Submitter : Ms. Barbara Strother **Date:** 07/26/2005

Organization : Metropolitan Washington DC Chapter, NASW

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3844-P-129-Attach-1.DOC

CMS-3844-P-129-Attach-2.DOC

NASW. DC METRO CHAPTER
National Association of Social Workers

Attachment #129

July 26, 2005

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

Re: CMS-3844-P, Proposed rule: Medicare and Medicaid Programs: Hospice Conditions of Participation, "PERSONNEL QUALIFICATIONS" and "SOCIAL WORK"

Dear Mr. McClellan:

The Metropolitan DC Chapter of the National Association of Social Workers welcomes the opportunity to offer comments regarding the proposed regulations for the Medicare and Medicaid Programs: Hospice Conditions of Participation, referenced as CMS-3844-P, published in the *Federal Register* on May 27, 2005 (70 Fed. Reg. 30,840 (2005), to be codified as 42 CFR Part 418).

The National Association of Social Workers (NASW) works to enhance the professional growth and development of its members, to create and maintain professional standards, and to advance sound social policies. The local Metro Washington Chapter of NASW represents approximately 2,000 social workers who work in a full range of social and health fields and includes among its membership some of the nation's leading experts in social work programs. Because of our continued interest in maintaining the professional standards and excellence in service to our clients, we are submitting comments of the modification to the proposed regulations for hospice care.

The proposed regulations for the Condition of Participation for Hospice Care reflect a sound understanding of the purpose and practice of hospice and the inter-disciplinary efforts required to provide for end of life care. As the profession of social work has evolved, so has the role and responsibilities of social workers in hospice settings. Social workers focus on individuals as they are affected by their surroundings and assessments take the physical, psychological and social implications of a client's situation into consideration. Social workers who work in a hospice setting not only provide support and counseling for the patient, but also provide services to the family to help them develop an understanding of the dying process and to assist in negotiating a complex array of issues that must be addressed during a very difficult period and short span of time.

Because of the importance of understanding the psychosocial aspect of terminal illness, the need to provide leadership for an inter-disciplinary team of caregivers, and the complex issues

which individuals and families need to address during a terminal illness, the Metro Washington Chapter of the National Association of Social Workers urges that a Master's Degree in Social Work (MSW) and a year of experience in a health setting be required as a minimum qualification of social workers in the hospice program. In states where social workers are licensed, they should be required to have a license commensurate with a Master's Degree in Social Work (MSW) from an accredited program. In rural areas where an MSW is not available, a BSW who is supervised by a licensed clinical social worker, or a licensed mental health professional, is the minimum requirement recommended for a hospice social worker..

Thank you for your consideration of comments concerning changes in the Conditions of Participation in Hospice Care.

Sincerely,

Barbara Strother

Barbara Strother, LICSW
President, Metropolitan Washington DC Chapter
National Association of Social Workers

Submitter : Mr. Thomas Galluppi **Date:** 07/26/2005

Organization : Illinoisa HomeCare Council

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3844-P-130-Attach-1.DOC

Attachment #130

ILLINOIS HOMECARE COUNCIL
NATION'S FIRST HOMECARE ASSOCIATION

July 26, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS -3844-P
P.O. Box 8010
Baltimore, MD 221244-8010

RE: CMS-3844-P

Dear Sir or Madame:

Thank you for this opportunity to comment on the proposed Hospice Conditions of Participation (CMS-3844-P) published in the Federal Register on Friday, May 27, 2005 (Vol. 70, N0. 102, page 30839). The Illinois HomeCare Council (IHCC) is a trade association representing approximately 200 home care providers and suppliers in Illinois, many of whom provide hospice services. These comments have been developed by IHCC's Hospice Work Group and Regulatory and Reimbursement Committee members.

418.3 Definitions

IHCC members have concerns about the definition of "drug restraint" that is included in this section of the proposed rule. Because of the emphasis on palliative care, hospices use medications for symptom relief that are not usually used similarly in other settings, and when used in hospice are not considered to be drug restraints. Beyond these palliative uses, some medications may be used as drug restraints in limited circumstances.

Recommendation: IHCC recommends that the Centers for Medicare & Medicaid Services (CMS) revise the end of the definition to read "not a standard treatment for a medical or psychiatric condition within a hospice program."

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418.52 Patient's rights

IHCC generally supports this proposed Condition of Participation (COP) as it is similar to materials already in use in the industry. However a few concerns have arisen.

Standard (a) Notice of rights. Regarding (1), IHCC agrees that the patient rights notice should be presented to the patient in a language and manner that the patient understands. Typically, IHCC members have these materials available in English and in one or two other languages that are most commonly found in their service area. IHCC believes that it is unreasonable to expect a hospice to make its patient's rights statement available in translation for every potential hospice patient, but we are accustomed to using translators to facilitate communication in these instances.

Recommendation: CMS should interpret the proposed language to include the use of translators with patients who do not speak or read one of the primary languages represented in the hospice's service area.

Standard (b) Exercise of rights. IHCC has noted that CMS omitted the patient's right to refuse treatment. IHCC believes that all patients should be accorded this right.

Recommendation: Include language insuring that hospice patients have the right to refuse treatment in the list of rights patients may exercise.

418.54 Comprehensive assessment of the patient

Standard (a) Initial Assessment. IHCC members are concerned about the 24 hour time frame specified in this proposed regulation. While IHCC agrees that initial assessments must be done promptly, this rigid standard fails to allow the patient and his family an opportunity to request a specific date of admission to match their own needs.

IHCC is confused about what CMS means when it refers to the "physician's admission order for care" and requests clarification. Does this language refer to the physician's referral to hospice, the date the physician certifies that the patient is eligible for hospice, or the date the physician gives the hospice a start of care order? Each of these dates could be different.

Finally, IHCC is concerned that the proposed language requires that the initial assessment be completed by a registered nurse. IHCC members believe that the initial assessment should be conducted by a representative of the discipline that most directly addresses the patient's needs—in many instances this will be a nurse, but in some other instances it may be the social worker or another member of the team.

Recommendations: CMS should revise the time frame language for the initial assessment allowing for more flexibility that the current proposed 24 hour period. Perhaps CMS could consider an approach similar to that used in the COPs for home health agencies. Section 484.55 (a)(1) allows the agency to conduct the initial assessment visit within 48 hours of the patient's return home from an inpatient setting, within 48 hours of receipt of the referral, or on a physician ordered start of care date. IHCC also believes that hospice patients should have the right to participate in the selection of the start of care date based on their own perceived needs and schedules.

Second, CMS should further define the starting point of the time frame as being the physician's certification that the patient is eligible for hospice services. This is already a critical and clearly identified event in the flow of hospice events.

Finally, IHCC believes that CMS should allow any of the professionals involved in hospice care to conduct the initial assessment, rather than restricting this activity to the registered nurse. In this way, hospices will be able to continue to address their patient's needs individually from the beginning of hospice care.

Standard (b) Time frame for completion of initial assessment. IHCC is concerned that the 4 day time frame for completion of the comprehensive assessment is unrealistic. The time frame is particularly unrealistic because it requires the involvement of the patient's attending physician in the process. Sadly, hospices are frequently unable to secure the participation of the attending physician at all, much less within such a short time frame.

Recommendations: IHCC recommends that CMS extend the time frame for completion of the comprehensive assessment from 4 to 7 calendar days, and make the attending physician's involvement optional rather than mandatory. This approach will more realistically allow the Interdisciplinary Group (IDG) to complete its assessment and provide a more realistic opportunity for consulting with and involving the attending physician.

Standard (d) Update of the comprehensive assessment. IHCC members are opposed to the proposed requirement that comprehensive assessments should be updated every 14 days for every hospice patient. Such a short time frame is simply not appropriate for standard application to every hospice patient.

Recommendations: Change the language to require that the assessment be updated at least at the beginning or each new benefit period, or more often if the patient's condition warrants it.

Standard (e) Patient outcome measures. IHCC has mixed feelings about this requirement and the proposed requirements for a Quality Assessment and Performance Improvement COP. While IHCC strongly supports quality initiatives

in health care, including the use of standardized assessment measures, outcome measures and performance improvement, CMS' approach here appears to be rather unfair to the hospice provider community.

CMS appears to want the benefit of the use of a validated patient assessment and data collection tool, complete with outcomes and performance improvement efforts without investing in the development of tools to make this type of information available. Certainly, many hospices are already involved in these types of activities to one extent or another. However, CMS has provided no support for either individual provider or industry-wide efforts to define hospice quality and to design tools to measure it. The situation with hospice is a stark contrast to CMS' activities in relation to home health agencies and nursing homes both of which use assessment tools and standardized data sets whose development was supported by CMS. In addition, at least minor rate adjustments have been made available to these provider types to support the collection and reporting of this data.

IHCC finds it difficult to support this requirement and the Quality assessment and performance improvement COP if CMS does not intend to participate in and support the development of the tools needed to carry out these mandates. The cost of this endeavor should not fall upon the private sector alone, particularly if government wants to require the activities and share the subsequent information with the public.

Recommendations: CMS should invest in the development of standard definitions of hospice quality, assessment tools, standardized data sets and outcome measures before it requires that all hospices participating in Medicare implement a full blown assessment and quality improvement program. IHCC believes that these activities should not be required until there are valid, reliable and universally accepted tools available for use in completing these activities.

418.56 Interdisciplinary group care planning and coordination of services.

Standard (a) Approach to service delivery. IHCC supports the language included in the proposed standard that allows greater flexibility in designating a member of the IDG to take the lead in coordinating care for the patient. It is appropriate for the selection of the group member to be based on the needs of the patient. Care coordination by a nurse is not appropriate in every hospice case.

IHCC is confused by the language that appears in Standard (a) (2). What is meant by "policies governing the day-to-day provision of hospice care and services?" Hospices with multiple IDGs typically assign patients to one or another IDG and the patient remains in the care of that IDG unless there is a valid reason to make a change.

Recommendation: Clarify the language found in 418.56(a)(2).

Standard (c) Content of the plan of care. While IHCC supports CMS' efforts to involve family members in the care planning process as represented by language in this and other standards in this COP, members are concerned that the language in (c)(6) will produce rote documentation of family agreement with the plan of care. It seems to IHCC that what is more important are those situations in which the family does not agree with the plan of care, even though the patient does. These situations often require additional social work or pastoral counseling, as well as significant amounts of care coordination among service providers. IHCC believes that documentation of family issues is much more important than documentation of family agreement.

Recommendation: Revise the language in 418.56(c)(6) to emphasize documentation of family dynamics, disagreements or concerns that may have an impact on the staff's ability to implement the care plan the patient wants.

Standard (d) Review of the plan of care. As was noted above in the comments on Section 418.54(d), IHCC believes that requiring a comprehensive assessment and review of the plan of care every 14 days is onerous and not necessary for every hospice patient.

Recommendations: Revise this standard to require review of the plan of care at the beginning of each benefit period or more often if the patient's condition warrants it.

Standard (e) Coordination of services. IHCC strongly supports coordination of services among hospice personnel and between the hospice and other service providers involved in the care of the patient. However, IHCC members believe that it is inappropriate to require the hospice to "ensure" that information is shared "between" personnel in all settings since the hospice does not control all of the settings from which the patient may be receiving services. Certainly, the hospice is responsible for coordinating service delivery provided directly by its staff and by contractors providing services under arrangement. However, outside providers such as hospital outpatient departments, etc, are not under the hospice's control.

Recommendation: Revise the language to require that hospices make and document efforts to coordinate services with other entities providing services to the hospice patient.

418.58 Quality assessment and performance improvement

IHCC would like to reiterate the comments made regarding 418.54(e) in relation to this proposed COP. The recent experience of the National Quality Forum (NQF) in developing consensus standards on home health care is instructive in

this regard. NQF employed a very broad definition of home health care in its recent examination of existing quality measures in our field. While the NQF Steering Committee recommended consideration of three of the hospice quality measures developed by the National Hospice and Palliative Care Organization (NHPCO), the NQF Board determined that these measures did not meet NQF standards for endorsement. The only measures that met NQF standards for endorsement were OASIS measures.

This leads to the question: what standards are hospices participating in the Medicare program to use when implementing a quality assurance and performance improvement program? As noted above, it is premature for CMS to mandate a quality assurance and performance improvement program when there are no scientifically validated data sets or outcome measures available to use in such a program.

IHCC is also concerned that CMS has given the hospice governing body too great a hands-on role in the development and implementation of the quality assurance and performance improvement program. Not every hospice has a governing body sophisticated enough to play the role described in the proposed COP. The governing body should certainly be consulted and should receive regular reports of these efforts, but it should be up to the hospice whether or not to involve the governing body to the extent proposed here.

Recommendation: Delay adoption of a quality assurance and performance improvement COP until the necessary tools are available to use in implementing such a program.

418.60 Infection Control

IHCC supports the inclusion of this proposed COP.

418.64 Core Services

Standard (d) Counseling Services. IHCC members object to the requirement that bereavement counseling services be made available to the residents and employees of a SNF/NF, ICF/MR or other facility (418.64(d)(1)(ii)). Hospices are requires to provide bereavement counseling for family members for up to a year after the death of the patient. While IHCC recognizes that residents and occasionally employees of a long term care facility in which the patient resides take on the role of family and may be in need of support after the patient's death, requiring the hospice to provide bereavement counseling to facility employees for up to a year is unrealistic and cost prohibitive. In addition, most long term care facility employees and management personnel want nothing to do with this sort of intervention.

Regarding Standard(d)(2) Nutritional counseling, IHCC appreciates the flexibility CMS has introduced by allowing nurses and other individuals to address these issues, but believes that nutritional counseling should be considered a non-core service.

Recommendations: Eliminate the language requiring that bereavement counseling services be made available to long term care facility employees. If CMS determines that it must retain some portion of this proposed language, IHCC recommends that it be revised to clearly focus the hospice's responsibility on those residents and employees who took on a familial relationship to the patient. Otherwise, hospices may be held to variable standards by surveyors across the country.

Relocate the language in 418.64(d)(2) to 418.70 and include dietitian services in 418.72.

418.76 Home health aide and homemaker services

Standard (g) Home health aide assignments and duties. IHCC finds the language in (g)(2)(i) (home health aide services are ordered by the physician or nurse practitioner) to be unnecessary since the following rule ((g)(2)(ii)) requires that the home health aide services be included in the plan of care.

Recommendation: Delete the language found in Standard (g)(2)(i).

Standard (h) Supervision of home health aides. IHCC members find the home health aide supervision requirements proposed in (h)(1) to be excessive. In essence, CMS is requiring that each home health aide be directly observed in interaction with a patient at least every 28 days. It appears that CMS wants aides working in hospice to be competency evaluated 12 times per year. This is insulting to experienced and caring aides who are often the backbone of hospice service delivery. While this level of supervision might be justified for a period of time for an aide fresh out of training or one who has never before worked with terminal patients, it is not appropriate for experienced home health aides working in hospice. The proposed requirement will also increase hospice costs unnecessarily.

Recommendation: Delete the third sentence in the proposed standard 418.76(h)(1) requiring that aides be directly supervised every 28 days.

Standard (j) Homemaker qualifications. IHCC members welcome the clarification that a homemaker need not meet all of the qualifications of a home health aide if she has completed hospice orientation addressing the needs and concerns of patient and families coping with a terminal illness.

418.100 Organization and administration of services

Standard (a) Serving the hospice patient and family. IHCC is concerned about the use of the word "desires" in this context. Members find this term to be much too subjective.

Recommendation: Replace the word "desires" with one or more objective terms such as goals or preferences.

Standard (e) Professional management responsibility. IHCC is concerned about the use of the term "supervision" in describing the relationship between the hospice and contractors providing services under arrangement. Supervision is typically provided by the contractor while oversight is maintained by the hospice.

IHCC also finds the phrase "personnel having at least the same qualifications as hospice employees" ((e)(2)) confusing. It has always been IHCC's understanding that personnel providing services under arrangement must meet the qualifications established in the regulations. The regulations would be more understandable if this language were clarified.

Recommendations: Substitute the term "supervision" in reference to staff and services provided under arrangement with the word "oversight" in order to clarify the relationships between the hospice, the contracting organization and the employees of the contractor. Revise Section (e)(2) so that it requires that employees of contractors providing hospice services meet the qualifications required in the regulations of individuals in their profession or job description.

