, 2005

Patient's Rights – Proposed §418.52

Proposed **§418.52** states:

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

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

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

Conditions of Participation: Core Services
Proposed §418.64

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

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

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

Thank you for your time and consideration.

Kimberly P Lawrence

817-637-8556

Kimberly@ccsnationwide.com

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Calvert Hospice
Life, healing, hope.

July 22, 2005

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

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

Dear Administrator McClellan:

Calvert Hospice appreciates that the Centers for Medicare and Medicaid Services (CMS) has published proposals for revisions of the Conditions of Participation for hospice and takes this opportunity to comment on the Notice of Proposed Rulemaking, 70 *Fed. Reg.* 30840. Calvert Hospice endorses the comments of the National Hospice and Palliative Care Organization (NHPCO) and the Hospice Network of Maryland (HNM). Nonetheless, as a small hospice in a rural county in Southern Maryland, we would like to point out that some of the proposed conditions would impose significant hardship on our operations.

1. DEFINITIONS
   (a) ***Attending Physician*** - We strongly urge CMS to include specifically include in the definition of Attending Physician that the Hospice Medical director may serve at the patient's Attending Physician. Our patients in Calvert County receive care from many physicians through the Washington, D.C. metropolitan area, the Baltimore metropolitan area, Annapolis, and surrounding counties. Often they do not have a conveniently located local physician that the Hospice team may contact for orders and to sign the death certificate. Given that the number of physicians in the county is limited, it can be very useful if the Hospice Medical Director, a local internal medicine practitioner, can be named as the patient's Attending Physician.

   (b) ***Drug Restraint*** – We support the comments of NHPCO on this point. Appropriate treatment of a terminal condition may include therapies that, in other contexts, might be viewed as "drug restraint." We urge CMS to modify this definition as recommended by NHPCO.

2. PATIENT'S RIGHTS

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(410) 535-0892, (301) 855-1226 • (410) 535-5377 (fax) • 1-800-735-2258 for the hearing impaired
www.calverthospice.org
HOSPICE
NETWORK OF MARYLAND

(a) ***Exercise of rights and respect for property and person*** - We encourage CMS to adapt the regulatory language currently used for home health agencies in place of the formulation proposed which has been adapted from the skilled nursing facility regulations.

3. COMPREHENSIVE ASSESSMENT

(a) ***Initial assessment*** - The proposed regulations prescribe that the "hospice registered nurse must make an initial assessment within 24 hours after the hospice receives a physician's admission order for care (unless ordered otherwise by the physician). . . ." Because the notion of "admission order" is new to hospice, Calvert Hospice suggests that this provision be re-cast to prescribe an initial nursing assessment within 24 hours of the patient's admission to hospice, thereby encompassing the physician's certification of the patient as appropriate for hospice care and the process of admitting the patient at a time convenient for the patient and family.

(b) ***Time frame for completion of the comprehensive assessment*** – The proposed conditions establish at best a confusing process, and, at worst, an unworkable one. The assessment process leading to the development of a plan of care should consist of patient-centered, face-to-face assessments by a nurse, social worker and other hospice team members as appropriate. The four day time limit is insufficient to accomplish this most important task.

4. INTERDISCIPLINARY GROUP

(a) ***Approach to service delivery*** – Calvert Hospice would note again its comment at Item 1(a) above regarding the patient's Attending Physician. It is often not the case where the patient's Attending Physician and the hospice Medical Director are different individuals. Thus, Calvert Hospice urges CMS to eliminate the parenthetical phrase in proposed §418.56(a)(1)(i).

Calvert Hospice would also request that CMS return to the statutory language in §418.56(a)(1)(iv), so that the regulation would require a "pastor or other counselor."

5. VOLUNTEERS

(a) ***Level of Activity*** – Calvert Hospice urges CMS to adopt the revisions recommended by NHPCO and delete the addition of the phrase "day-to-day" in modifying "administrative" volunteer activity. The addition of "day-to-day" is confusing and should be eliminated.

6. ORGANIZATION AND ADMINISTRATION OF SERVICES

(a) ***Professional Management Responsibility*** – As proposed, the obligation to ensure supervision of staff of agencies with which hospices have a written agreement is unworkable. The hospice should be responsible for the oversight of the services provided and not the direct supervision of staff. This responsibility should be included in the written agreement with contracting agency, so that it, not the hospice, is directly responsible for the overall supervision of staff and the hospice remains responsible to the patient and to Medicare for the provision of the service.

7. MEDICAL DIRECTOR
   (a) ***Coordination of Medical Care –*** Calvert Hospice opposes the proposal to make the Medical Director responsible for directing the hospice's quality assessment and performance improvement program. The Medical Director has no special expertise regarding the identification of appropriate outcome measures, data elements, collection strategies or aggregation techniques. As the Medical Director is, in our hospice, a volunteer, it is surely an inappropriate utilization and waste of valuable resources to require that this member of the team perform this administrative role.

8. CLINICAL RECORDS
   (a) ***Authentication –*** CMS appears, once again, to be using an inappropriate model in crafting the proposed language. Hospice patients are cared for directly by hospice staff and by staff of agencies with which hospice has a written agreement. It should be sufficient for the contracting agency to have verified the signature and certify to that verification by contract rather than imposing the extraordinary administrative burden on the hospice to verify the signature of every physical therapist, respiratory therapist, nursing home aide or nurse who may offer treatment to the patient while he or she is under hospice care.

   (b) ***Discharge or transfer of care*** – Sending a complete copy of a patient's record to the Attending Physician or to the next facility is an extraordinarily onerous requirement for both the originating hospice and the receiving entity. Discharge orders, history and physical and medication profile should be sufficient. Even if all hospices had the funds to invest in electronic recordkeeping (as CMS is aware most do not), such duplication of data is unnecessary.

9. SNF/NF
   (a) Calvert Hospice has spent many years working with the two local SNFs in our service area to achieve a workable relationship integrating the roles of the staffs of both agencies to provide hospice care for the facilities' residents. The proposed regulations, without corresponding changes in the SNF/NF regulations, will virtually ensure that these efforts will have been for naught. Unfortunately, these provisions elevate hospice in an inappropriate way over the staff of the facility and, because there is no requirement that SNFs refer dying patients to hospice, will succeed in denying nursing home patients the services of hospice in their last days. Hospices

and SNFs are partners in the care of their patients, jointly developing care plans, jointly ensuring the best care for the patients and families. The proposed regulations should ensure that this equal partnership can be maintained.

(b) ***Written Agreement*** – Calvert Hospice would note that it is inappropriate for the written agreement between hospice and the facility to include the written consent of the patient or patient's representative. Perhaps it would be appropriate for CMS to require that the contract to include a provision that the hospice obtains the written consent of the patient or patient's representative as required by the conditions of participation.

In addition, rather than specify the conditions under which the facility immediately notify the hospice, it would be more appropriate for the contract to include a provision that the facility and hospice to develop and document a plan of communication that would ensure that the hospice is notified regarding any change in the patient's condition that would require alteration of the plan of care (including a transfer of the patient from the facility).

CONCLUSION

As noted, Calvert Hospice endorses the comments submitted by the NHPCO and urges CMS to incorporate the changes recommended by NHPCO, as well as those few additional suggestions we have offered, into the final version of the regulations.

Sincerely,

Lynn Bonde
Executive Director

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HOSPICE
and Palliative Care
OF ST. LAWRENCE VALLEY

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July 22, 2005

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

Dear CMS:

I am writing to comment on the proposed rules for the Hospice Conditions of Participation.

I am supportive of the intent of many of the proposed changes, but have concerns about some areas.

1. It would be a positive step to allow for a "qualified health care professional who is a member of the interdisciplinary group" to coordinate a patient's care, rather than restricting this role to a registered nurse, as under the current Conditions of Participation (Section 418.56). For many patients, psychosocial issues are paramount, and it would be appropriate to assign case management to a social worker rather than a nurse.
2. The emphasis on quality assessment and performance improvement is in accord with efforts taken by the National Hospice and Palliative Care Organization and hospices throughout the country. As described in your proposal, hospices would have flexibility in designing their particular performance improvement approach. I urge the standards be designed so that they can be scaleable to the size of the hospice (Section 418.58).
3. The requirement for hospices to track and collect controlled drugs would be unduly burdensome and risky for hospice nurses serving patients at home. Our nurses do oversee the amount of drugs being used, and take steps to reduce the possibility of diversion. However, the drugs belong to the patients, and we cannot monitor them 24 hours a day. Moreover, it would be dangerous for it to become known that Hospice staff sometimes collect and transport controlled substances. (Section 418.106(b)).
4. Throughout the proposed rules, there are increased duties proposed for the medical director. Most smaller hospices have part-time medical directors, who are in some cases volunteers. The requirement for the assumption of responsibilities currently carried out by other members of the IDG, such as communication with the attending physician for all patients in an SNF

(Section 418.112(d)) would pose problems for smaller hospices in recruiting and paying for additional hours of the time of a medical director.