418.102 Medical Director

IHCC objects to the language in this COP specifying that the medical director shall designate another physician to act as the medical director when he is not available. IHCC believes that such designation is the responsibility of the hospice organization, not the medical director alone.

Recommendation: Revise the language in this section so that the hospice administration selects a physician to function in the absence of the medical director.

Standard (b) Recertification of the terminal illness. IHCC finds the language in (b)(2) to be unclear and potentially problematic. First, certification of a terminal condition should be based on clinical evidence, not on whether or not the patient and his family want to continue hospice services. The certification of a terminal illness is a condition of initiation or continuation of hospice services.

IHCC is also concerned about the use of the term "expectations" in this instance. While our members agree that it is important for the medical director and hospice

staff to address themselves to the expectations of the hospice patient and his family, it does not seem to be appropriate to link this activity to recertification of the terminal illness.

Recommendation: Eliminate 418.102(b)(2) from the regulation.

Standard (c) Coordination of medical care. IHCC strongly objects to the language in this proposed section giving the medical director the responsibility for directing the proposed quality assessment and performance improvement program. While the medical director should certainly be involved in such an activity, few hospice medical directors are trained or qualified to direct it. In IHCC's experience, most hospice medical directors are strongly motivated to be involved in the clinical aspects of the hospice's activities, but have less motivation to be involved in administrative tasks. In addition, requiring the program to be directed by a physician will be far too expensive for most hospices to afford.

Recommendation: Delete the language requiring that the medical director direct the hospice quality assessment and performance improvement program. The hospice should be allowed to determine who will manage its performance improvement activities.

418.104 Clinical Records

Standard(a) Content. The preamble to the proposed regulations discusses the use of electronic health records (EHR) in hospice. As noted, this trend is just beginning to be felt in the hospice industry and many providers are enthusiastically exploring the few products that have become available. However, IHCC members are concerned that CMS will mandate the use of EHRs prematurely, particularly in light of the costs involved to providers of purchasing the systems and equipment necessary for implementation.

Most IHCC members who operate hospices also operate home health agencies. The movement toward EHRs is quite a bit further along in that sector of the home care industry. Member experiences with this technology have been mixed, and clearly the technology is still in its beginning stages. While IHCC members eagerly embrace the opportunities afforded by the EHR, the reality is not without pitfalls. IHCC members want to be sure that CMS does not mandate use of the EHR without providing sufficient support so help providers with the costs of implementing these systems both in terms of cash outlay, training requirements, loss of technology-phobic staff, etc.

Standard (b) Authentication. IHCC supports the longstanding healthcare industry standard that each individual contributing to a clinical record should take responsibility for his or her entries. In paper records this is achieved by signing and dating entries legibly in ink. In EHRs it is typically achieved through use of a

unique identifier that serves as an electronic signature. The date of the entry is usually recorded automatically by the software involved.

IHCC is concerned about the language at the end of the proposed standard that suggests that the primary author of an entry must review and approve the entry and indicate this by affixing either a handwritten or electronic signature. The authors of clinical record entries authenticate the entries when they are completed in hospice, and IHCC believes that any language that might be construed to require a subsequent review and authentication by the author is excessive. The exception is verbal orders given to hospice personnel by a physician. In these instances the verbal orders are documented in writing by the qualified recipient and sent to the physician for countersignature.

IHCC suspects that the language in the proposed rule reflects experience in the hospital setting where physicians dictate clinical record entries which are transcribed and ultimately given to the original author for review and signature. That scenario does not occur in the hospice setting.

Recommendation: Revise the final sentence of 418.104(b) to read: "The hospice must be able to authenticate the handwritten and electronic signature of each primary author."

Standard (d) Retention of records. IHCC believes that Medicare COPs in this instance should be consistent with other requirements that apply to hospices, particularly when the other requirements are promulgated within the Department of Health and Human Services. HIPAA regulations require that clinical records be retained for a minimum of six years, and CMS regulations have generally required that clinical records be retained for five years after the filing of the cost report covering the year in which services were rendered—an effective seven year retention period.

Recommendation: To lessen confusion, IHCC recommends that CMS work internally to standardize clinical record retention requirements and reflect the agreed upon time frame in the final hospice COPs. In the event that coordination is not feasible, IHCC suggests that CMS adopt the longest time frame mandated by a federal regulation in these rules since providers would be required to meet that regulation in any event.

Standard (e) Discharge or transfer of care. IHCC objects to the language at (e)(1) requiring that a hospice provide a copy of the entire clinical record to the receiving facility. An organization's clinical record contains considerable information that is not relevant to the patient's transfer and is often quite expensive and time consuming to reproduce in its entirety. The proposed standard also stands in stark contrast to the HIPAA "minimum necessary" standard, and receiving facilities would rather receive a summary of the patient's

condition and pertinent information about the hospice care received than a voluminous clinical record of an entire hospice stay.

Recommendation. Replace the proposed language with a requirement that the hospice send a transfer summary to the receiving facility that includes information pertinent to the reason for transfer, a brief history of the patient's course of treatment in the hospice, and any other information that may be relevant to the transfer.

418.106 Drugs, controlled drugs and biologicals, medical supplies, and durable medical equipment.

Standard (b) Controlled drugs in the patient's home. IHCC is extremely concerned about the language that appears in this standard, and the responsibility for the medications it implies resides with hospice personnel. In IHCC's view, the medications prescribed for and dispensed to a hospice patient belong to the patient, even though they are paid for by the hospice as part of the per diem payment approach. IHCC believes it is not appropriate for the hospice to be expected to take control of the controlled medications under any circumstances, including when the patient dies. IHCC believes that disposal of medications is the responsibility of the family or other caregiver, and, while hospice personnel can advise and assist the family, it cannot be held accountable for the ultimate disposal of medications that belong to the patient.

Further, IHCC is concerned about the use of the phrase "uses and potential dangers of controlled substances" in referring to how hospices should educate the patient and his family about his medications. Removing the stigma from the appropriate use of controlled substances to control pain and discomfort for hospice patients has been a longstanding goal of the hospice industry. This does not mean that hospices do not educate patients and their families about the proper handling and management of all of the patient's medications, including controlled substances. Quite the contrary. And such education is provided in the context of the patient's environment. However, hospices should not be required to describe controlled substances as "dangerous" when providing this education.

Recommendations: Delete language requiring that the hospice is responsible for tracking, collecting and disposing of controlled substances in the patient's home. Medications belong to the patient and are not the responsibility of the hospice beyond administration and education. Revise the sentence describing education of the patient and family members to state that they should be informed of the potential misuse or abuse of controlled substances, and of the need to track these medications and to dispose of them properly when the patient dies.

Standard (c) Use and maintenance of equipment and supplies. Section (c)(1) states that the hospice should be responsible for preparing a repair and

maintenance schedule in the absence of a manufacturer's recommendation for these activities. IHCC believes that this should be the responsibility of the vendor, and not the hospice.

Recommendation: Revise the language to require that the hospice insure that a repair and maintenance policy is available for each piece of equipment provided to the patient. This will allow for greater flexibility in assuring that equipment is maintained properly and that the methods for doing so are devised by experts.

418.108 Short-term inpatient care

The list of triggering events for inpatient care included in the proposed rule is incomplete. Short-term inpatient care is often required when the patient or a caregiver experiences a psychosocial or family crisis that makes caring for the patient in the home problematic.

Recommendation: Revise this language to include psychosocial and family/caregiver crises in the list of reasons that may necessitate a short-term inpatient stay.

Standard (a) Inpatient care for symptom management and pain control. IHCC members support the inclusion of inpatient hospice settings in (a)(1), but suggest that the term "Medicare certified" would be more accurate than "Medicare approved."

While IHCC appreciates CMS' efforts here to give hospices more flexibility regarding the level of nursing care available in the settings they select for inpatient care, IHCC believes strongly some standards should be developed. IHCC believes that inpatient care settings for symptom management and pain control should include nursing staff 24 hours per day, with at least one RN on site during the daytime and a minimum of LPN with RN on call at night. IHCC believes that respite care does not necessarily require 24 hour nursing, depending on the acuity levels of the patients being cared for in this setting.

Recommendations: Revise 418.110(b) to allow for inpatient hospice and hospital settings to provide nursing services with at least one RN on site during the daytime and a minimum of LPN with RN on call at night. Further revise the regulation to allow for respite settings to provide nursing services at least one shift per day at a minimum of LPN with RN on call.

418.110 Hospices that provide inpatient care directly.

Standard (b) Twenty-four four nursing services. See discussion and recommendations above at 418.108(a).

Standard (o) Seclusion and restraint. As noted in comments on 418.3 Definitions, it is important that the regulations address hospices' use of medications for palliative purposes and distinguish this from the use of chemical restraints. Hospices often use medications to treat terminal restlessness which in another setting might be viewed as a restraint. In hospice, treating terminal restlessness in this way is palliative in that it addresses symptoms in a manner that will make the patient more comfortable. The regulations should make clear, at a minimum, that this use of medications is not considered a restraint in the hospice setting, particularly in light of the requirement that any patient who dies while in restraint or seclusion must be reported to the CMS Regional Office.

Recommendation: Clarify the regulation to clearly exclude the use of medications to treat terminal restlessness from the scope of chemical restraints.

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

Standard (d) Medical director. The revised language significantly increases the role of the hospice medical director in the day-to-day management of the care of a resident of a long term care facility. Historically, the role of coordinating care has been given to a registered nurse who is part of the IDT responsible for the patient's care. IHCC believes that this approach has been appropriate historically, and is curious why CMS wishes to place these responsibilities in the hands of the medical director. Certainly, the medical director must be available to become involved should the RN need assistance or support. Involving the medical director routinely at this level will increase hospice costs without providing any clearly identified benefit.

Recommendation: Revise the second sentence in 418.112(d) to require that the medical director be available to assist the IDT in its efforts to communicate with the facility medical director, attending physician and other physicians involved in the patient's care.

418.114 Personnel qualifications for licensed professionals

Standard (c) Personnel qualifications when no State licensing, certification or registration requirements exist. IHCC supports the proposed rule as written.

Standard (d) Criminal background checks. IHCC supports requiring criminal background checks for all staff that have direct contact with patients, families and caregivers, but not for those whose responsibilities do not include these contacts. IHCC also supports access to the most comprehensive data source possible, provided that the cost and time period required to secure the information is not prohibitive.

Unfortunately, simply requiring that background checks be conducted is not adequate. IHCC members experiences with background check requirements promulgated by the State of Illinois highlight many of the complications of implementing what, on the surface, appears to be a simple and logical activity. In order for this type of requirement to be useful, the types of convictions that would prohibit an individual from employment must be specified, a waiver process must be in place so that an individual who was convicted many years ago but has been reformed is not automatically excluded from employment, protections must be extended to providers who choose not to permanently hire individuals with convictions, etc. Designing and implementing an effective and reasonable criminal background check program is challenging, at best.

Thank you again for the opportunity to comment on these proposed regulations.

Sincerely,

Thomas L. Galluppi
President

Submitter : Mrs. BarbarA Mulich **Date:** 07/26/2005

Organization : WV Center for End of Life Care

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

As a nurse practitioner in a rural community I support allowing NP's to serve as the patient's attending physician once a patient elects hospice care. I hope your intent in section 408 is to allow a NP to certify and recertify terminal illness otherwise it becomes one more hurdle for a practicing nurse practitioner. In the state of WV a nurse practitioner can practice independently so there is not a physician necessarily readily available to provide the recertification of terminal illness. Thank you.

Submitter : **Date: 07/26/2005**

Organization :

Category : **Nurse Practitioner**

Issue Areas/Comments

GENERAL

GENERAL

I hope that the use of the advanced practice nurse in the hospice setting will be considered in evaluating the hospice care conditions of participation.

Currently the wording in the conditions of participation does not allow the advance practice nurse employed by the hospice to bill medicare for their services.
The new conditions of participation should allow an advance practice nurse to treat hospice patients as deemed appropriate, and to bill for their services.
I would also like to request that the verbiage: advance practice nurse be utilized instead of nurse practitioner. Medicare allows all advance practice nurses to bill for their services, not just nurse practitioners. Advance practice nurse includes nurse practitioner, clinical nurse specialist, nurse midwife and nurse anethetist.
Please reconsider the wording of the conditions of participation so that advance practice nurses can be fully utilized in the hospice setting. The gain to patients and families and to hospice programs will be noticed in the quality of care provided.
Thank you for your time,
Dana Hansen

Submitter : Ms. Judy Regotti **Date:** 07/26/2005

Organization : TrinityCare Hospice

Category : Hospice

Issue Areas/Comments

Issues 1 - 10

Personnel Qualifications

Proposed 418.64(d)(2)Core Services.Counseling services.Nutritional counseling. We make a recommendation that uncomplicated nutritional counseling be done by nurses, however, this is an area of expertise that most nurses do not practice, and more that 50% of patients/families demonstrate the need for in-depth dietary and nutritional assessment and instruction. Our agency employs a registered dietitian and strongly advocates the the CoPs adopt this higher standard.

Proposed 418.76(h) Supervision of home health aide. We recommend clairification of 'therapist' we think it means a registered physical therapist. We are in agreement with the parameters for the supervisory visit every 14 days. (this is the standard for home health in the CoPs) and keep a joint visit supervisory requirement every 28 days. However, we recommend a language change to allow for an LVN/LPN to perform this duty under the direction of an RN. The RN can alternate on-site visits to the patient's home with the LVN/LPN (this language can be found in Home Health regulations,CoP 484.36(d)

Short Term Inpatient Care

Proposed 418.108. We recommend that language be added back from the initial CoPs that includes an allowance for the inpatient level of care for patients suffering from "caregiver breakdown" who's caregiver had been providing a skilled nursing duty. Caregiver breakdown is a crisis that is psychosocial in nature. Families/caregivers sometimes perform duties that are defined as "skilled nursing care" and when there is a caregiver crisis and the caregiver can no longer perform those duties or continue to keep the patient at home, the hospice cannot hire unskilled professionals to perform those duties, as the license of the unskilled professional prohibits them from doing so. Hospices must have the option of placing the patient at the General Inpatient level of care for a short period to make another plan, while providing continuity of care with skilled nursing interventions in the hospice Plan of Care. Respite care would be contranindicated in this situation, again for the reason of the skilled nursing needs of the patient. (nurses do not have to be on duty 24hours/day for the respite level)

Inpatient Care

Proposed 418.108 (a)(1)(2) We recommend that this standard language be changed to maintain the present language that 'for the General Inpatient level of care 24 hour registered nurse staffing is required'! This is the only solution to ensure that nurses are working within their practice acts. The CMS definition of General Inpatient care criteria warrants a regisitered nurse be on duty to perform the necessary assessments, and level of skilled nursing that may be required at any point in time of the general inpatient stay of a particular patient. LVN/LPN practice acts do not allow them to perform the level of skill that is often necessary and unable to be predicted i.e. transitioning a patient from oral administration of opioid medications to intervenous administration of opioid medications with titration for adequate pain management.
2. Respite care is entirely different in this regard and is usually a level of care offered to patients who's care doesn't require registered nursing skill. This level of care should be able to be provided in a facility that meets just the general nursing requirements.

Drugs, Supplies, and DME

Proposed 418.110. This section is the only place in the new CoPs that has language that pertains to pharmacy consultation. We recommend that this language be included in the appropriate section for all hospices, not just those that provide inpatient care directly. All hospices provide drugs to patients, and should have the requirements for pharmacist oversight.
Proposed 418.106(b)For freestanding home hospices we recommend a language change for this section, hospices that provide home services do not have the authority nor do we want to put our staff at safety risk to be 'collecting' controlled substances in the field. The medications belong to the patient once they are dispensed. When drugs are no longer needed, we recommend and have a procedure to dispose of them if patients consent, however, we would never want to put our staff safety in jeopardy by having them 'collect' the medications, placing them on their person and traveling with them, NOT A GOOD IDEA! We also recommend another language change. The hospice and palliative care movement has for 20 plus years now been on the forefront of educating patients/families about the safe use of opioid medication for pain at the end of life. By requiring hospices to educate about the potential dangers of these medictions we are giving conflicting messages. Please take the recommendation from those of us performing hospice services, the general public is already very, very educated on the dangers of these medications, and quite the opposite is usually required, that is, educating patients/families about the safe useful purpose of opioid medication at the end of life.

Submitter : Ms. Lisa Wickens **Date:** 07/26/2005

Organization : New York State Department of Health

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3844-P-134-Attach-1.DOC

CMS-3844-P-134-Attach-2.DOC

CMS-3844-P-134-Attach-3.DOC

CMS-3844-P-134-Attach-4.DOC

CMS-3844 – P

Comments on Proposed Hospice Conditions of Participation

PATIENT RIGHTS

418.52 Condition of Participation: Patient Rights

The patient has the right to be informed of his or her rights, and the hospice must protect and promote the exercise of these rights.

New York State supports this proposed condition. State hospice regulations have included a section on Patient/family rights {10 NYCRR 794.1} since the establishment of hospice regulations became effective March 22, 1984.

418. 52 Standard (b)(4)(i) Exercise of rights and respect for property and person

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

New York State supports the purpose of the proposed regulation that requires incident reporting to the State. However, we are concerned that this will be burdensome to state survey agencies given current State and Federal budgetary constraints since there will be increased utilization of state survey agency resources and staff receiving, tracking and investigating incident reports. Provisions to fund this activity must be made as part of federal budget to states.

ASSESSMENT TIME FRAMES

418.54 Standard (b) Timeframe for completion of the comprehensive assessment.

Std.: Timeframe for completion of the comprehensive assessment.
The hospice interdisciplinary group in consultation with the individual's attending physician, must complete the comprehensive assessment no later than four calendar days after the patient elects the hospice benefit.

New York State recommends a seven day time frame for completion of comprehensive assessments particularly considering the impact of weekends and holidays on the availability of specialty services, such as speech language pathology, physical therapy, etc. that may be required for completion of the assessment. Patients and their families are often facing physical, emotional and spiritual challenges related to transition from life to death at the time of hospice admission. Professional assessments may be lengthy and exhausting to the patient and family. The quality of the assessment could be effected by a time frame that does not provide needed flexibility for the patient and their family. An increase in the time frame during which the comprehensive assessment is to be completed

will afford all parties concerned with the process the opportunity to participate in a less rushed and stressful and subsequently higher quality assessment process.

PLAN OF CARE

418.56 Standard (c)(6) Content of the plan of care

The plan of care must include but not be limited to the interdisciplinary group's documentation of patient and family understanding, involvement, and agreement with the plan of care, in accordance with the hospice's own policies, in the clinical record.

New York State requests clarification of this proposed standard specifically regarding patient and family agreement with the plan of care. Families are not always in agreement with other family members and even with the self-directing patient. The fact that resolution of patient and individual family members discord may never occur must be considered.

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The hospice must develop, implement, and maintain an effective, ongoing, hospice-wide data-driven quality assessment and performance improvement program. The hospice's governing body must ensure that the program; Reflects the complexity of its organization and services; involves all hospice services (including those services furnished under contract or arrangement); focuses on indicators related to improved palliative outcomes; focuses on the end-of-life support services provided; and takes actions to demonstrate improvement in hospice performance. The hospice must maintain documentary evidence of its quality assessment and quality improvement program and be able to demonstrate its operation to CMS.

New York State supports this proposed requirement that hospices conduct quality assessment and performance improvement programs that include a focus on indicators related to outcomes of hospice care. We request however that surveillance guidance be provided to be able to effectively evaluate a hospice's compliance with this requirement during surveillance processes.

INFECTION CONTROL

418.60 Condition of Participation: Infection Control

The hospice must maintain and document an effective infection control program that protects patients, families, and hospice personnel by preventing and controlling infections and communicable diseases.

New York State supports the addition of a specific regulation that hospices conduct effective infection control programs. Such programs are currently required by State regulations.

STATUTORY NURSING WAIVER

418.66 Nursing Services Waiver of Requirement that Substantially All Nursing Services Be Routinely Provided Directly by a Hospice.

(a) 418.64(b) that a hospice provide nursing services directly, if the hospice is located in an non-urbanized area. The location of a hospice that operates in several areas is considered to be the location of its central office. The hospice must provide evidence to CMS that it has made a good faith effort to hire a sufficient number of nurses to provide services. CMS may waive the requirement that nursing services be furnished by employees based on the following criteria:

- *(1) The location of the hospice's central office is in a nonurbanized area as determined by the Bureau of the Census.*
- *(2) There is evidence that a hospice was operational on or before January 1, 1983 including-*
  - *(i) Proof that the organization was established to provide hospice services on or before January 1, 1983;*
  - *(ii) Evidence that the hospice-type services were furnished to patients on or before January 1, 1983; and*
  - *(iii) Evidence that the hospice care was a discrete activity rather than an aspect of another type of provider's patient care program on or before January 1, 1983.*
- *(3) By virtue of the following evidence that a hospice made a good faith effort to hire nurses:*
  - *(i) copies of advertisements in local newspapers that demonstrate recruitment efforts;*
  - *(ii) Job descriptions for nurse employees;*
  - *(iii) Evidence that salary and benefits are competitive for the area; and*
  - *(iv) Evidence of any other recruiting activities (for example, recruiting efforts at health fairs and contacts with nurses at other providers in the area);*
- *(a) Any waiver request is deemed to be granted unless it is denied within 60 days after it is received.*
- *(b) Waivers will remain effective for one year at a time from the date of the request.*
- *(c) CMS may approve a maximum of two one-year extensions for each initial waiver. If a hospice wishes to receive a one-year extension, the hospice must submit a request to CMS before the expiration of the waiver period, and certify that the conditions under which it originally requested the initial waiver have not changed since the initial waiver was granted.*

New York State has no hospice providers currently operating under this specific waiver.

HOME HEALTH AIDE SERVICES

418.76 Standard (f) Eligible training organizations

A home health aide training program may be offered by any organization except by a home health agency that, within the previous 2 years –

(1) Was out of compliance with the requirements of paragraph (b) or (c) of this section;
(2) Permitted an individual that does not meet the definition of a "qualified home health aide" as specified in paragraph "a" of this section to furnish home health aide services (with the exception of licensed health professionals and volunteers);
(3) Was subject to an extended (or partial extended) survey as a result of having been found to have furnished substandard care (or for other reasons at the discretion of CMS or the State);
(4) Was assessed a civil monetary penalty of $5,000 or more as an intermediate sanction;
(5) Was found by CMS to have compliance deficiencies that endangered the health and safety of the home health agency's patient's and had temporary management appointed to oversee the management of the home health agency;
(6) Had all or part of its Medicare payments suspended; or
(7) Was found by CMS or the State under any Federal or State law to have:
(i) Had its participation in the Medicare program terminated;
(ii) Been assessed a penalty of $5,000 or more for deficiencies in Federal or State standards for home health agencies;
(iii) Been subjected to a suspension of Medicare payments to which it otherwise would have been entitled;
(iv) Operated under temporary management that was appointed by a governmental authority to oversee the operation of the home health agency and to ensure the health and safety of the home health agency's patients; or
(v) Been closed by CMS or the State, or had its patients transferred by the State.

We request clarification of this standard and how it pertains to hospice, since it references training by home health agency providers and not hospice providers. Some hospices provide their own home health aide training programs in this state. Our interpretation of this standard as it is currently proposed is that when a hospice is cited with condition level deficiencies identified, it is precluded from providing home heath aide training for two years.

New York State supports the termination of home health aide training programs when the sponsoring provider is terminated from the Medicare and Medicaid programs. However, we recommend that CMS reconsider the requirement to rescind training program approvals for hospices when they are cited with condition level non-compliance and subsequently achieve correction. The inability of hospice providers to recruit and train home health aide staff who are needed to provide quality services will present a significant barrier in maintaining compliance with regulations.

418.76 Standard (h) Supervision of home health aides

A registered nurse or qualified therapist must make an onsite visit to the patient's home no less frequently that every 14 days to assess the home health aide's services. The home health aide does not have to be present during this visit. A registered nurse or qualified therapist must make an onsite visit to the location

where the patient is receiving care in order to observe and assess each aide while he or she is performing care no less frequently than every 28 days.

New York State requests clarification of what is meant by supervising "each aide while he or she is performing care no less frequently than every 28 days." Is this supervision of the patient's plan of care for home health aide service, which is to be documented in the patient's clinical record? Or is it supervision of home health aides' work, which is to be documented in personnel records?

For example, please consider the situation where a hospice patient has two aides on weekdays, one in the morning, one in the evening and a third aide who works weekends. Must each of the three home health aides be supervised in the patient's home every 28 days while providing care to this patient?

ORGANIZATION AND ADMINISTRATION

418.100 Condition of Participation: Organization and Administration of Services

The hospice must organize, manage and administer its resources to provide the hospice care and services to patients, caregivers and families necessary for the palliation and management of terminal illness.

New York State supports the proposed incorporation of several current conditions and standards into one condition addressing the requirements within the proposed regulation.

MEDICAL DIRECTOR

418.102 (c) Std.: Coordination of Medical Care.

The medical director or physician designee, and the other members of the interdisciplinary group are jointly responsible for the coordination of the patient's medical care in its entirety. The medical director or physician designee is also responsible for directing the hospice's quality assessment and performance improvement program.

New York State concurs that the medical director or physician designee are essential members of a hospice's quality assessment/performance improvement team. However, since medical practitioners in hospices, particularly smaller more rural programs, are often part time and may even be volunteer employees, it is may be unduly burdensome to require that the medical director or physician designee direct the quality assessment and performance improvement program. This may impact a hospice's ability to recruit such personnel and ultimately impact the availability of hospice services. We recommend that the proposed regulation be revised to state "The medical director or physician designee is also responsible for participating in the hospice's quality assessment and performance improvement program."

CLINICAL RECORDS

418.104 (e)(2) Discharge or transfer of care

If a patient revokes the election of hospice care, or is discharged from hospice because eligibility criteria are no longer met, the hospice must provide a copy of the clinical record and the hospice discharge summary of this section to the patient's attending physician.

While New York State generally supports the concepts in this regulation, we are concerned that this specific requirement will utilize hospice resources in preparation of voluminous hard copy records that the attending physician may not review. We recommend that the regulation be revised to require the provision of a discharge summary and a notification to the attending physician that the complete record or specific portions of the same will be provided upon request.

DRUGS, SUPPLIES AND DME

418.106 (b) Controlled drugs in the patient's home

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

New York State recommends that the language in this proposed regulation be revised to "The hospice must have a written policy for monitoring the use of and assisting in the disposal of controlled drugs. ..." This language, we believe clarifies the responsibilities of the hospice for controlled prescription drugs maintained in the patient's private home which is not subject to institutional regulations. Additionally this revised language addresses potential violations of state licensure regulations that preclude members of specific disciplines including nursing from "collecting" controlled substances prescribed for a patient residing in a private residence.

SHORT TERM INPATIENT CARE

418.108 Standard: Inpatient care for respite purposes

Inpatient care must be available for pain control, symptom management and respite purposes, and must be provided in a participating Medicare or Medicaid facility.

Std: Inpatient care for symptom management and pain *control. Inpatient care for pain control and symptom management must be provided in one of the following:*

(1) A Medicare-approved *hospice that meets the condition of participation for providing inpatient care directly as specified in 418.*110.

*(2) A Medicare-participating hospital or a skilled nursing facility that also meets the standards specified in 418.*110*(b) and (f) regarding 24-hour nursing service and patient care areas.*

Std: Inpatient care for respite purposes. Inpatient care for respite purposes must be provided by one of the following:

(1) A provider specified in paragraph (a) of this section.

(2) An Medicare/Medicaid approved nursing facility *that also meets the standards specified in 418.*110 (b) *and (f).*

New York State requests that a definition of both "inpatient care" and "respite" which addresses issues such as caregiver illness, exhaustion, and other psychosocial issues be provided. The Medicare Hospice Manual (Publication 21) provides definitions that have some specificity for reimbursement issues describing for example, psycho-social issues such as caregiver collapse that result in "inpatient care" to meet skilled needs versus "respite" care. Specific definitions would assist in clarifying what the objectives of short-term in-patient care are or should be for individual patients. Further, from a surveillance viewpoint, it would assist in the evaluation of the appropriateness of the plans of care to meet both patient and family needs.

SECLUSION AND RESTRAINT

418.110 (o) Standard: Seclusion and Restraint

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

(2) Seclusion and restraint can only be used in emergency situations if needed to ensure the patient's or others' physical safety, and only if less restrictive interventions have been tried, determined and documented to be ineffective.

(3) The use of restrain and seclusion must be -

(i) Selected only when less restrictive measures have been found ineffective to protect the patient or others from harm;

(ii) *Carried out in accordance with the order of a physician. The following will be superceded by more restrictive State laws:*

(A) Orders for seclusion or restraints must never be written as a standing or an as needed basis (that is, PRN).

(B) The hospice medical director or physician designee must be consulted as soon as possible if restrain or seclusion are not ordered by the hospice medical director or physician designee.

(C) A hospice medical director or physician designee must see the patient and evaluate the need for restraint or seclusion within 1 our after the initiation of this intervention.

(D) Each order for a physical restraint or seclusion must be in writing and limited to 4 hours for adults; 2 hours for children and adolescents ages 9 through 17; or 1 hour for patients under the age of 9. The original order may only be renewed in accordance with these limits for up to a total of 24 hours. After the original order expires, a physician must reassess the patient's need before issuing another seclusion and restraint order.

(i) In accordance with the interdisciplinary group and a written modification to the patient's plan of care;

(ii) Implemented in the least restrictive manner possible not to interfere with the palliative care being provided;

(iii) In accordance with safe appropriate restraining techniques;

(iv) Ended at the earliest possible time; and

(v) Supported by medical necessity and the patient's clinical record.

(4) A restraint and seclusion may not be used simultaneously unless the patient is –

(i) Continually monitored face to face by an assigned staff member; or

(ii) Continually monitored by staff using video and audio equipment. Staff must be in immediate response proximity to the patient.

(5) The condition of the patient who is in a restraint or seclusion must continually be assessed, monitored, and reevaluated by an assigned staff member.

(6) All staff who have direct patient contact must have ongoing education and training in the proper and safe use of seclusion and restraint application and techniques and alternative methods for handling behavior, symptoms and situations that traditionally have been treated through the use of restraints or seclusion.

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

New York State requests that the definitions of both seclusion and restraint be further clarified to address issues that are germane to hospice care but not other provider types and consequently may present challenges during surveillance activities. Hospice patients are dying and often seek and benefit from "privacy" which could appear to be "seclusion" as defined in the proposed regulations. For example, a hospice patient may be in a private room from which he or she cannot leave due to a deteriorating physical condition and at times may appear to be isolated. However, a single room in such a situation permits visits by family and other loved ones including young children 24 hours a day without impinging on the privacy and comfort rights of other residents of the facility. Likewise, the aggressive management of symptoms by a hospice provider may warrant the utilization of a medication that could be perceived as a "restraint" as defined in the proposed regulation. A hospice patient discusses at the time of admission what his or her wishes are for the end of their life. These may indicate that patient and family comfort and control of symptoms that may be distressing to them such as anxiety and agitation have more importance than maintaining alertness and a "restraint free" status. The hospice patient's wishes for what that patient perceives to be a dignified death should be incorporated into the plan of care to the fullest extent possible. Expansion of the definitions of these terms should incorporate concepts specific to hospice philosophy and the life cycle transition from life to death that often includes the patient's physical, emotional and spiritual withdrawal from the environment and will take into consideration the proven specialized expertise of hospice medical staff. Revisions to the proposed definitions will assist hospice and nursing home providers as well as state surveyors in differentiating between appropriate hospice care and less appropriate use of seclusion and/or restraints. This will help to ensure that hospice patients residing in residential facilities will have access to quality end of life care that meets their individual needs and wishes.

RESIDENTS RESIDING IN A FACILITY

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

In addition to meeting the conditions of participation at 418.10 through 418.116, a hospice that provides hospice care to residents of a SNF/NF, ICF/MR, or other residential facility must abide by the following additional standards.

New York State requests that CMS clarify what is meant by "other residential facility." There are multiple congregate living arrangements in this state that are not considered to be health care provider types but could be called "residential facilities." Definition of the term would specify which, if any, such entity(ies)' residents seeking hospice care would subject the hospice to this proposed requirement. Would "other facility" mean only those entities eligible to participate in the Medicare or Medicaid programs?