Thank you for your attention to these concerns.

Very truly yours,

Brian Gardam
Executive Director

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Sharon Mezzina RN
6130 60th Court
Vero Beach, Fl. 32967
smezzrn@yahoo.com
July 16, 2005

Center for Medicare & Medicaid Services—file CMS-3844-P,

I am a Certified Hospice and Palliative Care nurse and a Registered Nurse. I work at the Visiting Nurses' Association (VNA) Hospice House in Vero Beach Florida. Our unit is a free standing, 12 bed in-patient unit that serves the residents of Indian River County. I am also a student at Florida Atlantic University pursuing by advanced degree to become a nurse practitioner.

I am writing about the Proposed Rule: Medicare Hospice Benefit Conditions for Participation. I would like to encourage CMS to adopt the proposed definition of "attending physician" as stated in the proposal which includes the nurse practitioner. It is my understanding that the newly adopted definition will be listed in Section 418.114 under personnel requirements.

Nurse practitioners are uniquely qualified to be Primary Care Providers. Most people trust nurses and it is this trust that creates a strong relationship between the patient and the nurse practitioner. Nurse Practitioners have the caring perspective as nurses to see the patient as a whole being and they have the expertise to be the Primary Care Provider.

The Primary Care Provider is in an excellent position to discuss and obtain advance directives from patients signing onto hospice services. Securing these documents early in the patient's illness allows the Nurse Practitioner and nurses to maintain patient's rights through the illness and the dying process. Once these decisions are made, the patient can transition through a "good death" which is the backbone of the hospice philosophy.

Instating the nurse practitioner under the definition of "attending physician" allows them to provide continuity of care. For some citizens in rural areas, the nurse practitioner is the only practitioner they have available. They are highly skilled, qualified, knowledgeable and superb patient advocates. The proposed rule has clearly stated it wants the Conditions of Participation to be patient-centered, patient oriented; a job for patient advocates and nurse practitioners.

Please adopt the proposed definition of "attending physician" to include Nurse Practitioners.

Thank-you for time and consideration.

Respectfully,
Sharon Mezzina RN, CHPN
Sharon Mezzina RN, CHPN

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Hospice Care, Inc.

A nonprofit organization dedicated to patients and families facing serious illness and loss

July 21, 2005

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

Dear Sir/Madam:

Thank you for this opportunity to comment on the Medicare and Medicaid Programs: Hospice Conditions of Participation, Proposed Rule that appeared in the Federal Register on May 27, 2005. Hospice Care, Inc. is a non-profit organization, established in 1978, serving over 40 communities in the greater Boston area. We are an affiliate of the Visiting Nurse Association of Boston Foundation.

I would like to say that I appreciate the amount of time and energy that has gone into this effort. And I commend Mary Rossi-Coaju and Danielle Shearer for all their work. Their presentation in Baltimore was well done and very comprehensive. I give them a lot of credit for facing an audience of 100+ hospice managers/executives with such poise.

In general, I have found the new organization of the proposed CoPs helpful and more user friendly. For the most part, the new standards are consistent with the hospice community's interest in assuring quality and encouraging a greater degree of uniformity. Attached you will find comments on those standards which, as a result of group review, we feel need further clarification or where the standards may seem to pose implementation difficulties. In addition, I have **highlighted our priority issues in bold type.**

Thank you for your attention to this matter.

Respectfully submitted,

Diane M Bergeron, RN, MSM
Executive Director

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Hospice Care, Inc. is an affiliate of the Visiting Nurse Association of Boston Foundation

Proposed CoPs: file code **CMS-3844-P**

418.3 Definitions

Clinical note: **recommend** 'spiritual' be added to "any changes in physical, *spiritual* or emotional condition"

Drug restraint: **request clarification**, as some medications may be viewed as a chemical restraint in many instances, whereas in hospice the medications are likely being used for customary end-of-life treatment not as a restraint. **(Please see attachment I, our pharmacist addressed this in detail).**

Hospice Care: **consider** the inclusion of '*hospice is a comprehensive set of services **provided in the home, in the community and in facilities**, identified and coordinated by an interdisciplinary team…*'. It seems that there are an increasing number of Long Term Care facility based hospice programs that **only** provide hospice services to the residents of their facility and not in any other venue. I must say it is rather frustrating.

418.52 Patient's Rights

(a) Notice of Rights (1) *Translation*: **written/printed** requirement for translation of multiple languages would be a very expensive proposition, likely beyond the financial ability of most agencies. Oral **or** written notice would be more reasonable.

(a) Notice of Rights (3) *Tracking & disposing of controlled substances*: all the information that is currently given and discussed at admission is confusing and/or frightening enough no matter how we try to simplify the process. And the stigma attached to 'controlled substances' can be unsettling at best even in these circumstances. I would suggest that it is better to introduce the concept, if and when, a 'controlled substance' is added to the plan of care. That is not to say that the information should not be included in the patient/family admission packet.

(a) Notice of Rights (4) ***demonstrated*: please elaborate**; i.e. documentation of nod of head, verbal agreement or must the patient/family sign a document?

(b) Exercise of Rights (1) *Patient right*: would suggest adding (v) ***the right to refuse treatment***

(b) Exercise of Rights (4) *Hospice must:* recommend adding '*within 5 working days of the **discovery** of the incident*'

(e) Patient liability: Use of ABN in hospice is still rather confusing, request further clarification. Should 'patient' = primary caregiver/family, in certain circumstances, when the patient is not able? To what extent might we know the specific costs prior to the plan of care?

418.54 Comprehensive Assessment

(a) Initial Assessment: **the initial assessment within 24 hours is not a practical statement & the physician's admission order for care is somewhat ambiguous. I think I understand the intent, however I believe the wording needs some editing and further clarification, particularly for future referrence. A large number of hospice referrals are not physician driven. In fact, the primary physician may be reluctant to talk about hospice and the family makes the initial contact. We will then complete a consult and help the family/patient work with their physician. Therefore, an initial assessment has been completed prior to the order from the MD. Would that mean we would have to complete an additional 'initial' assessment? In addition, we may receive an admission 'order' from the physician on a Monday but the patient/family is in an approach-avoidance mode and insists that we can't visit until Friday the earliest. What would be the impact in this case?**

(b) Time frame: 4 days is a realistic time frame for most hospices. However, this time may have a negative impact for rural providers. Might this be interpreted in a broader sense, could phone contact be acceptable in some instances?

(e) Patient outcome measures: I believe 'outcome measures' are a necessary tool to quality and performance.

418.56 IDG care planning

(a) Approach to service delivery: (1) i **request remove** *'who is not the patient's attending physician'*

(c) Content of PoC: (6) There should be no requirement that the 'family' agree with the PoC, the patient drives the PoC as long as able. Further clarification is needed if the patient is not competent and there is disagreement among family members. Where does the Health Care Proxy fit in?

418.58 QA/PI

(b) Program data: **see attachment II** for detail

(e) Executive responsibilities: our QA/PI report is reviewed annually with our governing Board. And, if there are any issues that are identified at any other time, they are brought up at a scheduled Board meeting for review.

418.72 PT, OT and Speech

Would request **dieticians** added to the list of **non-core** services.

418.76 HHA & homemaker services

(h) Supervision of HHA: **this standard is confusing. The HHAs are currently supervised directly and indirectly twice a month, are you suggesting that the 28 day HHA assessment is in addition to what we currently do or instead of? Is the focus the patient, the aide or both? Is this intent to be a Human Resource function in addition to their annual evaluations? Our agencies HHAs are very experienced, we have little turnover, the last HHA hired was over 2 years ago. The clinical staff really knows the strengths and weaknesses of the individual HHAs. Imposing additional oversight would significantly increase the burden of the clinical staff who are already feeling a great deal of pressure. Essentially, we are doing this already, I would suggest that the current practice is more than adequate.**

418.100 Org & Admin services

Our management team & medical director had lengthy discussion regarding this standard. This standard is quite subjective and difficult, at best, to measure. How might this standard be audited? Family satisfaction survey? Families are often unrealistic with their expectations. We feel strongly that this standard needs modification and would like examples or language to be defined in the preamble and interpretive guidelines.