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

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

New York State is concerned that the term "does not directly impact" may not be accurate terminology in all situations where an individual revokes his or her hospice benefit. We might recommend revising "may not directly impact" if the definition of "other residential facility" is clarified.

A person's ability to continue to reside in certain types of residential facilities, which could be considered "other facility" in this state may be based on the services that are provided by hospice that allow a resident to remain in these types of entities. Revocation of the hospice benefit could impact the ability of the person to remain in their current domicile, which is why we request clarification of the term "other facility".

SOCIAL WORK

418.114 (c)(7) Social worker

A person who has a baccalaureate degree from a school of social work accredited by the Council on Social Work Education.

New York State regulations {10 NYCRR 700.2 (24)} define a social worker as "a person who holds a master's degree in social work after successfully completing a prescribed course of study at a graduate school of social work accredited by the Council on Social Work Education and the Education Department, and who is certified or licensed by the Education Department to practice social work in the State of New York. When employed by a certified home health agency, long-term home health care program or hospice, such social worker must have had one year of social work experience in a health care setting."

PERSONNEL QUALIFICATIONS

418.114 (d) Std: Criminal Background Checks

The hospice must obtain a criminal background check on each hospice employee and contract employee before employment at the hospice

New York State supports the concept of consumer protection and agrees with the concept that criminal background checks should be standard practice on unlicensed personnel. New York State does not currently believe that licensed professionals should be included in this requirement, since the licensing body of the state maintains authority over their licensure. Currently, New York State has a criminal background check requirement for unlicensed caregivers in nursing homes and home health agencies. The current costs of performing the criminal background check are significantly higher than the impact statement indicates. Costs for FBI criminal background checks for unlicensed caregivers in home health agencies and nursing homes is $24 per record. This cost does not include the administrative costs to agencies, nursing homes or to the state.

Submitter : Mr. Richard Harris

Date: 07/26/2005

Organization : NASW - Rhode Island Chapter

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

The Natioanl Association of Social Workers - RI Chapter is providing comment on the CMS-3844-P, Hospice Conditions for Participation. Specifically, the personnel qualifications for a hospice social worker. To meet the needs of Hospice clients requires a social worker who has a high level of expertise to practice with individuals and their families affected by dying, death, and bereavement. This position must work equally, ethically, culturally and effectively with the individual, family and community at large, all areas in which socil workers recieve professional training. Our organization is in agreement with and supports the National Association of Social Workers comments submitted to raise the standard qualification of a hospice social worker to a Master of Social Work degree from an accredited program. In rural areas where an MSW is not available, a BSW who is supervised by an MSW or a licensed mental health professional, is the minimum requirement recommended for a hospice social worker.

Thank you for the opportunity to comment on these important regulations.

Sincerely,

Richard Harris, LICSW
Executive Director, NASW - RI

Submitter : Ms. Lisa Wickens **Date:** 07/26/2005

Organization : New York State Department of Health

Category : State Government

Issue Areas/Comments

GENERAL

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"See Attachment"

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CMS-3844 – P

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- *(2) There is evidence that a hospice was operational on or before January 1, 1983 including-*
  - *(i) Proof that the organization was established to provide hospice services on or before January 1, 1983;*
  - *(ii) Evidence that the hospice-type services were furnished to patients on or before January 1, 1983; and*
  - *(iii) Evidence that the hospice care was a discrete activity rather than an aspect of another type of provider's patient care program on or before January 1, 1983.*
- *(3) By virtue of the following evidence that a hospice made a good faith effort to hire nurses:*
  - *(i) copies of advertisements in local newspapers that demonstrate recruitment efforts;*
  - *(ii) Job descriptions for nurse employees;*
  - *(iii) Evidence that salary and benefits are competitive for the area; and*
  - *(iv) Evidence of any other recruiting activities (for example, recruiting efforts at health fairs and contacts with nurses at other providers in the area);*
- *(a) Any waiver request is deemed to be granted unless it is denied within 60 days after it is received.*
- *(b) Waivers will remain effective for one year at a time from the date of the request.*
- *(c) CMS may approve a maximum of two one-year extensions for each initial waiver. If a hospice wishes to receive a one-year extension, the hospice must submit a request to CMS before the expiration of the waiver period, and certify that the conditions under which it originally requested the initial waiver have not changed since the initial waiver was granted.*

New York State has no hospice providers currently operating under this specific waiver.

HOME HEALTH AIDE SERVICES

418.76 Standard (f) Eligible training organizations

A home health aide training program may be offered by any organization except by a home health agency that, within the previous 2 years –

(1) Was out of compliance with the requirements of paragraph (b) or (c) of this section;

(2) Permitted an individual that does not meet the definition of a "qualified home health aide" as specified in paragraph "a" of this section to furnish home health aide services (with the exception of licensed health professionals and volunteers);

(3) Was subject to an extended (or partial extended) survey as a result of having been found to have furnished substandard care (or for other reasons at the discretion of CMS or the State);

(4) Was assessed a civil monetary penalty of $5,000 or more as an intermediate sanction;

(5) Was found by CMS to have compliance deficiencies that endangered the health and safety of the home health agency's patient's and had temporary management appointed to oversee the management of the home health agency;

(6) Had all or part of its Medicare payments suspended; or

(7) Was found by CMS or the State under any Federal or State law to have:

- *(i) Had its participation in the Medicare program terminated;*
- *(ii) Been assessed a penalty of $5,000 or more for deficiencies in Federal or State standards for home health agencies;*
- *(iii) Been subjected to a suspension of Medicare payments to which it otherwise would have been entitled;*
- *(iv) Operated under temporary management that was appointed by a governmental authority to oversee the operation of the home health agency and to ensure the health and safety of the home health agency's patients; or*
- *(v) Been closed by CMS or the State, or had its patients transferred by the State.*

We request clarification of this standard and how it pertains to hospice, since it references training by home health agency providers and not hospice providers. Some hospices provide their own home health aide training programs in this state. Our interpretation of this standard as it is currently proposed is that when a hospice is cited with condition level deficiencies identified, it is precluded from providing home heath aide training for two years.

New York State supports the termination of home health aide training programs when the sponsoring provider is terminated from the Medicare and Medicaid programs. However, we recommend that CMS reconsider the requirement to rescind training program approvals for hospices when they are cited with condition level non-compliance and subsequently achieve correction. The inability of hospice providers to recruit and train home health aide staff who are needed to provide quality services will present a significant barrier in maintaining compliance with regulations.

418.76 Standard (h) Supervision of home health aides

A registered nurse or qualified therapist must make an onsite visit to the patient's home no less frequently that every 14 days to assess the home health aide's services. The home health aide does not have to be present during this visit. A registered nurse or qualified therapist must make an onsite visit to the location

where the patient is receiving care in order to observe and assess each aide while he or she is performing care no less frequently than every 28 days.

New York State requests clarification of what is meant by supervising "each aide while he or she is performing care no less frequently than every 28 days." Is this supervision of the patient's plan of care for home health aide service, which is to be documented in the patient's clinical record? Or is it supervision of home health aides' work, which is to be documented in personnel records?

For example, please consider the situation where a hospice patient has two aides on weekdays, one in the morning, one in the evening and a third aide who works weekends. Must each of the three home health aides be supervised in the patient's home every 28 days while providing care to this patient?

ORGANIZATION AND ADMINISTRATION

418.100 Condition of Participation: Organization and Administration of Services

The hospice must organize, manage and administer its resources to provide the hospice care and services to patients, caregivers and families necessary for the palliation and management of terminal illness.

New York State supports the proposed incorporation of several current conditions and standards into one condition addressing the requirements within the proposed regulation.

MEDICAL DIRECTOR

418.102 (c) Std.: Coordination of Medical Care.

The medical director or physician designee, and the other members of the interdisciplinary group are jointly responsible for the coordination of the patient's medical care in its entirety. The medical director or physician designee is also responsible for directing the hospice's quality assessment and performance improvement program.

New York State concurs that the medical director or physician designee are essential members of a hospice's quality assessment/performance improvement team. However, since medical practitioners in hospices, particularly smaller more rural programs, are often part time and may even be volunteer employees, it is may be unduly burdensome to require that the medical director or physician designee direct the quality assessment and performance improvement program. This may impact a hospice's ability to recruit such personnel and ultimately impact the availability of hospice services. We recommend that the proposed regulation be revised to state "The medical director or physician designee is also responsible for participating in the hospice's quality assessment and performance improvement program."

CLINICAL RECORDS

418.104 (e)(2) Discharge or transfer of care

If a patient revokes the election of hospice care, or is discharged from hospice because eligibility criteria are no longer met, the hospice must provide a copy of the clinical record and the hospice discharge summary of this section to the patient's attending physician.

While New York State generally supports the concepts in this regulation, we are concerned that this specific requirement will utilize hospice resources in preparation of voluminous hard copy records that the attending physician may not review. We recommend that the regulation be revised to require the provision of a discharge summary and a notification to the attending physician that the complete record or specific portions of the same will be provided upon request.

DRUGS, SUPPLIES AND DME

418.106 (b) Controlled drugs in the patient's home

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

New York State recommends that the language in this proposed regulation be revised to "The hospice must have a written policy for monitoring the use of and assisting in the disposal of controlled drugs. ..." This language, we believe clarifies the responsibilities of the hospice for controlled prescription drugs maintained in the patient's private home which is not subject to institutional regulations. Additionally this revised language addresses potential violations of state licensure regulations that preclude members of specific disciplines including nursing from "collecting" controlled substances prescribed for a patient residing in a private residence.

SHORT TERM INPATIENT CARE

418.108 Standard: Inpatient care for respite purposes

Inpatient care must be available for pain control, symptom management and respite purposes, and must be provided in a participating Medicare or Medicaid facility.

Std: Inpatient care for symptom management and pain *control. Inpatient care for pain control and symptom management must be provided in one of the following:*

(1) A Medicare-approved *hospice that meets the condition of participation for providing inpatient care directly as specified in 418.*110.

*(2) A Medicare-participating hospital or a skilled nursing facility that also meets the standards specified in 418.*110*(b) and (f) regarding 24-hour nursing service and patient care areas.*

Std: Inpatient care for respite purposes. Inpatient care for respite purposes must be provided by one of the following:

(1) A provider specified in paragraph (a) of this section.

(2) An Medicare/Medicaid approved nursing facility *that also meets the standards specified in 418.*110 (b) *and (f).*

New York State requests that a definition of both "inpatient care" and "respite" which addresses issues such as caregiver illness, exhaustion, and other psychosocial issues be provided. The Medicare Hospice Manual (Publication 21) provides definitions that have some specificity for reimbursement issues describing for example, psycho-social issues such as caregiver collapse that result in "inpatient care" to meet skilled needs versus "respite" care. Specific definitions would assist in clarifying what the objectives of short-term in-patient care are or should be for individual patients. Further, from a surveillance viewpoint, it would assist in the evaluation of the appropriateness of the plans of care to meet both patient and family needs.

SECLUSION AND RESTRAINT

418.110 (o) Standard: Seclusion and Restraint

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

(2) Seclusion and restraint can only be used in emergency situations if needed to ensure the patient's or others' physical safety, and only if less restrictive interventions have been tried, determined and documented to be ineffective.

(3) The use of restrain and seclusion must be -

(i) Selected only when less restrictive measures have been found ineffective to protect the patient or others from harm;

(ii) *Carried out in accordance with the order of a physician. The following will be superceded by more restrictive State laws:*

(A) Orders for seclusion or restraints must never be written as a standing or an as needed basis (that is, PRN).

(B) The hospice medical director or physician designee must be consulted as soon as possible if restrain or seclusion are not ordered by the hospice medical director or physician designee.

(C) A hospice medical director or physician designee must see the patient and evaluate the need for restraint or seclusion within 1 our after the initiation of this intervention.

(D) Each order for a physical restraint or seclusion must be in writing and limited to 4 hours for adults; 2 hours for children and adolescents ages 9 through 17; or 1 hour for patients under the age of 9. The original order may only be renewed in accordance with these limits for up to a total of 24 hours. After the original order expires, a physician must reassess the patient's need before issuing another seclusion and restraint order.

(i) In accordance with the interdisciplinary group and a written modification to the patient's plan of care;

(ii) Implemented in the least restrictive manner possible not to interfere with the palliative care being provided;

(iii) In accordance with safe appropriate restraining techniques;

(iv) Ended at the earliest possible time; and

(v) Supported by medical necessity and the patient's clinical record.

(4) A restraint and seclusion may not be used simultaneously unless the patient is –

(i) Continually monitored face to face by an assigned staff member; or

(ii) Continually monitored by staff using video and audio equipment. Staff must be in immediate response proximity to the patient.

(5) The condition of the patient who is in a restraint or seclusion must continually be assessed, monitored, and reevaluated by an assigned staff member.

(6) All staff who have direct patient contact must have ongoing education and training in the proper and safe use of seclusion and restraint application and techniques and alternative methods for handling behavior, symptoms and situations that traditionally have been treated through the use of restraints or seclusion.

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

New York State requests that the definitions of both seclusion and restraint be further clarified to address issues that are germane to hospice care but not other provider types and consequently may present challenges during surveillance activities. Hospice patients are dying and often seek and benefit from "privacy" which could appear to be "seclusion" as defined in the proposed regulations. For example, a hospice patient may be in a private room from which he or she cannot leave due to a deteriorating physical condition and at times may appear to be isolated. However, a single room in such a situation permits visits by family and other loved ones including young children 24 hours a day without impinging on the privacy and comfort rights of other residents of the facility. Likewise, the aggressive management of symptoms by a hospice provider may warrant the utilization of a medication that could be perceived as a "restraint" as defined in the proposed regulation. A hospice patient discusses at the time of admission what his or her wishes are for the end of their life. These may indicate that patient and family comfort and control of symptoms that may be distressing to them such as anxiety and agitation have more importance than maintaining alertness and a "restraint free" status. The hospice patient's wishes for what that patient perceives to be a dignified death should be incorporated into the plan of care to the fullest extent possible. Expansion of the definitions of these terms should incorporate concepts specific to hospice philosophy and the life cycle transition from life to death that often includes the patient's physical, emotional and spiritual withdrawal from the environment and will take into consideration the proven specialized expertise of hospice medical staff. Revisions to the proposed definitions will assist hospice and nursing home providers as well as state surveyors in differentiating between appropriate hospice care and less appropriate use of seclusion and/or restraints. This will help to ensure that hospice patients residing in residential facilities will have access to quality end of life care that meets their individual needs and wishes.

RESIDENTS RESIDING IN A FACILITY

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

In addition to meeting the conditions of participation at 418.10 through 418.116, a hospice that provides hospice care to residents of a SNF/NF, ICF/MR, or other residential facility must abide by the following additional standards.

New York State requests that CMS clarify what is meant by "other residential facility." There are multiple congregate living arrangements in this state that are not considered to be health care provider types but could be called "residential facilities." Definition of the term would specify which, if any, such entity(ies)' residents seeking hospice care would subject the hospice to this proposed requirement. Would "other facility" mean only those entities eligible to participate in the Medicare or Medicaid programs?

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

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

New York State is concerned that the term "does not directly impact" may not be accurate terminology in all situations where an individual revokes his or her hospice benefit. We might recommend revising "may not directly impact" if the definition of "other residential facility" is clarified.

A person's ability to continue to reside in certain types of residential facilities, which could be considered "other facility" in this state may be based on the services that are provided by hospice that allow a resident to remain in these types of entities. Revocation of the hospice benefit could impact the ability of the person to remain in their current domicile, which is why we request clarification of the term "other facility".

SOCIAL WORK

418.114 (c)(7) Social worker

A person who has a baccalaureate degree from a school of social work accredited by the Council on Social Work Education.

New York State regulations {10 NYCRR 700.2 (24)} define a social worker as "a person who holds a master's degree in social work after successfully completing a prescribed course of study at a graduate school of social work accredited by the Council on Social Work Education and the Education Department, and who is certified or licensed by the Education Department to practice social work in the State of New York. When employed by a certified home health agency, long-term home health care program or hospice, such social worker must have had one year of social work experience in a health care setting."