(a) Service the patient/family: (1) **would suggest adding '*to the extent possible within the context in which the patient is living*' following dignity; and.**

(a) Service the patient/family: (2) ***'desires'* could be a huge issue with many families. We suggest 'goals' within reason and/or according to the PoC.**

(b) Governing Body: request expanded definition of administrator

(e) Professional Mgm't: Hospice should have professional oversight for the services provided **not the contracted staff.**

418.102 Medical Director

(c) Coord of medical care: **'patient's medical care in its entirety'? What does this mean? What about dialysis and other specialty areas? Should this not be in conjunction with.... other physician as necessary?**

(c) Coord of medical care: **Our medical director strongly disagrees with 'directing' the QA/PI program… participating or playing an active role is more accurate. 'Directing' the QA/PI program is an administrative function under the auspices of the Executive Director with the involvement of the medical director. The medical director should be involved, but not have the primary responsibility. Our medical director recommends the use of the American Academy of Hospice & Palliative Care's definition of medical director.**

418.104 Clinical records

******** see **Attachment III** for a summary of the components of the electronic health record as requested

(b) Authentication: **this is not practical for home hospice care. We do not have the luxury of having the MDs on-site. We do check licensure on-line with the state registry. This would be a huge undertaking and may be setting us up for failure. I understand the intent, particularly coming from a hospital based background, however the full execution of this standard is doubtful.**

(d) Disch or transfer of care: **no facility or physician that I know of wants to receive a 'full' copy of the patient's medical record. This would be very costly, time consuming, cumbersome and generally annoying to the receiver. In addition, this standard would move us beyond the HIPAA Minimum Necessary Standard. And, to the best of my knowledge, it is not done in any other aspect of healthcare. What we really need is comprehensive discharge or transfer summary documentation.**

<u>418.106</u> <u>Drugs, controlled drugs</u>

(b) Controlled drugs: request changing '<u>potential dangers</u>' of controlled substances' to '**<u>safety</u>**' of controlled substances. 'Potential dangers' have a negative connotation.

(c) DME use & maint: the DME vendor is responsible for the repair and routine maintenance of the equipment, not hospice. The DME vendor is also responsible for the policies & procedures related to the repair and maintenance. Hospice is responsible for the professional management of the contract.

<u>418.108</u> <u>Short-term IP care:</u>

General inpatient care should be appropriate and available to families who are experiencing a short-term crisis of a psychosocial nature. Criteria for the GIP and respite should be clear <u>and</u> separate as this is often a point of misunderstanding by professionals and the public.

(a) IP care for symptom mgm't & pain control: **The CoPs should retain the requirement that an <u>RN be on-site</u> at facilities providing the GIP benefit either as freestanding units or as contracted facilities. GIP, as the most acute level of hospice care, warrants the expertise and care of a RN to monitor pain and symptoms deemed unmanageable at the routine level of care.**

<u>418.110</u> <u>Hospice providing IP care:</u>

(a) Staffing: **RN should be on-site 24/7 to provide direct care.**

(d) (6) (v) should be (iv)

(o) Seclusion & restraint: **At the end-of-life, certain medications can be a necessary treatment in the management of terminal agitation and/or to induce sedation for those experiencing intractable pain & suffering. Certain drugs are used to manage the treatment of symptoms and not intended as a restraint. There is a concern that some surveyors who are not expert in EoL care may view such treatments as chemical restraint rather than responsible and acceptable practice.**
(please see Attachment I)

(o) (3) (ii) (a) 'Orders for seclusion or restraints must never be written as a standing order or on <u>an as needed basis</u>'. Our medical director recommends **<u>unless the 'as needed' is defined and has set parameters.</u>**

<u>418.112 hospice care in SNF… other facilities:</u>

(e) Medical director: The medical director (suggest adding here) **<u>and/or other MDs providing care</u>** must provide overall coordination of the medical care of the hospice resident.

Our medical director recommends that the focus be on overall communication between facility staff, the attending MD & the hospice IDG team to optimize the care of the patient.

This standard as it is stated is operationally not feasible.

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

<u>418.114 Personnel qualifications:</u>

(c) (7) Social Worker: There was consensus that the minimum education requirement for a direct care social worker should be a MSW. The level of clinical judgement and independence required in the culture and environment of an individual's home is gained through experience, education and training. However, a waiver exemption could be afforded where the hospice can demonstrate undue difficulty in recruiting a master's prepared social worker.

(d) background checks: CORI checks should be required for all hospice staff and volunteers.

LONG-TERM PHARMACY SOLUTIONS, INC.
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July 13, 2005

Diane Bergeron, RN, MSN
Executive Director
Hospice Care Inc.

RE: Drugs used as a restraint with regard to the 2005 CMS proposed conditions of participation.

Dear Diane:

With regard to our conversation concerning drugs being used as a restraint, I have performed a literature search and given careful consideration using my clinical experience; and I submit the following synopsis.

Drugs that can be potentially used as a chemical restraint, or sometimes considered a chemical restraint, fall under several drug categories:

Antipsychotic/Neuorleptic agents:

Butyrophenones	**i.e., Haloperidol (Haldol^{R})**
Phenothiazines	**i.e., Chlorpromazine (Thorazine^{R})**
	i.e., Perphenazine (Trilafon^{R})
	i.e., Prochlorperazine (Compazine^{R})
Benzisoxazole	**i.e., Risperidone (Risperidal^{R})**
Thienobenzodiazepine	**i.e., Olanzapine (Zyprexa^{R})**
Dibenzothiazepine	**i.e., Quetiapine (Seroquel^{R})**

Anti-anxiety Agents:

Benzodiazepines	**i.e., Lorazepam (Ativan^{R})**
	i.e., Diazepam (Valium^{R})

Although all of the above mentioned drugs could be considered chemical restraints, they are commonly used for symptom management in palliative and hospice care. In addition to pain, patients who are approaching the end of life commonly have other symptoms such as delirium (AKA: agitation, terminal restlessness, acute confusion), dyspnea, nausea, depression, among many other symptoms.

I will focus on ***delirium*** as this seems to be the area of greatest concern regarding drug restraint.

Delirium is a common psychiatric disorder in terminally ill patients. It is a disturbance of consciousness and cognition with a sudden onset that may be accompanied by increased psychomotor activity. Its prevalence in dying patients is believed to be up to 60%. Delirium often heralds the end of life and may require sedation in 25% to 50% of patients.[1] Delirium can deeply disturb the patient and family. "All episodes of delirium interfere with meaningful interpersonal contact with loved ones due to clouding of consciousness."[2] Because the period before death is a special time for patients and family members, it is imperative pharmacological and non-pharmacological measures be taken to control delirium. With the exception of treating delirium due to drug withdrawal or anticholinergic excess, neuroleptics are first line pharmacological agents for symptom management. Haloperidol is usually the agent of choice for most patients. It has a favorable side effect profile and can be administered orally, transdermally, or parenterally. Other neuroleptics may also control delirium as well as being good antiemetics. However, they may have higher incidence of extrapyramidal side effects and sedation. The newer atypical neuroleptics: olanzapine, quetiapine, and risperidone, can be useful particularly in patients with Parkinson's disease and other neuromuscular disorders or in patients with a history of extrapyramidal side effects from neuroleptics. As noted in the International Association for Hospice and Palliative Care manual of palliative care, second edition, section 4, symptom control "haloperidol is the agent of choice in treating delirium in terminally ill patients because it improves cognitive function and provides sedation."[3] Also noted in Symptom Management Algorithms, A Handbook for Palliative Care, second edition, haloperidol and lorazepam are first line agents for treatment of agitation and anxiety. It should be noted that lorazepam as well as benzodiazepines can sometimes cause paradoxic agitation and over sedation.[4]

"Haloperidol is the agent of choice for the management of delirium associated with hyperactivity at end of life period. A well designed double blind study[5] comparing haloperidol (a high potency neuroleptic) chlorpromazine (a low potency neuroleptic) and lorazepam (a benzodiazepine) in the treatment of delirium in hospitalized patients with AIDS, found haloperidol to be the preferred drug."[6]

These facts along with my clinical experience using haloperidol as well as other neuroleptics and benzodiazepines for symptom management lead one to the conclusion that these drugs, when used properly, are not chemical restraints, but a powerful tool in our armamentaria. To restrict the use of these medications would be a disservice to our patients and their families; and greatly impact our mission of providing quality end of life care to our terminally ill patients.

Table 1

Medications commonly used to manage delirium in end of life care

Medication	Approximate Dosage Range	Route of Administration*
Neuroleptics		
Haloperidol	0.5-5mg every 2-12 hrs	PO IV SL SC IM TD
Chlorpromazine**	12.5 to 50mg every 4 to 12 hrs	PO IV IM TD
Perphenazine* **	4-12mg every 4 to 12 hrs	PO TD
Olanzapine	5 to 20mg daily	PO
Quetiapine	50 to 300mg twice daily	PO
Risperidone	1 to 4mg daily	PO
Benzodiazepines		
Lorazepam	0.5 to 2mg every 1-4 hrs	PO IV SL SC IM TD
Diazepam	2 to 10mg every 4-6 hrs	PO IV SL SC IM TD

*PO = By Mouth
I V = Intravenous
SL = Sublingual
SC = Subcutaneous
IM = Intramuscular
TD = Transdermally
**Chlorpromazine also works well in the treatment of hiccough.
***Perphenazine is also used as an antiemetic drug or a combination with other antiemetics.

I hope you have found this information helpful. If you have any questions or desire additional information, please feel free to call.

Regards,

Steven D. Geoffroy, RPh
President

REFERENCES

[1]InTouch: Robert A. Milch, M.D., "Message from Robert A. Milch, M.D.", pg 2, Cheektowaga, NY: March 2003

[2]American Family Physician: Douglas D. Ross, M.D., PH.D., and Carla S. Alexander, M.D.: Management of Common Symptoms in Terminally Ill Patients: Part II.; Volume 64, No. 6., Pg. 1019, Sept. 15, 2001

[3]International Association for Hospice and Palliative Care: Manual of Palliative Care; http://www.hospicecare.com/manual/sysptoms-main.html, July 7, 2005

[4]Symptom Management Algorithms: Linda Wrede-Seaman, M.D.; A Handbook for Palliative Care, Second Edition, Intellicard, Yakima, WA; www.Intelli-card.com; 1999

[5]American Family Physician: Breitbart W, Marotta R, Platt MM, Wwisman H, Derevenco M, Grau C, etal. A double-blind trial of haloperidol, chlorpromazine, and lorazepam in the treatment of delirium in hospitalized AIDS patients. Am J Psychiatry 1996; 153:231-7

[6]American Family Physician: Douglas D. Ross, M.D., PH.D., and Carla S. Alexander, M.D.: Management of Common Symptoms in Terminally Ill Patients: Part II.; Volume 64, No. 6., Pg. 1021, Sept. 15, 2001

Hospice Care, Inc.

Attachment II

Outcome Measures Collected

1. Perforum Benchmarking which includes but not limited to the following:
    - NHPCO Dataset
    - NHPCO Family Evaluation of Hospice Care
    - NHPCO End Result Outcome Measures
    - Financial indicators
    - LOS indicators
    - Infection Control
    - Falls
    - Med errors

2. Concurrent Patient Satisfaction telephone surveys (LOS 7-21 days)

3. Long term Care Referrer Survey (annual mailed)

4. Physician Referrer Satisfaction Survey (annual mailed)

Attachment III

Hospice Care, Inc.

Electronic Health Record Contents

Demographic Information
Allergies
Precautions
Advanced Directives
Associated Physicians
Associated Hospice Personnel
Related Parties (PCG, Friends etc..)
Admission Information (Date, Referral Info)
Insurance Information
Diagnoses
Physician Orders
Medications
Care Plan
Level Of Care (Routine, Inpatient, etc..)
All Visit Documentation

POC Implementation Notes

Advantages to electronic documentation:

- Increased communication as all team members have access to the medical record in the field
- Increased accuracy
- Eliminates support staff from entering information that clinical staff have written out
- Documentation is available to others much sooner

Challenges in transitioning Clinical staff to electronic documentation:

- Lack of familiarity with basic computer skills
- Resistance to changing their practice
- Finding training time within their busy schedule
- Belief by many clinicians that the computer is impersonal in the home setting

Hospice Care, Inc Progress as of July 2005

- Off Hours team has full electronic access to patient information
- Admission team is using laptops, admissions done by staff nurses are still being done on paper
- 4 out of 10 staff nurses are completely electronic
- Clinical Managers document telephone calls electronically
- 85% of all field staff will be electronic by October 2005
- Early in 2006 the bulk of our medical records will be paperless

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Hospice
& PALLIATIVE CARE, INC.
Serving Oneida, Herkimer and Eastern Madison Counties

July 22, 2005

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

Dear Sir/Madam,

Enclosed you will find an orginal and two copies of proposed changes to the Hospice Conditions of Participation suggested by Hospice & Palliative Care, Inc., 4277 Middle Settlement Road, New Hartford, New York 13413.

We appreciate this opportunity to be heard on matters that will utimately guide the way we and our loved ones will experience at the end of life.

Thank you for your consideration of these proposed changes.

Sincerely,

Pi Gentile

Pi Gentile
Executive Director

4277 Middle Settlement Road, New Hartford, New York 13413 • (315)735-6484 • Fax: Administration - (315) 793-8852, Clinical - (315) 735-8545
Accredited by The Joint Commission on Accreditation of Healthcare Organizations
The recognized leader in end-of-life care since 1977.
www.hospicecareinc.org

July 22, 2005

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

Re: Hospice Conditions of Participation: Proposed Rule published on May 27, 2005 in the Federal Register. Hospice and Palliative Care, Inc. has carefully reviewed the Proposed Rule and wishes to submit the following recommendation for changes, which are in italics.

Section 418.3 Definitions
Section (a) Notice of Rights
(a) (3) Attending physician - add: *The hospice medical director, hospice physician or nurse practitioner may also act as the patient's attending physician.*

- **Drug restraint** – amend to read: Drug Restrint means a medication used to control behavior or to restrict the patient's freedom of movement, *which is not a standard hospice treatment or not requested by the patient or the patient's surrogate.*
- **Licensed Professional** – amend to include *dietary therapy* after occupational therapy.
- **Nursing Services** – include *care provided by a licensed nurse or under the supervision of a licensed nurse as allowed by law.*
- **Add a definition for patient's residence**: meaning *wherever the patient lives.*

Section 418.52 Condition of Participation: Patient's Rights
Section (a) Standard: Notice of Rights

- (a) (3) – Change to read: *"The hospice must inform the patient and family of the hospice's drug policies and procedures regarding management and disposal of controlled substances during the comprehensive assessment."*
- (a) (1) (v.) Add to this section: *The right of the patient to be involved in his or her plan of care.*
- (a) (1) (vi.)Add to this section: *The right of the patient to refuse treatment.*

Section (b) Exercise Rights and Respect for Property or Person

- (b) (3) at the end of the sentence add: *, "and practice".*
- (b) (4) revise the language to read: *"The hospice must investigate complaints made by a patient or the patient's family or guardian regarding treatment or care that is (or fails to be) furnished, or regarding the lack of respect for the patient's property by anyone furnishing services on behalf of the hospice, and must document both the existence of the complaint and the resolution of the complaint."*

Section (e) Patient Liability

- Amend this standard to read: *"Before care is initiated, the patient must be informed, verbally and in writing, and in a language that he or she can understand, if payment may be expected from the patient, as well as, hospice's intention to bill Medicare or Medicaid, third-party payers, or other resources of funding known to the hospice."*

Section 418.54 Condition of Participation: Comprehensive Assessment of the Patient

- In the last sentence of this standard, change the word "*care*" to the word "*assessment*". This would allow hospices to include items not related to the terminal illness that the hospice would want to assess.

Section (a) Standard: Initial Assessment

- As there is not a physician's "admission order" for care in Hospice, it is recommended that this be changed to *Physician's certification to consistent with the Hospice statute.* Also, to the bracketed phrase in the sentence ending with "…unless ordered by the physician", add *"or requested by the patient or family…"*.

Section (b) Standard: Timeframe for completion of the comprehensive assessment

- Recommend that the standard allow up to 7 days to complete the comprehensive assessment and that the following phrase be added after the phrase, "individual's attending physician", *"if he or she is willing to participate…". The proposed 4 days is too intrusive upon the patient and family.*

Section (c) Content of the comprehensive assessment,
(3) (ii). Drug Therapy – add a notation that *Hospice cannot be held responsible for being aware of drugs that Hospice is not informed of by the patient, family, physician or other health care provider.*

Section (d) Standard: Update of comprehensive assessment

- It is strongly recommended that "*every 14 days*" be changed to *"every two weeks,"* or *"15 days."* This wording would accommodate the flexibility needed for holidays and emergencies and synchronize with Hospice's re-certification period of 90/90/60 days.

Section 418.56 Contition of Participation: Interdisciplinary group care planning and coordination of services

Section (a) Standard: Approach to Service Delivery

- (1) (i) This is changed to read: *"the hospice Medical Director or physician designee".*

- (2) Change to read: *"If a hospice has more than one interdisciplinary group, there will be consistency across teams and an inclusive process for developing policies that represent all disciplines and teams, with final authority resting with the governing body and senior management."* In this manner, it is established that the Board determines the policy which is carried out consistently among teams of the organization.

Section (c) Standard: Content of the Plan of Care

- (c) (6) Remove the word *"agreement"* and therefore, the interdisciplinary group would document in the clinical record, the patient and family's understanding and involvement with the Plan of Care in accordance with the hospice's policies.

Section (d) Standard: Review of plan of care

- Modify the standard to change "every 14 days" to *"every two weeks", or "15 days."* This change would provide the flexibility needed to accommodate holidays and emergencies and synchronize with Hospice mandated certification periods.

- Modify the language to read: *The Medical Director or physician designee and the interdisciplinary team, "in collaboration with the individual's attending physician to the extent possible" must review..*

Section 418.58 Condition of Participation: Quality assessment and performance improvement

The hospice industry is in the developmental stage of identifying and measuring data for improvement. We urge CMS to recognize that full development of a hospice QAPI will occur over an extended period of time although the preliminary pieces are in place in many hospices.

The increased demands in quality assessment and performance will add significant cost burdens for hospice. This needs to be recognized and addressed in the hospice reimbursement system.