PERSONNEL QUALIFICATIONS

418.114 (d) Std: Criminal Background Checks

The hospice must obtain a criminal background check on each hospice employee and contract employee before employment at the hospice

New York State supports the concept of consumer protection and agrees with the concept that criminal background checks should be standard practice on unlicensed personnel. New York State does not currently believe that licensed professionals should be included in this requirement, since the licensing body of the state maintains authority over their licensure. Currently, New York State has a criminal background check requirement for unlicensed caregivers in nursing homes and home health agencies. The current costs of performing the criminal background check are significantly higher than the impact statement indicates. Costs for FBI criminal background checks for unlicensed caregivers in home health agencies and nursing homes is $24 per record. This cost does not include the administrative costs to agencies, nursing homes or to the state.

Submitter : **Date: 07/26/2005**

Organization : **American Pharmacists Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-3844-P-137-Attach-1.DOC

American Pharmacists Association

Improving medication use. Advancing patient care.

APhA

Attachment #137

July 25, 2005

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-3844-P
PO Box 8012
Baltimore, MD 21244-8012

Re: CMS-3844-P

Dear Sir/Madam:

The American Pharmacists Association (APhA) welcomes the opportunity to submit comments on the proposed changes to the hospice conditions of participation for the Medicare and Medicaid programs. APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 53,000 practicing pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in advancing the profession. APhA, dedicated to helping all pharmacists improve medication use and advance patient care, is the first-established and largest association of pharmacists in the United States.

Hospice programs that provide end-of-life care to terminal patients must meet certain requirements in order to receive reimbursement from the Medicare or Medicaid program. The proposed rule contains a number of changes to the existing conditions of participation for hospice programs. The changes are part of an effort by the Centers for Medicare and Medicaid Services (CMS) to modernize the outdated conditions of participation and move toward a patient-centered, outcomes-oriented system that uses an interdisciplinary approach to deliver patient care. The proposed requirements address a range of wide range of topics including patient rights, patient care, personnel requirements, and hospice program administration. APhA's comments will focus on four of the conditions of participation requirements, specifically:

- Proposed Section 418.54 on comprehensive assessment of the patient,
- Proposed Section 418.56 on interdisciplinary group care planning and coordination of services,
- Proposed Section 418.106 on drugs, controlled drugs and biologicals, medical supplies, and durable medical equipment (DME), and
- Proposed Section 418.110 on hospices that provide inpatient care directly.

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www.aphanet.org • www.pharmacist.com

PATIENTS RIGHTS

§ 418.54 Condition of Participation: Comprehensive Assessment of the Patient

Under the proposed rule, hospice programs must conduct a comprehensive assessment of the patient's need for medical, nursing, psychosocial, emotional and spiritual care. An initial assessment must be conducted within 24 hours after admission to a hospice program to identify a patient's immediate needs, with a comprehensive assessment completed within the following four days. The comprehensive assessment must then be updated at least every 14 days.

The proposed rule includes a number of patient evaluations that must be conducted as part of the comprehensive assessment including a review of the patient's current medications to identify ineffective drug therapy, unwanted side and toxic effects, and drug interactions. APhA strongly supports this requirement. Many patients, especially seniors – who make up over 80% of hospice patients – are using multiple medications to control a number of chronic conditions when they enter hospice care.[1] After entering hospice care, patients are generally prescribed additional medications to ease physical symptoms that cause discomfort or distress. Medications are one of the primary tools health care professionals have to increase a terminal patient's level of comfort. Because of the important role medications play for hospice patients, and the potential for medication-related problems due to use of multiple drug therapies, it is critical that hospice programs conduct regular patient-specific medication reviews.

According to the proposed regulation, the initial assessment should be conducted by a nurse, with the comprehensive assessment conducted by an interdisciplinary team in consultation with the patient's attending physician. The regulation does not appear to require a pharmacist to serve as a member of the interdisciplinary team that conducts the medication review. APhA requests that the Agency clarify in the final rule that pharmacists are a required participant in the patient's medication review. Pharmacists are the ideal health care professional to conduct medication reviews. As the medication experts on the health care team, pharmacists can help identify and prevent drug-related problems, such as those caused by therapeutic duplication, improper dosing, allergy interactions, and drug-drug interactions, as well as identify ineffective medication therapy, therapy in need of a dosage adjustment, and the need for additional or different therapies to optimally control a hospice patient's physical symptoms.

It appears that the Agency understands the important role pharmacists play in other areas of the proposed rule such as the conditions of participation in Sections 418.110(m) and 418.110(n) which require the use of a pharmacist to direct a hospice program's pharmaceutical services and provide consultations related to the provision of pharmaceutical care. APhA strongly recommends that CMS extend this recognition of the pharmacist's role to the comprehensive patient assessment requirement.

PLAN OF CARE

§ 418.56 Condition of Participation: Interdisciplinary Group Care Planning and Coordination of Services

The proposed rule requires the interdisciplinary team, in conjunction with the patient's attending physician, to prepare a written plan of care for each patient that specifies the hospice care and services required to meet the patient's needs. The plan of care must include information related to the

[1] National Hospice and Palliative Care Organization. www.nhpco.org.

management of pain and symptoms, necessary drugs and medical treatment, and necessary medical supplies and appliances, among other needed services.

APhA is concerned that the rule only requires the participation of a physician, a registered nurse, a social worker, and a spiritual advisor when developing the patient's plan of care. Because medication therapy is such an important component of hospice services, and a required component of the plan of care, it is unclear why the Agency has failed to require the participation of a pharmacist when developing the plan of care. As we have discussed above, the pharmacist is the most knowledgeable health care professional with respect to medications. Pharmacists are a logical and necessary addition to a hospice program's interdisciplinary team and we urge CMS to revise the regulation to require the participation of a pharmacist when developing the plan of care.

DRUGS, SUPPLIES, and DME

§ 418.106 Condition of Participation: Drugs, Controlled Drugs, Biologicals, Medical Supplies, and Durable Medical Equipment

CMS proposes a number of requirements in the rule related to the supply, administration, use, maintenance, and disposal of medications and medical equipment. Among the Agency's proposed conditions is a requirement that all drugs and biologicals be administered in accordance with accepted hospice and palliative care standards according to the patient's plan of care. The rule continues to state that the interdisciplinary team must determine the patient's or caregiver's ability to self-administer the medications. With this requirement, APhA again recommends that the Agency consider including the pharmacist as a member of the interdisciplinary team. Pharmacists play an instrumental role in ensuring the appropriate delivery and administration of drugs and biologicals, and pharmacists can provide patients and their caregivers with training and instruction for the self-administration of medications.

Proposed Section 418.106 also contains a requirement that the hospice program must discuss the use and disposal of controlled substances with the patient and the patient's caregivers during the initial hospice assessment. The discussion must also include the potential dangers of controlled substances such as controlled substance abuse. Although APhA understands the need to educate patients and their caregivers on controlled substances, potential problems associated with their use, and the need for proper disposal, we do not believe the initial hospice assessment is the most appropriate setting for this discussion. The initial hospice assessment will likely be a stressful and traumatic time for terminal patients and their families. Requiring patient and caregiver education on issues such as potential problems associated with medications and medication disposal policies during the initial assessment will only add additional stress to patients and their caregivers during a highly emotional time. Instead, APhA recommends that the Agency allow hospice programs flexibility to discuss these issues with patients and their caregivers at the time controlled substances are prescribed and/or dispensed for the patient, or during the development of the patient's plan of care. Patients and their caregivers are more likely to understand and comprehend the discussion at this time.

INPATIENT CARE

§ 418.110 Condition of Participation: Hospices that Provide Inpatient Care Directly

In the proposed rule, the Agency revises the current condition of participation for "pharmaceutical services" by separating the requirements into two different standards. The first standard, Section 418.100(m), requires inpatient hospice programs to provide pharmaceutical services such as drugs and biologicals as well as have a written process in place to ensure dispensing accuracy. Under the requirement, hospices are also required to evaluate a patient's response to medications, identify adverse

reactions, and take appropriate corrective action. APhA supports this standard. Medications are a crucial component of palliative care and hospices must have processes in place to ensure that they can furnish necessary medications to patients, evaluate clinical outcomes, and address potential medication problems.

The second standard, Section 418.100(n), requires a hospice to use a licensed pharmacist to provide consultation on all aspects of pharmaceutical care in the facility including the ordering, storage, administration, disposal, and record keeping of drugs and biologicals. While the second standard generally reflects the same language contained in the current requirement, APhA is extremely pleased with the Agency's proposal to make this requirement a separate standard to illustrate the "higher level of importance" of this requirement.[2] We support the Agency's proposal to make the "pharmacist" requirement a separate standard.

In closing, we would like to repeat our request that CMS add a condition of participation requiring hospice programs to include a pharmacist(s) on the interdisciplinary team. The Agency should also further clarify that a pharmacist must participate in the medication review conducted as part of the comprehensive assessment of the patient, as well as the development of the patient's plan of care. There are many examples of pharmacist-provided services having a positive impact on the health care system including in patients suffering a terminal illness or injury. The positive impact pharmacists have on patient care was recently recognized by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 which included coverage for pharmacist-provided medication therapy management services. Through these activities, pharmacists contribute to better patient care and improved patient outcomes. From a financial standpoint, the services pharmacists provide can reduce patient-related costs. Most importantly, by participating in medication reviews and the development of a patient plan of care, pharmacists can help ensure that hospice patients receive the critical mediations needed for symptom control and pain relief.

Thank you for your consideration of the views of the nation's pharmacists. Please contact Susan K. Bishop, Associate Director, Regulatory Affairs at 202-429-7538 or SBishop@APhAnet.org, or Susan C. Winckler, Vice President, Policy and Communications at 202-429-7533 or SWinckler@APhAnet.org, with any questions.

Sincerely,

John A. Gans, PharmD
Executive Vice President

cc: Susan C. Winckler, RPh, Esq, Vice President, Policy & Communications and Staff Counsel
Susan K. Bishop, MA, Associate Director, Regulatory Affairs

[2] 70 FR at 308,57.

Submitter : Mr. Stephen Karp **Date:** 07/26/2005

Organization : National Association of Social Workers, CT chapter

Category : Social Worker

Issue Areas/Comments

Issues 1 - 10

Social Work

The minimum requirements for a qualified social worker should be a Master degree in Social Work (MSW) from a Council on Social Work Education accredited program. If a MSW is not available and efforts to recruit a MSW have been unsuccessful, only than a Baccalaureate degree in Social Work and supervision by preferably a MSW or if not available another master level trained mental health provider is a must.

Hospice social work is by nature a clinical function that needs to be performed by a professional social worker. When ever possible, that person should be a licensed social worker, licensed at the clinical level of licensure if the state has such a level.

The psycho-social aspects of hospice social work can only be adequately performed by an individual with social work training, a degree in social work and preferably at least two years experience in social work functions related to health care. The family dynamics, the mental and social needs of the patient and family members, and the clinical level of understanding that is needed speaks to master level training.

In addition, most states license social workers at the clinical level and in many cases, such as Connecticut, clinical social work can only be performed by MSW's under professional supervision or Licensed Clinical Social Workers. Federal requirements for social work in hospice should be consistent with state laws where such laws apply.

Only professional social workers can perform social work functions. Just as CMS would not allow non-nurses to do nursing, CMS must not allow non-social workers to be eligible to perform social work functions.

Submitter : Mrs. N. Jean Macdonald **Date:** 07/26/2005

Organization : Indiana Association for Home & Hospice Care

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-3844-P-139-Attach-1.DOC

CMS-3844-P-139-Attach-2.DOC

July 26, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 445-G
Washington, DC 20201

Attention: CMS-3844-P – Comments on the Proposed Medicare Hospice Benefit Conditions of Participation

Dear Administrator McClellan:

The Indiana Association for Home and Hospice Care (IAHHC) represents the majority of home health agencies, home support agencies, and hospices in Indiana. We appreciate CMS's effort in developing new Conditions of Participation (COPs) for hospice. As a state association affiliated with the National Association for Home Care and Hospice/ Hospice Association of America, IAHHC supports the comments provided by NAHC/HAA.

IAHHC members, however, have a few separate comments. The skills of state surveyors are of great concern to members. From our experience with OASIS outcome measurements in the home health setting, surveyors are still in the cross the "T" and dot the "I' mentality. A complete change in focus to evaluation of patient outcomes and the quality of care must be instituted. The new hospice regulations make patient outcomes a priority. Thus re-education must be a priority.

OUTCOME-BASED PERFORMANCE MEASURES/QAPI

Outcomes-based performance measures are a relatively new concept for hospices. From the experience of home health agencies and OBQI utilizing OASIS, IAHHC suggests that measures be developed with industry wide providers and educational processes such as those developed for the home health providers through the QIOs be instituted. The learning curve for home health was long and not without problems even with a prescribed data collection system, As a member of both NAHC/HAA and NHPCO, IAHHC feels strongly that CMS should not have so blatantly discuss NHPCO's data collection and reporting since membership in NHPCO is required to participate.

ASSESSMENT TIME FRAMES

Comprehensive Assessment 418.54 --IAHHC cautions CMS in the reliance of coordination of care with attending physicians. Members are concerned that throughout the proposed regulations, the attending physician's involvement is stressed. Hospices need to be able to document an attending physician's reluctance to coordination of care.

IAHHC members are concerned that the COPs implementation of a four (4) day window for the completion of the comprehensive assessment may be impractical for a family's involvement. Families are dealing with the diagnosis of a terminal illness and may be overwhelmed with visits from all disciplines that are represented on the IDT. IAHHC suggest a requirement of seven (7) calendar days.

COORDINATION OF SERVICES

Again, IAHHC members expressed concern with the requirement that the attending physician be significantly involved in the plan of care. Though this is should be an integral part of the patient's care, it is not always important to the physician. When patients are referred from a clinic that is staffed with residents, this may be nearly impossible.

INFECTION CONTROL

Upon first reading of this section, IAHHC members commented that CMS seemed to be turning a hospice into a public health organization. Such statements as "It is essential that agencies consider the devastating effects of rampant communicable disease as they carry out the quality assessment and performance improvement programs." reiterate providers' concerns. Hospices deal with the patient's and family's physical, emotional, and spiritual needs. Acting a the public health department is an unnecessary burden on providers. The standard of teaching patient and family infection control and monitoring patient infections should be sufficient.

The additional concern involves the short stay patient who dies a few days after admission. How will hospices complete a comprehensive assessment with the involvement of the IDT and also educate "on the use of standard precautions for the safety of the patient, family, and caregivers"? How will surveyor cite providers when all the "education" is not completed?

MEDICAL DIRECTOR

The Medical Director of the hospice is an integral part of the IDT, but most are busy physicians who have a medical practice. They may be volunteers or receive payment. The requirement that they "be responsible for the hospice's quality assessment and performance improvement program", puts an unnecessary burden on the hospice medical director. Such a requirement, along with the provision that the medical director regularly communicate with the attending, may make hiring a medical director more difficult. Many hospice's, especially in rural areas, commented that they are just happy when the have a medical director that attends IDT and answers pages. CMS must be cautious in over regulating the role of medical director.

DRUGS, SUPPLIES, and DME

Hospices have always been concerned with controlled drugs and family access. Hospices have educated families and have developed policies concerning disposal of medication after the patient's death. Nevertheless, the proposed regulations appear to place sole responsibility on the hospice for actions taken by a family.

SHORT TERM INPATIENT
IAHHC wishes to thank CMS for the removal of the 24/7 registered nurse requirement. Hospices will be able to contract with more inpatient units. This will be especially helpful in rural areas.

SOCIAL WORK
Though a mastered prepared social worker is preferred, CMS must be sensitive to hospice providers who are unable to hire such social workers. Hiring the best prepared and most experiences social worker may not mean the social worker has a master's degree.

The Indiana Association for Home & Hospice Care is pleased to submit our comments on the proposed hospice regulations and thanks the many CMS employees who have worked so diligently preparing the regulations

Sincerely yours,

N. Jean Macdonald

N. Jean Macdonald, RN, BSN, MS
Director of Public Policy

Submitter :

Date: 07/26/2005

Organization :

Category : **Nurse**

Issue Areas/Comments

Issues 1 - 10

Clinical Records

THE DOCTORS IN OUR AREA DO NOT WANT A COPY OF THE CLINICAL RECORD WHEN A PT REVOKES OR IS DISCHARGED. WE SEND ANY UPDATES TO THEIR OFFICE THAT MAY BE NEEDED.

Inpatient Care

OUR HOSPICE BELIEVES THAT A RN IS NOT NEEDED FOR RESPITE BUT A RN IS NEEDED FOR INPATIENT CARE

Issues 11 - 18

Plan Of Care or Coordination of Services

THE SUPERVISION OF THE HCA EVERY 28 DAYS IS TOO OFTEN. IT WILL BE VERY DIFFICULT TO DIRECTLY SUPERVISE THE HCAS IN THAT MANNER

Submitter : Mr. Paul Weil

Date: 07/26/2005

Organization : Hospice of North Idaho, Idaho State Hospice Org.

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3844-P-141-Attach-1.DOC

To whom it may concern:

The following are comments on the proposed changes in the conditions of participation as outlined in the May 27, 2005 Federal Register.

``PATIENTS RIGHTS" – 418.52
(a) *Notice of rights*: Hospices can decide how to communicate a patient's rights to a patient (i.e. written, verbal or via an interpreter.

(b,4) In regards to reporting to appropriate authorities alleged violations involving mistreatment, neglect or verbal, mental, sexual and physical abuse possible mistreatment: A more realistic time frame would be 5 days from the discovery of the incident.

(e) *Patient Liability*- It is an extra, unneeded burden for Hospice to collect a Medicaid patient's liability for the patients Medicaid Room and Board Payments in a nursing home.

418.54
(a) Initial assessment: The initial assessment visit should be made with 24 hours after the hospice receives a physician's admission order **or requested by the family**. It is not uncommon for the family to want additional time beyond 24 hours to have hospice come to the house.

(c) *Content of the comprehensive assessment*: It is unrealistic to make a bereavement assessment at the time of the initial comprehensive assessment. Bereavement needs become more identifiable as the IDG becomes more familiar with the patient and family. High-risk bereavement issues should be identified.

(d) Update of the comprehensive assessment: It would be adequate to have the update closest to the recertification timeframe be acceptable as an update at the time of recertification.

(e) Patient outcome measures: Each hospice should be given some autonomy in determines appropriate outcome measures. Measures should address the following:

- Provide the desired physical comfort and emotional support,
- Promote shared medical decision-making,
- Treat each person as an individual by understanding his/her needs and expectations,
- Attend to the needs of those that care for and love the dying person.

418.58
(b) *Program Data:* Quality indicators that are used in hospice care should be used. Examples are the following:

- Pain

- Nausea
- Shortness of Breath
- Skin integrity
- Constipation
- Appropriate intervention for identified emotional/spiritual challenges

418.72

(h) *Supervision of home health aides.* It is realistic to have a registered nurse or qualified therapist assess each aid via communication with patient and family every 28 days. Onsite visit when the aid is performing care no less frequently than every 60 days would be appropriate.

418.100
(e) *Professional management responsibility*- Hospice should be required for the oversight of staff and services for all arranged services and ensure that qualified personnel provide the services.

418.102
When covering a vacation of a medical director, a hospice may make arrangements with a physician group to provide call coverage.

418.106
(b) *Controlled substances in the patient's home:* In the education of the family an adequate requirement would be to educate the family in the "appropriate" use of controlled substances.

418.114
(c,7) Requirements for a social worker " A social worker is a person who **has** a baccalaureate degree **or a masters in social work** …"

(d) Criminal background checks – It would be adequate to only require background checks on employees who are involved in patient care.

Thank you,

Paul Weil
Executive Director, Hospice of North Idaho
Vice President, Idaho State Hospice Organization

Submitter : Helen Rubenstein **Date:** 07/26/2005

Organization : Evercare Hospice Inc.

Category : Hospice

Issue Areas/Comments

GENERAL

GENERAL

See Attachments

CMS-3844-P-142-Attach-1.DOC

CMS-3844-P-142-Attach-2.DOC

Evercare

952-936-7105
9900 Bren Road East
Minnetonka, MN 55343

Attachment #142

July 26, 2005

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8012
Baltimore, MD 21244-8012

Attention: CMS-3844-P

Dear Dr. McClellan:

Thank you for the opportunity to present comments on the *Medicare and Medicaid Programs: Hospice Conditions of Participation; Proposed Rule,* 70 Fed. Reg. 30,840 (May 27, 2005) (to be codified at 42 C.F.R., pt. 418).

Evercare Hospice, Inc. is a business unit of Ovations, the division of UnitedHealth Group that focuses on meeting the health care needs of the over-50 population. We have been honored to serve Medicare hospice beneficiaries in Arizona, Colorado and Maryland and look forward to continued participation in the Medicare hospice program as it changes.

Before detailing our major areas of comment, I want to let you know that we applaud CMS' outcome-oriented approach to the proposed rule and the added flexibility that approach can provide to hospices in accommodating their specific circumstances and meeting the needs of individual patients. I hope that our comments will assist CMS in furthering that approach.

Highlights of Our Comments

1. **Clarification of overlapping responsibilities among hospice and other providers.** Several of the proposed conditions and standards could result in duplicate, uncoordinated and perhaps inconsistent actions by hospice, nursing homes, DME providers and other entities. For example, section 418.100(e) requires hospice to retain administrative and financial management, and supervision of staff and services for all arranged services, to ensure the provision of quality of care. Currently available guidance from CMS on "under arrangement" relationships speaks to oversight and accountability in a provider/supplier relationship but does not address the circumstance when the arrangement is between two

certified providers with independent duties and responsibilities to the Medicare program for continued participation.

Section 418.52(b), which requires hospice to report, investigate and take appropriate corrective action with regard to alleged violations involving mistreatment, neglect or abuse may result in conflicting obligations between a hospice and a nursing home. We suggest that the rule be clarified with regard to the respective role of hospice in relation to other providers in addressing potential violations. An allegation of inappropriate behavior will only rarely, if ever, be related solely to the patient's terminal illness. Therefore, scope of the hospice responsibilities should be more specifically related to behavior by hospice employees or contractors combined with a duty to report to facility management. The duty to report to facility management could be included in the agreement between the providers.

Similarly, section 418.110(o) regarding use of seclusion and restraints, creates obligations for hospice that may reside more appropriately with the facility. Whereas hospice staff provides intermittent care to a patient, the facility is available and responsible for regular monitoring of patients, as required by the rule. We suggest that this rule establish accountability in hospice by recognizing its responsibility with regard to seclusion and restraints in relation to the duties of other providers.

Section 418.106(c) requires hospice to perform routine and preventive maintenance on durable medical equipment. Hospice does not generally own DME or have the expertise to be responsible for its maintenance. Instead, we suggest that CMS require that the party responsible for DME maintenance be identified in contracts between a hospice and its DME vendors.

2. Recognition of the unique circumstances affecting provision of hospice care in the home. Compliance with several of the proposed conditions of participation and standards may be difficult or impossible in the home setting. For example, section 418.106(b) establishes a standard for controlling drugs in the patient's home. Hospice can educate the family regarding drug safety and proper disposal and monitor controlled drugs. However, unlike a facility setting where protocols can be established and enforced for controlling drugs, Hospice's ability to track and control drugs is limited by the cooperation of the patient and family.

Likewise, the various requirements relating to seclusion and restraint, section 418.110(o), may be difficult or impossible to comply with in the home. For example, hospital beds leased for home use may come equipped with bed rails, which most laypersons think of as a safety device. Hospice should be required to educate patients and family members about the dangers of such devices, but cannot assure that they will not be used. Indeed, hospice staff may not be aware of their use. Consequently, hospice cannot be expected to carry out the extensive assessment, evaluation and monitoring requirements of this section in the home setting.

3. Clarification that hospice's direct responsibility for the patient's care is limited to the terminal illness. While hospice has a responsibility to coordinate care with others who are providing care for non-terminal conditions, the rule should recognize that hospice's direct responsibility is to provide care related to the terminal illness. Several provisions should be clarified in this regard. For example, the pain management and symptom control standard, section 418.52(c), provides that "the patient has a right to receive effective pain management and symptom control *from the hospice.*" (Emphasis added.) However, hospice can only be responsible for pain management and symptom control for conditions related to the terminal illness. Section 418.54 (c)(2) provides for a drug profile as part of the comprehensive assessment. The profile should include noting whether a particular drug is related to the terminal illness to determine whether hospice is responsible for providing the drug. Section 418.102(c) provides that medical director, along with the interdisciplinary group, is jointly responsible for the coordination of the patient's medical care "in its entirety." While hospice should be expected to coordinate and collaborate with other care providers it should only be expected to be responsible for providing care for the terminal illness.

4. Recognition that the patient's wishes are primary and that the patient's authorized representative is the patient's surrogate decision maker. Several provisions refer to the role of the family. The concerns and feelings of all family members must be taken into account and handled with sensitivity. However, unless the rule is clear that the patient and/or his or her authorized representative is the final decision maker, disagreements among family members can impede the delivery of care to the patient. Section 418.56(c)(6) requires documentation of patient and family "understanding, involvement, and agreement" with the plan of care. This section implies that the family's agreement to the plan of care is required. While it may be appropriate to document all family members' understanding, involvement and agreement or lack of agreement, consent of persons other than the patient and his or her representative should not be required. Similarly, section 418.102(b) requires that the "family's expectations and wishes for the continuation of hospice care" be reviewed as part of the recertification process. While wishes of the family should be recognized, it should be made explicit that when the wishes of a competent patient and the family are in conflict, the wishes of the patient are controlling. If the patient is incompetent, the decisions of the authorized representative must control.

5. Recognition of limitations to the role of the hospice medical director. Because the hospice medical director is typically a part-time position filled by a physician with an active medical practice, the medical director's required duties should be limited to those services that he or she is in the best position to provide. For example, section 4128.102(c) requires the medical director to direct the hospice's quality assessment and performance improvement (QAPI) program. Although the medical director should participate in the QAPI program, the medical director may not have the time or expertise to direct it. Section 418.112(d) requires the medical director to provide overall coordination of the medical care of the hospice patients who reside in a facility. However, medical directors often rely on other professional members of the interdisciplinary group to communicate with facility staff.

We greatly appreciate this opportunity to share our comments about the proposed rule, and look forward to working with you. Please do not hesitate to contact me (or my colleagues) if you have any questions or need further information. Thank you.

Sincerely,

Sheila McMillan
Chief Operating Officer, Evercare

CMS – 3844 - 5

2005 PROPOSED MEDICARE CONDITIONS OF PARTICIPATION FOR HOSPICE PROGRAMS

EVERCARE HOSPICE COMMENTS

July 26, 2005

2005 CMS PROPOSED COPS	*EVERCARE COMMENTS*
§ 418.2 Scope of the part. This part establishes requirements and the conditions of participation that hospices must meet, and be in compliance with, in order to participate in the Medicare program. Subpart A of this part sets forth the statutory basis and scope and defines terms used in this part. Subpart B of this part specifies the eligibility requirements and the benefit periods. Subpart C of this part specifies the conditions of participation that hospice providers must meet regarding patient and family care. Subpart D of this part specifies the organizational environment that hospice providers must meet as conditions of participation. Subpart E is reserved for future use. Subpart F specifies coinsurance amounts applicable to hospice care.	

2005 CMS PROPOSED COPS	*EVERCARE COMMENTS*
§ 418.3 Definitions For the purposes of this part—	
Attending physician means a— (1) (i) Doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she performs that function or action; or (ii) Nurse practitioner who meets the training, education and experience requirements as the Secretary may prescribe; and (2) Is identified by the individual, at the time he or she elects to receive hospice care, as having the most significant role in the determination and delivery of the individual's medical care.	**Reference: § 418.3 Attending physician** **Issue:** The proposed regulation contemplates greater requirements for nurse practitioners to serve as attending physician than provided by the statue. **Proposed Language:** Nurse practitioner who **is legally authorized to practice advanced practice nursing by the state in which he or she performs that function;** **Rationale:** Section 408 of the MMA adds nurse practitioner to the definition of attending physician without imposing additional requirements on nurse practitioners who carry out this role. Requirements for nurse practitioners' training, education and experience are established by state licensing legislation and carried out by state boards of nursing. The type of care that nurse practitioners will provide as attending physicians in hospice is consistent with the type of care that they provide in other settings. Therefore no additional requirements are needed and would be unduly burdensome on the nurse practitioners and the body required to administer them.
Bereavement counseling means emotional, psychosocial, and spiritual support and services provided after the death of the patient to assist with issues related to grief, loss, and adjusting.	
Cap period means the 12-month period ending October 31 used in the application of the cap on overall hospice reimbursement specified in §418.309.	
Clinical note means a notation of a contact with the patient that is written and dated by any person providing services and that describes signs and symptoms, treatments and medications administered, including the patient's reaction and/or response, and any changes in physical or emotional condition.	
Drug restraint means a medication used to control behavior or to restrict the patient's freedom of movement, which is not a standard treatment for a patient's medical or psychiatric condition.	**Reference: §418.3 Drug restraint** **Issue:** Definition of drug or chemical restraint is similar but does not match that of other Medicare certified providers. **Proposal:** CMS should consider making the definition of drug restraint consistent with the definition of chemical restraint as applied to other Medicare certified providers.

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	Rationale: Different definitions of drug or chemical restraint for hospice and nursing homes will cause confusion when two certified providers are simultaneously caring for a hospice patient.
Employee means a person who works for the hospice and for whom the hospice is required to issue a W–2 form on his or her behalf, or if the hospice is a subdivision of an agency or organization, an employee of the agency or organization who is appropriately trained and assigned to the hospice or is a volunteer under the jurisdiction of the hospice.	
Hospice means a public agency or private organization or subdivision of either of these that is primarily engaged in providing hospice care as defined in this section.	
Hospice care means a comprehensive set of services described in 1861(dd)(1) of the Act, identified and coordinated by an interdisciplinary team to provide for the physical, psychosocial, spiritual, and emotional needs of a terminally ill patient and/or family members, as delineated in a specific patient plan of care.	
Licensed professional means a licensed person sanctioned by the State in which services are delivered, furnishing services such as skilled nursing care, physical therapy, speech-language pathology, occupational therapy, and medical social services.	
Palliative care means patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice.	
Physical restraint means any manual method or physical or mechanical device, material, or equipment attached to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body.	**Reference: §418.3 Physical restraint** **Issue:** The definition of physical restraint is overly restrictive. **Proposal:** A definition should be developed that takes into account the use of physical restraint in the hospice setting. **Rationale:** This definition of physical restraint is the same as the one adopted in the hospital Conditions of Participation and the interpretive language of the nursing home regulations. Examples of physical restraints often utilized in nursing homes where we provide hospice care are bedrails, safety belts in wheelchairs and trays that prohibit patients from getting out of chairs. The broad definition of physical restraint to include such devices as bed rails is also not practicable as applied in a home care setting. For example, patients often rent or lease hospital beds for home use that may come equipped with bedrails which

2005 CMS PROPOSED COPS	*EVERCARE COMMENTS*
	most laypersons think of as a safety feature.
Progress note means a written notation, dated and signed by any person providing services, that summarizes facts about the care furnished and the patient's response during a given period of time.	
Representative means an individual who has the authority under State law (whether by statute or pursuant to an appointment by the courts of the State) to authorize or terminate medical care or to elect or revoke the election of hospice care on behalf of a terminally ill patient who is mentally or physically incapacitated. This may include a legal guardian.	
Restraint means either a physical restraint or a drug used as a restraint.	
Satellite location means a Medicare-approved location from which the hospice provides hospice care and services within a portion of the total geographic area served by the hospice location issued the provider agreement number. The satellite location is part of the hospice and shares administration, supervision, and services in a manner that renders it unnecessary for the satellite location to independently meet the conditions of participation as a hospice.	
Seclusion means the confinement of a person in a room or an area where a person is isolated and physically prevented from leaving.	
Terminally ill means that the patient has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course.	