Section 418.64 Condition of Participation: Core Services

It is strongly recommended that hospices be allowed to contract for continuous care staffing on a "routine basis." Continuous care is a key component of hospice, allowing many patients to stay at home rather than go into a facility. Hospices need the flexibility of contracting routinely for this Core service due to the unpredictable demands and commensurate unavailability of qualified staff.

Section 418.76 Home health aide and homemaker services

Section (h) Standard: Supervision of home health aides

- (i) Remove the phrase *"qualified therapist"* as it does not apply to hospice regulations. We strongly recommend that *"every 14 days"* be changed to *"every two weeks"*, or *"15 days."*

- (j) Homemaker qualifications – Recommend that CMS uses the definition of homemaker in NYS statute. New York State has specific requirements for homemakers that are different from home health aides. To require a home health aide be used for homemaker services is inefficient use of very limited resources, which will only worsen with time.

- **Section 418.100 Condition of Participation: Organization and Administration of Services**

Section (e) Standard: Professional management responsibility

- Should be revised to: *Furnished in a safe and effective manner by qualified personnel.*

Section 418.102 Condition of Participation: Medical Director

- In the first paragraph, the third sentence should read: *"When the Medical Director is not available, a physician designated by the Medical Director or the Hospice, assumes the same responsibilities and obligations of the Medical Director."*

Section (c) Standard: Coordination of medical care

- Change the last sentence to read: *"The Medical Director or physician designee is also responsible for participating in the hospice's quality assessment and performance improvement program. The program may be directed by the Medical Director, physician designee or other qualified professional."*

Section 418.104 Condition of Participation: Clinical Records

Section (a) Standard: Content

- (2) Amend to state, *the election statement, which is required to include a consent to start hospice services as well as the patient rights.*

Section (b) Standard: Authentication

- This section is not applicable for a hospice services. It is recommended that this section be excluded. Hospices do not have a mechanism to authenticate a signature of a covering physician beyond the initial verbal order taken by a registered nurse.

Section (e) Standard: Discharge or transfer of care

- It is recommended that the requirement for a hospice "to provide a copy of the clinical record to the patient's attending physician in the case of revocation or discharge", be removed. The hospice does provide a discharge summary which is a succinct summary that provides all information that most physicians find acceptable.

  If this standard must continue as proposed, it is recommended that the hospice "offer" the attending physician or the accepting facility a copy of the complete medical record or any parts thereof which they feel are needed. It is our belief that this would satisfy the "minimum necessary requirements" of HIPAA standards.

Section 418.106 Condition of Participation: Drugs, Controlled Drugs and Biologicals

Section (a) Standard: Administration of drugs and biologicals

- Section (a)(2): After the present paragraph, add the following: *If the patient and/or family are determined to be unable to safely administer drugs and biologicals, the patient and family will be encouraged to relocate the patient to a setting where administration assistance can be routinely offered. However, it is recognized that the patient if competent and the patient's surrogate if the patient is not competent, can refuse to relocate. Given patient rights and the home setting, hospice will be expected to provide reasonable assistance. Hospice will not be expected to restrict the provision of medications unless there is a blatant safety issue for non-competent adults or children in the home.*

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

- The first sentence should be revised to read: *"The hospice must have a written policy for disposing of controlled drugs that are in the Plan of Care and maintained in the patient's home."*

Section 418.108 Condition of Participation: Short-term inpatient care

We recommend a revision to the introduction as follows: *"Short-term General Inpatient Care and Respite Care are coordinated by the hospice in a participating Medicare or Medicaid facility."*

(a) Standard: Inpatient care for symptom management, pain control (add): <u>and psychosocial issues</u>

- Pain control and symptom management would be done on an inpatient basis either because of the specific need for the staff and equipment availability, or, because of the inability of the hospice and/or the patient's caregivers to assure that the services are properly provided in the home.

It is further recommended that short-term inpatient care is permitted for symptom management, pain control, and psychosocial issues. It is imperative that psychosocial issues/caregiver collapse be covered under general inpatient care. There are multiple situations where the patient's caregiver cannot assure that services will be properly provided in the home.

It is further recommended that there is a need for an RN presence on a 24-hour a day basis for the general inpatient level of care. It is felt that RN presence on a 24 hour basis for respite care is not seen as presenting the equivalent need.

(a) (1) Note that it should be a Medicare *"certified"* hospice, not a Medicare "approved" hospice.

(b) (2) Recommend changing the word "approved" to *"participating"* nursing facility. It would read: "A Medicare/Medicaid *participating* nursing facility...

<u>Section 418.110 Condition of Participation: Hospices that provide inpatient care directly</u>

Item (o) Standard: Restraint and seclusion

- It is recommended that this entire standard be eliminated as it is inappropriate to hospice regulations.

<u>Section 418.12 Conditions of Participation: Hospices that provide hospice care to residents of a SNF/ICF, MR or other facilities</u>

Clarify what is meant by "other facility," and define "nursing facility". Also clarify that this section should specifically apply only to Medicare and Medicaid participating faacilities. This condition cannot successfully be implemented until there is in the SNF/NF requirements, a parallel condition that confirms their requirements. We recommend that the effective date of this section by delayed until the companion section is enacted or that it be at least incorporated by reference in to the SNF/NF requirements. We understand that the nursing home COPS will add a section on nursing homes and hospice care. Does this condition match the requirements that will be proposed for nursing homes?

It is also requested that CMS work with surveyors on this issue and that hospices be allowed some leniency until the nursing faciliy regulations are complete.

Can this Condition be phased in?

(d) Standard: Medical Director

- It is recommended to eliminate the first sentence. Insert the statement: *"The Hospice IDG must communicate with appropriate members of the SNF clinical staff. Also, the Hospice Medical Director, or physician designee may communicate with the Medical Director of the SNF/NF, the patient's attending physician, and other physicians participating in the provision of care for the terminal illness and related conditions, in order to insure quality care for patients and families."*

(e) Standard: Written agreement

- (1) Modify the "written consent" to *"election statement"*.

(f) Standard: Hospice Plan of Care

- (f) (3) Recommend changing the 14-day requirement for care plan review to "*15 days*" which is in line with the current re-certification periods.

- (f) (4) Change the wording to read: "*Any changes in the Plan of Care must be discussed among representatives of both facilities and must be approved by the hospice before implementation.*

(g) Standard: Coordination of services

- (6) “Physician orders”, by assumption they refer to “hospice” physician orders.

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

- Change sentence to read: “*Discharge from or revocation of hospice care may not affect the eligibility to continue to reside in an SNF, NF, ICF/MR, or other facility.*”

  A concern is that while discharge from the hospice does not always mean discharge from the facility, it is believed that patients should not experience the trauma of an external move because they perhaps have stabilized and may not continue to be eligible for hospice.

418.114 Condition of participation: Personnel qualifications for licensed professionals

The use of State licensure as a standard for social workers is of concern to many hospices. Patient and family needs at the end-of-life present an extremely intense and demanding set of variables and require skills and training that are often more than a non-Masters Social Worker will possess. Every effort should be made by hospice to employ this level of professional worker and regulatory support for such a course is important.

Hospice Care, Inc.
Foundation
Board Of Directors
Members (7)

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* Terms expire in May.
** On both HCFI and HCI Boards

Resolution 10/31/01, authorizing amendment to the By-laws of HCFI, Article VI., P.2 Number of Directors, that the parameters for the number of directors has been modified to read “no less than three (3) and no more than seven (7)”; and, Article IX “to reflect that a majority of the Board will function as a quorum”.

Revised 5/25/2005
See\barbara\foundation

Mrs. Linda Gail Russell 2006-2
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255 Genesee Street
Utica, NY 13501
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Terms from 5/26/04 – 5/26/05

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VNAA Visiting Nurse Associations of America®

the voice of home healthcare

July 19, 2005
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-3844-P
P.O. Box 8010
Baltimore, MD 21244-8010

Dear Dr. McClellan:

I am writing on behalf of the Visiting Nurse Association of America (VNAA) to comment on the proposed Medicare and Medicaid Hospice Conditions of Participation, CMS-3844-P. The VNAA represents over 400 non-profit; community based Visiting Nurse Associations across the United States. We appreciate the opportunity to provide input on this important regulation. We support this effort to strengthen the Medicare and Medicaid hospice programs and improve the quality of care furnished to patients.

PATIENT RIGHTS

Section 418.52(a)(3) -- We agree that the patient and family need to know about drug policies and procedures, but in our experience, providing this at the admission is too much for people to absorb. We suggest this requirement be moved into the comprehensive plan of care time frame.

Section 418.52 (b)(2)(3) -- We are support assuring that when a patient's rights are exercised by a representative that that person has clear authority to do. We are concerned, however, that in deferring exclusively to state law, those patients who become incompetent during the later phases of their illness may technically be without a "representative." We suggest that a representative also be defined as one who was designated in advance by the patient in writing as well as a representative recognized under the common law with in the State. The rule should make clear that these concepts be added to apply in situations where a representative determination under state law is unclear or has not yet taken place.

ASSESSMENT TIMEFRAMES

Section 418.54(a) -- We believe the 24-hour period for the initial assessment should be made slightly more flexible to comport the operational realities of hospice care. We suggest that the assessment be completed no later than the close of the day following the day the patient is referred. This will accommodate the situation, for example, in which a referral is not received at 10 AM but the scheduling needed to complete the initial assessment would be disruptive if it had to be completed by 10 AM the next day. We strongly support completing the initial assessment no later than close of business on that following day, however.

Section 418.54(b) -- We believe the 4-day time frame to complete the comprehensive assessment is reasonable in most cases and is a worthwhile goal. But there are many situations in which the 4-day time frame is not feasible. The most frequent delay we encounter is getting information back from the patient's attending physician. Such delays are out of the hospice's control will create a compliance problem for the hospice with no realistic steps it can take to assure physician compliance. We also believe that the 4-day limit is unrealistic around holiday weekends when it is particularly challenging to gather all the information and expertise needed. Therefore, while 4-days is a good goal, we recommend that the time-frame for compliance regarding the comprehensive assessment be extended to 7-days after hospice election.

OUTCOME MEASURES

Section 418.54 (e) -- We strongly endorse the rule's emphasis on moving to patient outcome measures and the flexibility reflected in the rule as hospices experiment, test and adopt outcome measures. We urge that the final rule and subsequent interpretive guidelines make clear that hospice outcome measures are in a developmental stage and that compliance should not be evaluated based on the use of specific measures that are not mandated in regulations.

PLAN OF CARE

Section 418.56 (c)(6) – While we support the requirement that patients understand, be informed and be in agreement with the plan of care, the broader requirement that the "family" also agree with the plan of care is unrealistic. We often find that part of the family may agree and part may disagree, and more critically, often patients agree while the family may disagree. We believe that the plan of care is and must remain centered on the patient's needs and preferences, and while we seek family support and agreement, this is sometimes simply not realistic. We urge that his reality be reflected in the final rule.

QAPI

Section 418.58 (e) -- We support the requirement for governing body involvement but believe it is important that its role be one of assuring the implementation, maintaining and reviewing the outcomes of QAPI. The proposed requirement that the governing body "define" and "prioritize" QAPI activity over-reaches into the responsibility of the hospice managers and clinicians. We suggest the final rule reflect the responsibility of the governing body to implement an effective QAPI process but not suggest micromanagement of that process by the governing body.

ORGANIZATION AND ADMINISTRATION

Sections 418.100(A)(2) -- We are concerned that this provision will suggest that patients and families may expect that every “desire” they have must be met by the hospice. While infrequent, we do have patients and families that have very unrealistic expectations of the hospice program and this type of language could easily support such expectations. We suggest that language be substituted in the final rule that defines “desires” in term of reasonable expectations related to the goal of achieving the highest functional capacity of the patient.

MEDICAL DIRECTOR

Section 418.102(c) -- The requirement that the hospice medical director be responsible for “directing” the hospice’s QAPI is not realistic or appropriate. It both undervalues the contributions of the other hospice team members and places expectations on the medical directors which are not consistent with their training or conditions of employment. It would be more appropriate to give the Medical Director responsibility to provide oversight to the QAPI program and review the reports of the QAPI activity.

CLINICAL RECORDS

Section 418.104(e)(1) – The requirement that the patient’s entire medical record be forwarded on transfer or discharge is well intended but very wasteful. In our experience few entities either request or use more than the summary section of the medical record. Thus, even were we to take on the burden of shipping the entire record, the intended affect will not be achieved because it will not be used at the receiving end. We recommend that the requirement we limited to a complete summary and the entire record be furnished only upon request.

DRUGS, SUPPLIES AND DME

Section 418.106(b) -- We believe it is unrealistic for the hospice staff to take on the responsibility for collecting controlled drugs. We propose that the policy allow for the proper disposal of controlled drugs since we do not believe it is prudent or practical for hospice clinical staff to provide collection services of controlled drugs from patient homes.

Section 418.106(c) -- We do not believe that hospices are or can become prepared to maintain or repair DME furnished by other Medicare or Medicaid providers. The enrolled or certified DME supplier should continue to be responsible for the maintenance and repair of all the equipment provided.

SHORT TERM INPATIENT CARE

Section 418.108(a) -- While we agree that there need not be <u>direct</u> 24-hour nursing care furnished in these settings, we believe that there should be nursing available <u>on-site</u>, on a 24-hour basis.

SECLUSION AND RESTRAINT

Section 418.110(o)(3)(ii)(C) -- Allowing only one hour for the hospice medical director to see and evaluate the patient is not a viable option. A reasonable amount of response time must be provided since the physician is not on site or non-compliance will be assured.

Section 418.110(o)(3)(ii)(D) – We believe more practical timeframes for restraint orders would be: 8-hour intervals over a 24-hour period for adults while sleeping and 4-hour intervals while awake; 6-hour intervals while sleeping for 9 to 17 year olds, 2-hour intervals over 24-hours while awake; 2-hour intervals while sleeping for under 9 years old, 1-hour while awake. We also believe there should be a requirement for reordering restraint but not a required re-assessment every 24-hours because this places a unrealistic and unnecessary burden on the physician in many situations.

RESIDENTS RESIDING IN A FACILITY

Section 418.112(d) & (e) -- It is not reasonable to expect a hospice to secure the cooperation of nursing facilities with the hospice conditions of participation relating to patients residing in such facilities until the nursing facilities are placed under parallel requirements. We strongly urge that parallel provisions be put into SNF COPs simultaneously or the hospice provisions be made effective for hospice compliance purposes only when nursing facility rules go into effect.

We also believe that section (d) should be extended beyond the hospice medical director to include the other staff and members of the hospice team who must coordinate care at the nursing facility.

PERSONNEL QUALIFICATIONS

Section 418.114(c)(3)(4) -- We believe it is important to maintain the principle that any physical therapy delivered by a person at the BA level be supervised by a Master's level PT.

Once again, the VNAA would like to thank you for the opportunity to comment on these rules. As our comments reflect, we are supportive of strengthening the hospice conditions of participation. Our comments are directed at providing feasible approaches to achieve our common purpose in that regard. You may direct any questions you have regarding these comments to Bob Wardwell at our Washington office at 240-485-1855.

Sincerely,

Carolyn Markey
President and CEO

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Require that patient rights are ensured.

The Patient Rights CoP emphasizes a hospice's responsibility to respect and promote the rights of each hospice patient.

STATUTORY NURSING WAIVER

> *"Condition of Participation: Nursing Services Waiver of Requirement That Substantially All Nursing Services Be Routinely Provided Directly by a Hospice (Proposed Sec. 418.66)*
>
> *The requirements for obtaining a nursing services waiver as provided by section 1861(dd)(5) of the Act is currently set forth in Sec. 418.83, and remains virtually unchanged in this proposal. This condition provides hospices the opportunity to obtain a waiver from the requirement that substantially all nursing services be routinely provided directly by the hospice., ..."*

In our experience, the Statutory Nursing Waiver has been nothing but confusing and ineffective. Even though the waiver clearly states it is intended for *nonurbanized* areas:

> *"CMS may waive the requirement in Sec. 418.64(b) that a hospice provide nursing services directly, if the hospice is located in a nonurbanized area."*

> *"The Act specifies that to obtain a waiver a hospice must be located in an area that is not an urbanized area"*

We have still seen many hospices and even many surveyors attempt to apply it to hospices in urban areas

An additional problem is the following statement:

> *" The location of a hospice that operates in several*
> *areas is considered to be the location of its central office.....*
> *(1) The location of the hospice's central office is in a*
> *nonurbanized area as determined by the Bureau of the Census."*

It would not matter if the central office is located in an urban area in regards to the service area of the branch office. That is why hospices set up branch offices, to effectively service patients who are located great distances from the central office. To judge a small rural branch office by the large staff available to the urban central office does not make sense. If the central office could effectively service the rural patients in the first place, there would be no need for a branch office.

This is just an example of the confusion this waiver brings to the entire outside staffing concept. The real issue is that we have seen to many conflicting interpretations surrounding all the regulations that attempt to regulate or quantify the hospice's ability to contract qualified outside agency to care for its patients when there is a shortage of staff within the hospice coupled with unpredictable and expanding patient care level requirements.

> *...This waiver, set in statute, may be obsolete. We do not know how many hospices meet the criteria for the waiver, nor do we know if any hospices actually use the waiver. We request comments on the use of this waiver.*

I agree the waiver is obsolete. Once again, it states above that it is intended for use by hospices in non-urban areas. We have personally witnessed over and over again the surveyors attempt to apply the waiver to hospices in urban areas. Secondly, it is a bad concept when applied to continuous care staffing. Even if a hospice has been responsible and hired enough staff for their patient load, there will be occasions when a patient or two needs care above their normal census. There is no time for a hospice to file a waiver when someone is lying in a bed at home having pain crises, or any other critical care need.