2005 CMS PROPOSED COPS *Subpart C*	*EVERCARE COMMENTS* *Patients Rights*
§ 418.52 Condition of participation: Patient's rights. The patient has the right to be informed of his or her rights, and the hospice must protect and promote the exercise of these rights.	
(a) Standard: Notice of rights. (1) The hospice must provide the patient or representative with verbal and written notice of the patient's rights and responsibilities in a language and manner that the patient understands during the initial evaluation visit in advance of furnishing care. (2) The hospice must comply with the requirements of subpart I of part 489 of this chapter regarding advance directives. The hospice must inform and distribute written information to the patient concerning its policies on advance directives, including a description of applicable State law. (3) The hospice must inform the patient and family of the hospice's drug policies and procedures, including the policies and procedures regarding the tracking and disposing of controlled substances. (4) The hospice must maintain documentation showing that it has complied with the requirements of this section and that the patient or representative has demonstrated an understanding of these rights.	**Reference: § 418.52(a)(1)** **Issue:** Requiring written notice in languages understood by all potential patients is overly burdensome. **Proposal:** This standard should be consistent with guidance regarding the Title VI prohibition against discrimination affecting Limited English Proficient (LEP) Persons promulgated by the HHS Office of Civil Rights. **Rationale:** To support consistent application of standards regarding LEP, CMS should incorporate by reference this guidance which clarifies the nature and extent of a provider's obligations and emphasizes voluntary compliance and the provision of technical assistance by the DHHS. See http://www.hhs.gov/ocr/lep (Fact sheets last revised August 2003).
(b) *Standard: Exercise of rights and respect for property and person.* (1) The patient has the right— (i.) To exercise his or her rights as a patient of the hospice; (ii.) To have his or her property and person treated with respect; and (iii.) To voice grievances regarding treatment or care that is (or fails to be) furnished and the lack of respect for property by anyone	

2005 CMS PROPOSED COPS *Subpart C*	*EVERCARE COMMENTS* *Patients Rights*
who is furnishing services on behalf of the hospice; and (iv.) To not be subjected to discrimination or reprisal for exercising his or her rights. (2) If a patient has been adjudged incompetent under State law by a court of proper jurisdiction, the rights of the patient are exercised by the person appointed pursuant to State law to act on the patient's behalf. (3) If a State court has not adjudged a patient incompetent, any legal representative designated by the patient in accordance with State law may exercise the patient's rights to the extent allowed by State law. (4) The hospice must— (i.) Ensure that all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property are reported to State and local bodies having jurisdiction (including to the State survey and certification agency) within at least 5 working days of the incident, and immediately to the hospice administrator. Investigations and/or documentation of all alleged violations must be conducted in accordance with established procedures. (ii.) Immediately investigate all alleged violations and immediately take action to prevent further potential abuse while the alleged violation is being verified; (iii.) Take appropriate corrective action in accordance with State law if the alleged violation is verified by the hospice administration or an outside body having jurisdiction, such as the State survey agency or local law enforcement agency; and (iv.) Investigate complaints made by a patient or the patient's family or representative regarding treatment or care that is (or fails to be) furnished, lack of respect for the patient or the patient's property by anyone furnishing services on behalf of the hospice, and	**Reference: § 418.52(b)(4)** **Issue:** The proposed regulation will result in the hospice and a Medicare certified nursing home having conflicting obligations. In addition, the requirements may be unrealistic or inappropriate for hospice care in a patient's home. **Proposal:** The duty to report, investigate and take corrective action regarding potential mistreatment, neglect and abuse should be consistent with state law. CMS should also clarify investigative responsibilities and accountabilities in the hospice - nursing home relationship. **Rationale:** Most State adult protection statutes incorporate a more objective standard (e.g., "reason to believe" or "upon reasonable inquiry") which allows the provider an opportunity for initial fact-gathering and evaluation of an alleged incident before a report or comprehensive investigation is triggered. In addition, because the proposed language is adopted in full from the Medicare Medicaid Requirements for Participation under 42 C.F.R. § 483.13. Concurrent accountability between two certified providers will result potentially in conflicting reporting behaviors, redundant or overlapping responsibilities to investigate allegations related to shared patients, and conflicting or uncoordinated protective and remedial actions. Finally, the proposed requirement is not feasible in a home based care setting where the provider is present only intermittently and may not have access to relevant information regarding allegations against family members, visitors, etc. Therefore, the scope of the hospice responsibility in the home should be limited to employees or contractors who have a duty under state law to report to appropriate state agencies.

2005 CMS PROPOSED COPS ***Subpart C***	*EVERCARE COMMENTS* ***Patients Rights***
document both the existence of the complaint and the steps taken to resolve the complaint.	
(c) *Standard: Pain management and symptom control.* The patient has a right to receive effective pain management and symptom control from the hospice.	**Reference: § 418.52(c)** **Issue:** Hospice is responsible only for pain management and symptom control related to the terminal illness. **Proposed Language:** The patient has a right to receive effective pain management and symptom control from the hospice **for symptoms related to the terminal illness**.
(d) *Standard: Confidentiality of clinical records.* The hospice must maintain the confidentiality of clinical records. Access to or release of patient information and clinical records is permitted in accordance with 45 CFR parts 160 and 164.	
(e) *Standard: Patient liability.* Before care is initiated, the patient must be informed, verbally and in writing, and in a language that he or she can understand, of the extent to which payment may be expected from the patient, Medicare or Medicaid, third-party payers, or other resources of funding known to the hospice.	**Reference: § 418.52(e)** **Issue:** Hospice should not be responsible for explaining the payment structures of other entities not providing hospice care. In addition, the duty to inform patients with LEP should be consistent with other LEP requirements. **Proposal:** Hospice should be required to inform the patient of the extent to which payment to hospice may be expected from the patient and other resources. Additionally, this standard should be consistent with guidance regarding the Title VI prohibition against discrimination affecting Limited English Proficient (LEP) Persons promulgated by the HHS Office of Civil Rights. **Rationale:** Hospice may not have the knowledge to inform the patient regarding the payment structures of other entities. *See* comment to §418.52(a)(1) regarding accommodation for LEP.

2005 CMS PROPOSED COPS Subpart C	*EVERCARE COMMENTS*
§ 418.54 Condition of participation: Comprehensive assessment of the patient. The hospice must conduct and document in writing a patient-specific comprehensive assessment that identifies the patient's need for hospice care and services, and the patient's need for medical, nursing, psychosocial, emotional, and spiritual care. This care includes, but is not limited to, the palliation and management of the terminal illness and related medical conditions.	
(a) *Standard: Initial assessment.* The hospice registered nurse must make an initial assessment visit within 24 hours after the hospice receives a physician's admission order for care (unless ordered otherwise by the physician), to determine the patient's immediate care and support needs.	**Reference: § 418.54(a)** **Issue:** As written, the standard does not require election of the hospice benefit before an initial assessment is required. **Proposed Language:** The hospice registered nurse must make an initial assessment visit within 24 hours after **the patient or Representative elects hospice care and** hospice receives a physician's admission order for care (unless ordered otherwise by the physician), to determine the patient's immediate care and support needs. **Rationale:** There is no basis to perform an initial assessment if the patient has not elected hospice.
(b) *Standard: Time frame for completion of the comprehensive assessment.* The hospice interdisciplinary group in consultation with the individual's attending physician must complete the comprehensive assessment no later than 4 calendar days after the patient elects the hospice benefit.	
(c) *Standard: Content of the comprehensive assessment.* The comprehensive assessment must identify the physical, psychosocial, emotional, and spiritual needs related to the terminal illness that must be addressed in order to promote the hospice patient's well-being, comfort, and dignity throughout the dying process. The comprehensive assessment describes— (1) The nature and condition causing admission (including the presence or lack of objective data and subjective complaints); (2) Complications and risk factors that affect care planning; (3) Factors that must be considered in developing individualized care plan interventions, including—	

2005 CMS PROPOSED COPS Subpart C	*EVERCARE COMMENTS*
(i.) Bereavement. An initial bereavement assessment of the needs of the patient's family and other individuals focusing on the social, spiritual, and cultural factors that may impact their ability to cope with the patient's death. Information gathered from the initial bereavement assessment must be incorporated into the bereavement plan of care.	**Reference: § 418.54(c)(3)(i)** **Issue:** The initial bereavement assessment should be included in the hospice plan of care and any separate bereavement plan should be separately defined and described. **Proposed Language:** An initial bereavement assessment of the needs of the patient's family and other individuals focusing on the social, spiritual, and cultural factors that may impact their ability to cope with the patient's death. Information gathered from the initial bereavement assessment must be incorporated into the **hospice** plan of care. **Rationale:** The initial bereavement assessment should be included in the hospice plan of care at the time of hospice election. Ongoing assessment during the end of life process should be included in the progress of the plan of care, as clinicians observe the family/caregivers interaction with the dying process. A separate bereavement plan of care should be initiated after the patient's death.
(ii.) Drug therapy. A review of the patient's prescription and over-the-counter drug profile, including but not limited to identification of the following— (i.) Ineffective drug therapy; (ii) Unwanted drug side and toxic effects; and (iii) Drug interactions.	**Reference: § 418.54(c)(3)(ii)** **Issue:** The drug profile should identify whether drugs are related to the terminal illness **Proposed Language:** A review of the patient's prescription and over-the-counter drug profile, including but not limited to identification of the following— . . . (iv) Whether drugs are related to the terminal illness. **Rationale:** Fiscal responsibility requires identifying whether medications are related to the terminal illness.
(4) The need for referrals and further evaluation by appropriate health professionals.	
(d) *Standard: Update of the comprehensive assessment.* The update of the comprehensive assessment must be accomplished by the hospice interdisciplinary group and must consider changes that have taken place since the initial assessment. It must include information on the patient's progress toward desired outcomes, as well as a reassessment of the patient's response to care. The assessment update must be accomplished— (1) As frequently as the condition of the patient requires, but no less frequently than every 14 days; and (2) At the time of each recertification.	

2005 CMS PROPOSED COPS ***Subpart C***	*EVERCARE COMMENTS*
(e) *Standard: Patient outcome measures.* (1) The comprehensive assessment must include data elements that allow for measurement of outcomes. The hospice must measure and document data in the same way for all patients. The data elements must take into consideration aspects of care related to hospice and palliation. (2) The data elements must be an integral part of the comprehensive assessment and must be documented in a systematic and retrievable way for each patient. The data elements for each patient must be used in individual patient care planning and in the coordination of services, and must be used in the aggregate for the hospice's quality assessment and performance improvement program.	

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§ 418.56 Condition of participation: Interdisciplinary group care planning and coordination of services. The hospice must designate an interdisciplinary group or groups as specified in paragraph (a) of this section which, in consultation with the patient's attending physician, must prepare a written plan of care for each patient. The plan of care must specify the hospice care and services necessary to meet the patient and family-specific needs identified in the comprehensive assessment and as it relates to the terminal illness and related conditions.	
(a) *Standard: Approach to service delivery.* (1) The hospice must designate an interdisciplinary group or groups composed of individuals who work together to meet the physical, medical, social, emotional, and spiritual needs of the hospice patients and families facing terminal illness and bereavement. Interdisciplinary group members must provide the care and services offered by the hospice, and the group in its entirety must supervise the care and services. The hospice must designate a qualified health care professional that is a member of the interdisciplinary group to provide coordination of care and to ensure continuous assessment of each patient's and family's needs and implementation of the interdisciplinary plan of care. The interdisciplinary group must include, but is not limited to, individuals who are qualified and competent to practice in the following professional roles: (i) A doctor of medicine or osteopathy (who is not the patient's attending physician). (ii) A registered nurse. (iii) A social worker. (iv) A pastoral, clergy, or other spiritual counselor. (2) If the hospice has more than one interdisciplinary group, it must designate in advance only one of those groups to establish policies governing the day-to-day provision of hospice care and services.	**Reference: § 418.56(a)(1)(i)** **Issue:** A patient's attending physician should be permitted to be the hospice medical director, serving both as a member of the IDG and the attending physician. **Proposed Language:** (i) A doctor of medicine or osteopathy. **Rationale:** Often the hospice medical director, who serves as the physician member of the IDG, becomes the attending physician when the patient is admitted to hospice. The proposed language would preclude any hospice medical director who also has an active practice to sit on the IDG for his or her own patients. In addition, two different physicians may not be available to perform these functions, particularly in rural areas.

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(b) *Standard: Plan of care.* All hospice care and services furnished to patients and their families must follow a written plan of care established by the hospice interdisciplinary group in collaboration with the attending physician. The hospice must ensure that each patient and family and primary caregiver(s) receive education and training provided by the hospice as appropriate to the care and services identified in the plan of care.	
(c) *Standard: Content of the plan of care.* The hospice must develop a written plan of care for each patient that reflects prescribed interventions based on the problems identified in the initial comprehensive and updated comprehensive assessments, and other assessments. The plan of care must include but not be limited to—	**Plan of Care**
(1) Interventions to facilitate the management of pain and symptoms; (2) A detailed statement of the scope and frequency of services necessary to meet the specific patient and family needs; (3) Measurable targeted outcomes anticipated from implementing and coordinating the plan of care;	**Reference: § 418.56(c)(1)-(3)** **Issue:** This section contains numerous terms that are ambiguous and difficult for surveyors to evaluate. **Proposal:** The following highlighted terms should be deleted or defined: (1) Interventions to **facilitate** the management of pain and symptoms; (2) A **detailed** statement of the **scope** and frequency of services necessary to meet the **specific** patient and family needs; (3) Measurable **targeted** outcomes **anticipated** from implementing and coordinating the plan of care; **Rationale:** Hospice and surveyors will need guidance to know what is expected with regard to the highlighted language.
(4) Drugs and treatment necessary to meet the needs of the patient; (5) Medical supplies and appliances necessary to meet the needs of the patient; and	**Reference: § 418.56(c)(5)** **Issue:** This section should reference the terminal illness. **Proposed Language:** Medical supplies and appliances **related to the terminal illness that are** necessary to meet the needs of the patient; and **Rationale:** The standard should explicitly state that supplies and appliances referenced in the plan of care are related to the terminal illness because hospice is responsible only for care relating to the terminal illness.

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(6) The interdisciplinary group's documentation of patient and family understanding, involvement, and agreement with the plan of care, in accordance with the hospice's own policies, in the clinical record.	**Plan of Care** **Reference: § 418.56(c)(6)** **Issue:** This information is more appropriately placed in narrative documentation. **Proposal:** Delete from the plan of care. **Rationale:** This information may change as circumstances change. Gathering the IDG to alter the plan of care for this purpose would be cumbersome. Instead, it is recommended that CMS add regulatory or interpretive language indicating that there may be more than one document included in the plan of care such as MARs, TARs, protocols or clinical pathways. It should be recognized that he plan of care is a process, not just a single document. **Issue:** The reference to "family" should be changed to Representative. **Proposed Language:** The interdisciplinary group's documentation of patient **or Representative's** understanding, involvement and agreement in the plan of care…. **Rationale:** Only the understanding, involvement and agreement of the patient or patient's Representative (if the patient chooses or is incapacitated) should be required to be documented. Although other family members do not have formal standing in the plan of care process, this section implies that their agreement must be obtained. It may, however, be appropriate to document all family members' understanding, involvement and agreement or lack of agreement in the narrative documentation, which may change over time as circumstances change.
(d) *Standard: Review of the plan of care.* The medical director or physician designee, and the hospice interdisciplinary team (in collaboration with the individual's attending physician to the extent possible) must review, revise and document the plan as necessary at intervals specified in the plan but no less than every 14 calendar days. A revised plan of care must include information from the patient's updated comprehensive assessment and the patient's progress toward outcomes specified in the plan of care.	
(e) *Standard: Coordination of services.* The hospice must develop and maintain a system of communication and integration, in accordance with the hospice's own policies and procedures, to—	

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(1) Ensure the interdisciplinary group, through its designated professionals, maintains responsibility for directing, coordinating, and supervising the care and services provided; (2) Ensure that care and services are provided in accordance with the plan of care; (3) Ensure that the care and services provided are based on all assessments of the patient and family needs; and (4) Provide for and ensure the ongoing sharing of information between all disciplines providing care and services in the home, in outpatient settings, and in inpatient settings, irrespective whether the care and services are provided directly or under arrangement.	