We do not understand why the CoPs seem to single out continuous care:

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

This would be the perfect example of the type of care that hospices *cannot* plan staffing for. e. g., If a hospice has hired a continuous care staff to handle it's average continuous care load of 3 patients, what happens when one weekend the hospice has all their CC staff working, and three additional patients go into a pain crises that requires constant monitoring? Should we assume that the hospice should hire and retain staff sufficient for its highest potential needs? That is obviously impractical. Under that scenario, the hospices would go out of business as they would be paying staff that isn't working a great deal of the time. We must remember, the Medicare reimbursement rates are calculated based on the actual estimated cost of patient care, which includes the average pay rates in a given area. While a percentage is built in for operating overhead, there is certainly not a built in "buffer" to account for overstaffing for potential peak patient loads. In other words, the reimbursement rates do not have an extra percentage built in to pay for two or three nurses getting paid for 40 hours that they are not working, just in case the hospice needs them. Also, because the reimbursement rates are calculated so carefully, there is an automatic obstacle to prevent hospices from over using agency, which is of course more expensive than their own staff. Finally on this point, Medicare does not reimburse a nickel more for agency, so there is no additional expense to the taxpayer.

> *[[Page 30886]]*
>
> *"The hospice may contract for*
> *physician services as stated in Sec. 418.64(a). A hospice may use*
> *contracted staff provided by another Medicare certified hospice to*
> *furnish core services, if necessary, to supplement hospice employees in*

> *order to meet the needs of patients under extraordinary or other non-routine circumstances, as described in Sec. 418.64."*

Why can a hospice contract for physicians or other specialized care, but it seems that the regulations deliberately skirt the issue of LVNs and continuous care, or outright oppose the use of agency in continuous care?

All this still does not address the main point of patient care. In the Introduction it states:

> *"As a result, we are revising the Medicare hospice requirements, which are also used by Medicaid, to focus on a patient-centered, outcome-oriented process that promotes patient care foremost, rather than penalizing unproductive providers."*

All of the above seems to contradict your own goals set forth in these CoPs. If even one patient goes without care and suffers needlessly, when there may be a qualified, licensed professional a phone call away, there will have been a failure in the system.

Why is there an obvious bias against Agency?

The following is an excerpt from Page 30842:

> *"Below is a list of*
> *the most cited deficiencies found by surveyors (year ending September 3, 2002):*
> 1. *Plan of care was not complete.*
> 2. *No written plan was established.*
> 3. *Plan was not reviewed at specific intervals.*
> 4. *Plan did not include an assessment of needs.*
> 5. *Plan was not established before providing care.*
> 6. *RN supervisory visits were not made for home health aide services.*
> 7. *No plan of care was included for bereavement services.*
> 8. *Hospice did not conduct a self-assessment of quality and care provided.*
> 9. *Clinical record was not maintained for every patient.*
> 10. *Interdisciplinary group did not review and update the plan of care for each patient.*
>
> *We note that 8 of the 10 top deficiencies are related to plan of care, assessment, and quality assurance."*

Note that there is nothing in your own list that has anything to do with problems arising from the use of qualified agency, so why the obvious slant against agency that is in the proposed CoPs?

Doctor's offices and clinics are allowed to utilize temporary staffing. If you go to the emergency room you often receive care from nurses or doctors who are not employees of the hospital, but are provided by agency. Even in surgery you may be put under general anesthesia by a temporary staff member, some even brought in from outside the country.

Yet the stance taken throughout the CoPs is that hospice should not utilize outside agency. This is contrary to accepted practice throughout the medical community. The issues of orientation to policy and specialized training needs have been effectively dealt with in all the above examples. Actually, the regulations had effectively addressed that to some degree in:

> **42 CFR § 418.80 Condition of participation—Furnishing of core services.**
>
> *"....A hospice may use contracted staff if necessary to supplement hospice employees in order to meet the needs of patients during periods of peak patient loads or under extraordinary circumstances.*
>
> *If contracting is used, the hospice must maintain professional, financial, and administrative responsibility for the services and must assure that the qualifications of staff and services provided meet the requirements specified in this sub-part.*

Unfortunately, any "permission" granted by this regulation is effectively contradicted or negated by other language throughout the old as well as proposed CoPs. The government obviously recognized a need for supplemental care at some point. Why allow for it in one section, then disallow it every other time it is addressed?

> [[Page 30850]]
>
> *Condition of Participation: Licensed Professional Services (Proposed Sec. 418.62)*
> *Sections of current regulations at Sec. 418.82, Nursing services; Sec. 418.84, Medical social services; and Sec. 418.92, Physical therapy, occupational therapy and speech-language pathology, identify detailed tasks that must be performed by agency staff.*
> *We are proposing to delete Sec. 418.82, Sec. 418.84, and Sec. 418.92, and replace them with a more simplified condition, licensed professional services.*
>
> *This section has been revised to reflect changes to the Act made by section 946 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (``MMA''). In accordance with that provision, we are proposing to allow a hospice (the primary hospice) to enter into arrangements with another Medicare certified hospice to obtain core hospice services. This could be done under extraordinary or other non-routine circumstances. Pursuant to Section 1861(dd)(5)(D) of the Act, as added by section 946(a) of the MMA, those circumstances are: Unanticipated periods of high patient loads; staffing shortages due to illness or other short-term temporary situations that interrupt patient care such as natural disasters; and temporary travel of a patient outside the hospice's service area.*

You have proposed that the solution to staffing shortages is that hospices would contract with each other. I fear this will result in patients going without care. Hospices are very competitive, and there will be too many instances of hospices electing to deny needed care rather than turn over all information about a patient to a competitor. This plan might work for highly specialized services that are used on a sporadic basis, such as a speech therapist, but I do not believe that hospices will be comfortable with swapping nurses back and forth.

Still, the above section completely avoids the question of hospices using qualified agency LVNs to assist during peak patient loads for continuous care.

[Page 30851]]

> *" In this standard we have also proposed to allow hospices to provide certain types of nursing services under a legally binding written contract. .....These nursing services must be highly specialized and provided non routinely and so infrequently that their provision by hospice employees would be impracticable and prohibitively expensive. ......Highly specialized services, as described, would not include continuous care because, while time intensive, such care does not require highly specialized nursing skills."*

This has all the appearances of a ban on contracting for LVN staffing for continuous care under any circumstances. While it may be intended to delineate between highly specialized nursing services and those services that are not, it is our experience that surveyors will take the most restrictive interpretation of any regulation, and therefore will tell hospices that they may not contract for LVNs for continuous care under any circumstances.

The Bottom Line

All the above probably appears to be convoluted and confusing. But that is my point exactly. Because of the contradictory nature of much of the regulations, I fear that there will be many patients that have a desperate need for around the clock care who will be denied that care and suffer needlessly' if for no other reason that the hospices and surveyors will be confused as to the exact intention of some of the regulations.

I believe that the correct spirit exists in the following:

"Require that patient rights are ensured.

The Patient Rights CoP emphasizes a hospice's responsibility to respect and promote the rights of each hospice patient."

Note that it says "each patient", not most patients, substantially all patients, or all the patients that a hospice can cover with their own staff. I am not and would never suggest that hospices should be able to utilize unqualified staff on their patients or avoid the responsibility of hiring their own staff. I simply request that there be some sort of language in the regs that clearly states:

> *A hospice may utilize contracted staff for continuous care during peak patient loads provided:*
>
> 1. *The hospice retains responsibility and supervision for the patient and care plan.*
> 2. *The contracted staff is appropriately licensed or certified per their discipline.*

3. *The staff has been trained to the nature of hospice and palliative care, as well as the hospices policies and procedures.*

I want nothing more than the knowledge that we are working together to get all hospice patients all the care they need. As long as the staff is appropriately trained and supervised, I see no reason that a patient should be denied care because the nurse is contracted rather than directly employed by the hospice. The source of the care is invisible to the patient; only the quality is of concern. Page 30849 states:

> *"We expect that a hospice would take immediate action to correct any identified problems that directly or potentially threatened the care and safety of patients."*

We all share in this responsibility together. Please help us help those that need it most. Thank you for your time.

Sincerely,

Bob Allen
Continuous Care Solutions

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HOME HEALTH
CARE ASSOCIATION
OF MASSACHUSETTS, INC.

July 5, 2005

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

Dear Sir/Madam:

On behalf of the nearly 40 hospices affiliated with our member home health agencies, the Home & Health Care Association of Massachusetts appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) 2005 Proposed Medicare Conditions of Participation for Hospice Programs.

The Home & Health Care Association of Massachusetts (HHCAM) is the trade association that represents the home health industry in Massachusetts. The following comments represent the suggestions of our 100 member agencies and their clinical staff members who care for patients in the community.

We concur with the hospice industry that the proposed COPs are more logical in the way they are organized and therefore more user friendly and helpful. This in turn will encourage a greater degree of uniformity among hospice providers and ensure that a high standard of quality hospice care is available for patients and their families – wherever they are receiving that care.

§ 418. 54 Condition of Participation: Comprehensive assessment of the patient

(a) Standard: Initial Assessment

The requirement for the assessment within 24 hours is not practical. About half of hospice referrals come from a non-physician and is not subject to an attending physician order. Even with a physician referral, the first physician order may be for a consult not for an admission. Whatever the source of the referral, the patient/family not the hospice is ultimately in control as to when the admission takes place as the patient must elect the benefit. The language should be changed to make available to the patient/family a *visit or contact within 24 hours* or as otherwise requested by the patient/family.

(b) Standard: The time frame for completion of the comprehensive assessment within 4 calendar days is realistic and necessary given that 1/3 of hospice patients die within 7 days. Once the patient is "ready" the process needs to move quickly.

§ 418.56 Condition of Participation: Interdisciplinary group care planning and coordination of services

We agree that it is appropriate that the new COPs require a "qualified health care professional" rather than the RN to coordinate the care. This takes into account the uniqueness of each patient and their particular needs which may determine which member of the IDT is most appropriate.

At © Standard: Content of the Plan of Care

(6) IDT's documentation of patient and family understanding, involvement, and *agreement* with the plan of care…

We recognize that the unit of care is both patient and family. This regulatory language may be problematic in situations where the family is not in agreement with the plan of care but the patient is. We would suggest that there needs to be some clarification in situations where there is a difference of opinion, and the patient is competent to make his/her own decisions. In these situations a hospice would be in compliance if the patient is in agreement with the plan of care.

At (d) Review of the Plan of Care. The requirement for the hospice medical director to collaborate with the attending MD may be desirable but is not always possible. The attending MD may not wish to participate with this level of patient care and/or time constraints may make this difficult. This issue should be considered by the IDT and decided on an individual patient basis.

§418: 58 Condition of Participation: Quality Assessment and Performance Improvement

Quality Assessment and Performance Improvement is a complex area as the home health OBQI process has demonstrated. We recommend that CMS work with the hospice industry in their efforts to develop standardized outcome measures that truly measure the care being provided. "Adverse Events" also needs clarification. It is essential that language in the interpretive guidelines is included that differentiates hospice care from other community-based care when reviewing adverse events.

§418: 76 Condition of Participation: Home Health Aide and Homemaker Services
(h) Supervision of home health aides

We support the concept of a supervisory visit being done with the aide present to supervise the care plan no less frequently than every 28 days. This insures that what the aide is doing continues to meet the patient and family needs and those tasks being delegated by the nurse or therapist are being done appropriately. In fact, this has become a community standard in Massachusetts and is part of the policies in many home health agencies. It is a clinical function and not a "human resource" one.

With this proposed standard, a clarification is needed. As written, the regulation is not clear. In-person supervision of every aide who works for the hospice every 28 days would be very burdensome especially where there may be several aides with one patient and aides work with more than one patient during the course of a 24 hour period.

There are many ways to assess the competency of an aide including the competency assessment done when the aide is hired. Short length of stay should not be the determining factor for a "human resource" issue. To meet the CMS goal of closer supervision of aides, HHCAM strongly recommends that the Conditions of Participation require documentation in the personnel file of aide assessment done every six months for newer aides and yearly for those with more experience.

§418:100 Condition of Participation: Organization and Administration of Services

(a) Standard: Serving the hospice patient and family

(2) That each patient experience hospice care…..*consistent with patient and family needs and desires.*

As in §418.56 © (6), although the patient and family are the unit of care, the language of the standard should reflect the primacy of the patient's wishes, needs, etc. that take precedence if there is a conflict.

Further, words such as "dignity, needs, and desires" are subjective in nature and can create problems for providers during a survey. A "difference of opinion" with a surveyor is not an uncommon occurrence and a survey process that has no appeal rights for providers can result in a hospice program receiving deficiencies when it is the "Standard" that is unclear!

(f) Standard: Hospice satellite locations

Based on the experiences of home health providers, this language is a welcome addition to the COPs. CMS must provide further clarification so the standard is clear and interpreted in the same manner by all state survey agencies. Interpretive Guideline safeguards such as clarifying level of administration, staffing and the distance of the service area from the main office are necessary and needed to maintain high quality care.

§418.102 Condition of Participation: Medical Director

© Standard: Coordination of Medical Care

"…..the medical director…..is also responsible for directing the hospice's quality assessment and performance improvement program."

Most physicians have a passive understanding of and little interest in QAPI! And, in many hospices, the medical director is a volunteer or part time. HHCAM recommends strongly that Quality Assurance & Performance Improvement, as with many of the other hospice program requirements, should be under the general direction of the hospice program executive director. He/She may then delegate this responsibility to the most appropriate member of the hospice staff. This individual may vary from hospice to hospice depending on the interests and credentials of the hospice staff. §418: 58 (Quality Assessment and Performance Improvement) provides the necessary framework to further support this effort.

As a general comment, the proposed COPs hint at a heightened level of responsibility and importance of the hospice medical director. The custom of hospice is that the medical director is a member of an interdisciplinary team and carries equal weight with the other members.

§ 418.112 Condition of Participation: Hospice in the SNF

At (d) Medical Director: The requirement for communication between the hospice medical director, attending physician, SNF medical director and other physicians will restrict access to hospice care for nursing home patients. The communication should be *encouraged* when the involved parties express a desire to be involved and/or the IDT feels this would be helpful.

§418.104 Condition of Participation: Clinical Records
© Standard: Discharge or Transfer of care

If a patient transfers to another facility or hospice, that provider would do their own comprehensive assessment. Sending a patient's clinical record is burdensome and unnecessary. The COPs should require following the minimum necessary standard, so that a discharge summary would be adequate. If specific issues come up after that, they can be addressed on an individual basis.

§418.106 Condition of Participation: Drugs, controlled drugs and biologicals, medical supplies, and durable medical equipment.

(b) Standard: Controlled Drugs in the Patient's Home

The language in this standard must be redrafted to address safety rather than its current focus on a host of potential dangers. It is difficult enough to provide pain management without mandated language that further scares the family. Concerns about addiction are prevalent with families given the media's focus on the dangers. Hospice COPs should focus on providing symptom relief in a safe manner.

Also at §418.52 Patient Rights (a) (1) Information about tracking and disposal of controlled substances is too overwhelming and frightening for families on admission.

The written information in the patient/family handbook is sufficient. The discussion can be held at a more appropriate time.

© Standard: Use and Maintenance of Equipment
"where there is no manufacturer recommendation for a piece of equipment, the hospice must develop its own repair and maintenance policies…"

Repair and maintenance is not an area of expertise for a hospice! The language of the standard needs to reflect that this is the responsibility of the DME provider/vendor. The regulations should require that the responsibility for the hospice is to be sure these policies exist and that schedules are in place and being followed.

§418.108 Condition of Participation: Short-term in-patient care

HHCAM recommends that "crises of a psychosocial/family nature" should be added to the "purposes" list for respite care. Fragile and/or dysfunctional families may need this added support to enable them to deal with their own issues and continue providing care and support to a hospice patient.

(a) Standard: Inpatient Care for pain control and symptom management need the *assessment skills of a nurse* and to meet the need, the COPs should require a registered nurse be on site on a 24 hour basis. This would be our comment for §418.110 Condition of Participation: Hospices that provide inpatient care directly

(o) Standard: Seclusion and restraint
The concepts of seclusion and restraint in a hospice are different than in a nursing home. With a survey process that has no appeal rights, there must be language in the Interpretive Guidelines that clarify and reflect acceptable home-based hospice practice.

For example, surveyors who survey nursing homes need to be aware that seclusion is the restricted confinement of a person alone in a room where they are physically prevented from leaving. They also need to know that medications that in other settings are used to restrain may be the appropriate intervention for terminal agitation which is a common occurrence during the last few hours of life

§ 418.114 Condition of Participation: Personnel Qualifications for licensed professionals
© Standard: Social Worker

Patients and/or families in a hospice program have many complex end of life issues with which to deal. These issues frequently exacerbate long-standing problems. It is important that an MSW be required as the base-line qualification for a hospice social worker. HHCAM recommends that CMS reinstate the current requirement so that the standard of care for hospice patients is that care is provided by an MSW or by a social work assistant with a bachelor's degree under the supervision of an MSW.

(c) Standard: Criminal background Checks

HHCAM supports CMS'position requiring criminal background checks on each hospice employee before employment.

It is the position of the HHCAM that working with patients and families in the isolation of the home setting at a vulnerable time in their lives demands the added protection of background checks – for all staff of the hospice who work directly with the patients and their families in the home. It is not something that can be ignored for expediency. Absent a state mechanism for doing this, contracting with national companies would allow hospices to comply with this standard.

We appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) 2005 Proposed Medicare Conditions of Participation for Hospice Programs. HHCAM supports your efforts in revising these regulations and in recognizing that the world of community-based care is far different than it was in 1983 when these regulations were finalized.

Very truly yours,

Helen Siegel, RN, MS, MBA
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