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§ 418.58 Condition of participation: Quality assessment and performance improvement. The hospice must develop, implement, and maintain an effective, ongoing, hospice-wide data-driven quality assessment and performance improvement program. The hospice's governing body must ensure that the program: Reflects the complexity of its organization and services; involves all hospice services (including those services furnished under contract or arrangement); focuses on indicators related to improved palliative outcomes; focuses on the end-of-life support services provided; and takes actions to demonstrate improvement in hospice performance. The hospice must maintain documentary evidence of its quality assessment and performance improvement program and be able to demonstrate its operation to CMS.	
(a) *Standard: Program scope.* (1) The program must at least be capable of showing measurable improvement in indicators for which there is evidence that improvement in those indicators will improve palliative outcomes and end-of-life support services. (2) The hospice must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that enable the hospice to assess processes of care, hospice services, and operations.	
(b) *Standard: Program data.* (1) The program must utilize quality indicator data, including patient care, and other relevant data, in the design of its program. (2) The hospice must use the data collected to— (i) Monitor the effectiveness and safety of services and quality of care; and (ii) Identify opportunities for improvement. (3) The frequency and detail of the data collection must be specified by the hospice's governing body.	
(c) *Standard: Program activities.* (1) The hospice's performance improvement activities must— (i) Focus on high risk, high volume, or problem-prone areas; (ii) Consider incidence, prevalence, and severity of problems in those areas; and (iii) Affect palliative outcomes, patient safety, and quality of care. (2) Performance improvement activities must track adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning	

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throughout the hospice. (3) The hospice must take actions aimed at performance improvement and, after implementing those actions; the hospice must measure its success and track performance to ensure that improvements are sustained.	
(d) *Standard: Performance improvement projects.* (1) The number and scope of distinct improvement projects conducted annually must reflect the scope, complexity, and past performance of the hospice's services and operations. (2) The hospice must document what quality improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.	
(e) *Standard: Executive responsibilities.* The hospice's governing body is responsible for ensuring the following: (1) That an ongoing program for quality improvement and patient safety is defined, implemented and maintained; (2) That the hospice-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety, and that all improvement actions are evaluated for effectiveness; and (3) That clear expectations for patient safety are established.	**QAPI** **Reference: § 418.58(e)(3)** **Issue:** The references to patient safety are redundant. **Proposed Language:** Delete (e)(3). **Rationale:** The issue of patient safety is adequately addressed throughout the regulations, including §418.116 which requires compliance with state and federal laws related to patient safety.

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§**418.60 Condition of participation: Infection control.** The hospice must maintain and document an effective infection control program that protects patients, families and hospice personnel by preventing and controlling infection and communicable diseases.	
(a) *Standard: Prevention.* The hospice must follow accepted standards of practice to prevent the transmission of infections and communicable diseases, including the use of standard precautions. (b) *Standard: Control.* The hospice must maintain a coordinated agency-wide program for the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases that— (1) Is an integral part of the hospice's quality assessment and performance improvement program; and (2) Includes: (i.) A method of identifying infectious; and communicable disease problems; and (ii.) A plan for the appropriate actions that are expected to result in improvement and disease prevention.	
(c) *Standard: Education.* The hospice must provide infection control education to staff, patients, and family members or other caregivers.	

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§ 418.62 Condition of participation: Licensed professional services. (a) Licensed professional services provided directly or under arrangement must be authorized, delivered, and supervised only by health care professionals who meet the appropriate qualifications specified under 418.114 and who practice under the hospice's policies and procedures. (b) Licensed professionals must actively participate in the coordination of all aspects of the patient's care, in accordance with current professional standards and practice, including participating in ongoing interdisciplinary comprehensive assessments, developing and evaluating the plan of care, and contributing to patient and family counseling and education; and (c) Licensed professionals must participate in the hospice's quality assessment and performance improvement program and hospice sponsored in-service training.	

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§ 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 § 418.64(a). A hospice may, under extraordinary or other non-routine circumstances, enter into a written arrangement with another Medicare certified hospice program for the provision of core services to supplement hospice employee/staff to meet the needs of patients. Circumstances under which a hospice may enter into a written arrangement for the provision of core services include: Unanticipated periods of high patient loads, staffing shortages due to illness or other short-term temporary situations that interrupt patient care; and temporary travel of a patient outside of the hospice's service area.	
(a) *Standard: Physician services.* The hospice medical director, physician employees, and contracted physician(s) of the hospice, in conjunction with the patient's attending physician, are responsible for the palliation and management of the terminal illness, conditions related to the terminal illness, and the general medical needs of the patient. (1) All physician employees and those under contract, must function under the supervision of the hospice medical director. (2) All physician employees and those under contract shall meet this requirement by either providing the services directly or through coordinating patient care with the attending physician. (3) If the attending physician is unavailable, the medical director, contracted physician, and/or hospice physician employee is responsible for meeting the medical needs of the patient.	**Reference: § 418.64(a)** **Issue:** The hospice medical director has responsibility for the patient's terminal illness but not for the general medical needs of the hospice patient in a nursing home. **Proposal:** Delete "and the general medical needs of the patient." **Rationale:** The coordination of physician services in nursing home/hospice relationships is challenging at best. This language may cause additional confusion and should be deleted. If in that setting the community based attending is not responsive it is the nursing home Medical Director who is responsible for the general medical needs particularly under new interpretive guidance issued by CMS recently.
(b) *Standard: Nursing services.* (1) The hospice must provide nursing care and services by or under the supervision of a registered nurse. Nursing services must ensure that the nursing needs of the patient are met as identified in the patient's initial comprehensive assessment and updated assessments.	

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(2) If State law permits nurse practitioners (NPs) to see, treat and write orders for patients, then NPs may provide services to beneficiaries receiving hospice care. The role and scope of the services provided by a NP that is not the individual's attending physician must be specified in the individual's plan of care. (3) Highly specialized nursing services that are provided so infrequently that the provision of such services by direct hospice employees would be impracticable and prohibitively expensive, may be provided under contract.	**Reference: § 418.64(b)(2)** **Issue:** It is not necessary to specify the role and scope of services provided by an NP in an individual's POC. **Proposal:** Delete second sentence. **Rationale:** Nurse practitioners' scope of practice is established by state law. The role and scope of services by an NP is not normally specified in the plan of care and no rationale for this addition to the care plan is included in the preamble. Under the cumulative effect of this and similar proposed regulations the size of the plan of care is growing exponentially and the requirements becoming unnecessarily burdensome.
(c) *Standard: Medical social services.* Medical social services must be provided by a qualified social worker, under the direction of a physician. Social work services must be based on the patient's psychosocial assessment and the patient's and family's needs and acceptance of these services.	
(d) *Standard: Counseling services.* Counseling services for adjustment to death and dying must be available to both the patient and the family. Counseling services must include but are not limited to the following: (1) *Bereavement counseling.* The hospice must: (i) Have an organized program for the provision of bereavement services furnished under the supervision of a qualified professional with experience in grief/loss counseling. (ii) Make bereavement services available to the family and other individuals in the bereavement plan of care up to one year following the death of the patient. Bereavement counseling also extends to residents and employees of a SNF/NF, ICF/MR, or other facility when appropriate and identified in the bereavement plan of care. (iii) Ensure that bereavement services reflect the needs of the bereaved. (iv) Develop a bereavement plan of care that notes the kind of bereavement services to be provided and the frequency of service delivery. A special coverage provision for bereavement counseling is specified in §	

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418.204(c). (2) *Nutritional counseling.* Nutritional counseling, when identified in the plan of care, must be performed by a qualified individual, which include dietitians as well as nurses and other individuals who are able to address and assure that the dietary needs of the patient are met. (3) *Spiritual counseling.* The hospice must: (i) Provide an assessment of the patient's and family's spiritual needs; (ii) Provide spiritual counseling to meet these needs in accordance with the patient's and family's acceptance of this service, and in a manner consistent with patient and family beliefs and desires; (iii) Facilitate visits by local clergy, pastoral counselors, or other individuals who can support the patient's spiritual needs to the best of its ability. The hospice is not required to go to extraordinary lengths to do so; and (iv) Advise the patient and family of this service.	

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§ 418.66 Condition of participation: Nursing services—Waiver of requirement that substantially all nursing services be routinely provided directly by a hospice. (a) CMS may waive the requirement in § 418.64(b) that a hospice provide nursing services directly, if the hospice is located in a nonurbanized area. The location of a hospice that operates in several areas is considered to be the location of its central office. The hospice must provide evidence to CMS that it has made a good faith effort to hire a sufficient number of nurses to provide services. CMS may waive the requirement that nursing services be furnished by employees based on the following criteria: (1) The location of the hospice's central office is in a nonurbanized area as determined by the Bureau of the Census. (2) There is evidence that a hospice was operational on or before January 1, 1983 including— (1) Proof that the organization was established to provide hospice services on or before January 1, 1983; (2) Evidence that hospice-type services were furnished to patients on or before January 1, 1983; and (3) Evidence that hospice care was a discrete activity rather than an aspect of another type of provider's patient care program on or before January 1, 1983. (3) By virtue of the following evidence that a hospice made a good faith effort to hire nurses: (i) Copies of advertisements in local newspapers that demonstrate recruitment efforts; (ii) Job descriptions for nurse employees; (iii) Evidence that salary and benefits are competitive for the area; and (iv) Evidence of any other recruiting activities (for example, recruiting efforts at health fairs and contacts with nurses at other providers in the area). (b) Any waiver request is deemed to be granted unless it is denied within 60 days after it is received. (c) Waivers will remain effective for 1 year at a time from the date of the request. (d) CMS may approve a maximum of two 1-year extensions for each initial waiver. If a hospice wishes to receive a 1-year extension, it must submit a request to CMS before the expiration of the waiver period, and certify that the conditions under which it originally requested the initial	

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waiver have not changed since the initial waiver was granted.	

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§ 418.70 Condition of participation: Furnishing of non-core services. A hospice must ensure that the services described in § 418.72 through § 418.78 are provided directly by the hospice or under arrangements made by the hospice as specified in § 418.100. These services must be provided in a manner consistent with current standards of practice.	

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§ 418.72 Condition of participation: Physical therapy, occupational therapy, and speech-language pathology. Physical therapy services, occupational therapy services, and speech-language pathology services must be available, and when provided, offered in a manner consistent with accepted standards of practice.	

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§ 418.74 Waiver of requirement—Physical therapy, occupational therapy, speech-language pathology, and dietary counseling. (a) A hospice located in a non-urbanized area may submit a written request for a waiver of the requirement for providing physical therapy, occupational therapy, speech-language pathology, and dietary counseling services. The hospice may seek a waiver of the requirement that it make physical therapy, occupational therapy, speech-language pathology, and dietary counseling services (as needed) available on a 24-hour basis. The hospice may also seek a waiver of the requirement that it provide dietary counseling directly. The hospice must provide evidence that it has made a good faith effort to meet the requirements for these services before it seeks a waiver. CMS may approve a waiver application on the basis of the following criteria: (1) The hospice is located in a non-urbanized area as determined by the Bureau of the Census. (2) The hospice provides evidence that it had made a good faith effort to make available physical therapy, occupational therapy, speech-language pathology, and dietary counseling services on a 24-hour basis and/or to hire a dietary counselor to furnish services directly. This evidence must include— (i) Copies of advertisements in local newspapers that demonstrate recruitment efforts; (ii) Physical therapy, occupational therapy, speech-language pathology, and dietary counselor job descriptions; (iii) Evidence that salary and benefits are competitive for the area; and (iv) Evidence of any other recruiting activities (for example, recruiting efforts at health fairs and contact discussions with physical therapy, occupational therapy, speech-language pathology, and dietary counseling service providers in the area). (b) Any waiver request is deemed to be granted unless it is denied within 60 days after it is received. (c) An initial waiver will remain effective for 1 year at a time from the date of the request. (d) CMS may approve a maximum of two 1-year extensions for each initial waiver. If a hospice wishes to receive a 1-year extension, it must submit a request to CMS prior to the expiration of the waiver period and certify that conditions	**Reference: §418.74** **Issue:** Reference to dietary counseling is confusing. **Proposal:** Use terminology consistent with §418.64. **Rationale:** Section 418.64 refers to nutritional counseling. The same term should be used for the same function throughout the regulations or the difference between the two roles should be clarified. **Issue:** Shortages of health care professionals are not limited to non-urbanized areas. **Proposal:** (a) A hospice may submit a written request for a waiver of the requirement for providing physical therapy, occupational therapy, speech-language pathology, and dietary counseling services. The hospice may seek a waiver of the requirement that it make physical therapy, occupational therapy, speech-language pathology, and dietary counseling services (as needed) available on a 24-hour basis. The hospice may also seek a waiver of the requirement that it provide dietary counseling directly. The hospice must provide evidence that it has made a good faith effort to meet the requirements for these services before it seeks a waiver. CMS may approve a waiver application on the basis of the following criteria: (1) **Evidence of a shortage of the required type of health care professional in the area in which the area in which the services are to be provided.** **Rationale:** Shortages are dependent on a number of different marker conditions, only one of which is geography. Waivers should be available in any location in which a shortage exists and other criteria are met.

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under which it originally requested the waiver have not changed since the initial waiver was granted.	

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§ 418.76 Condition of participation: Home health aide and homemaker services. All home health aide services must be provided by individuals who meet the personnel requirements specified in paragraph (a) of this section. Homemaker services must be provided by individuals who meet the personnel requirements specified in paragraph (j) of this section.	
(a) *Standard: Home health aide qualifications.* (1) A qualified home health aide is a person who has successfully completed— (i) A training program and competency evaluation as specified in paragraphs (b) and (c) (ii) of this section respectively; or (iii) A competency evaluation program; or (iv) A State licensure program that meets the requirements of paragraphs (b) and (c) of this section. A home health aide is not considered to have completed a training program, or a competency evaluation program if, since the individual's most recent completion of the program(s), there has been a continuous period of 24 consecutive months during which none of the services furnished by the individual as described in § 409.40 of this chapter were for compensation. If there has been a 24-month lapse in furnishing services, the individual must complete another training and/or competency evaluation program before providing services, as specified in paragraph (a)(1) of this section.	
(b) *Standard: Content and duration of home health aide classroom and supervised practical training.* (1) Home health aide training must include classroom and supervised practical classroom training in a practicum laboratory or other setting in which the trainee demonstrates knowledge while performing tasks on an individual under the direct supervision of a registered nurse or licensed practical nurse, who is under the supervision of a registered nurse. Classroom and supervised practical training combined must total at least 75 hours. (2) A minimum of 16 hours of classroom training must precede a minimum of 16 hours of supervised practical training as part of the 75 hours. (3) A home health aide training program must address each of the following subject areas: (i) Communication skills, including the ability to read, write, and verbally	

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report clinical information to patients, care givers, and other hospice staff; (ii) Observation, reporting, and documentation of patient status and the care or service furnished; (iii) Reading and recording temperature, pulse, and respiration; (iv) Basic infection control procedures; (v) Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor; (vi) Maintenance of a clean, safe, and healthy environment; (vii) Recognizing emergencies and the knowledge of emergency procedures and their application; (viii) The physical, emotional, and developmental needs of and ways to work with the populations served by the hospice, including the need for respect for the patient, his or her privacy, and his or her property; (ix) Appropriate and safe techniques in performing personal hygiene and grooming tasks, including items on the following basic checklist— (A) Bed bath; (B) Sponge, tub, and shower bath; (C) Hair shampoo (sink, tub, and bed); (D) Nail and skin care; (E) Oral hygiene; and (F) Toileting and elimination; (x) Safe transfer techniques and ambulation. (xi) Normal range of motion and positioning. (xii) Adequate nutrition and fluid intake. (xiii) Any other task that the hospice may choose to have an aide perform. The hospice is responsible for training home health aides, as needed, for skills not covered in the basic checklist, as described in paragraph (b)(3)(ix) of this section. (4) The hospice must maintain documentation that demonstrates that the requirements of this standard are met.	
(c) *Standard: Competency evaluation.* An individual may furnish home health services on behalf of a hospice only after that individual has successfully completed a	

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competency evaluation program as described in this section. (1) The competency evaluation must address each of the subjects listed in paragraphs (b)(1) through (b)(3) of this section. Subject areas specified under paragraphs (b)(3)(i), (b)(3)(iii), (b)(3)(ix), (b)(3)(x) and (b)(3)(xi) of this section must be evaluated by observing an aide's performance of the task with a patient. The remaining subject areas may be evaluated through written examination, oral examination, or after observation of a home health aide with a patient. (2) A home health aide competency evaluation program may be offered by any organization, except as specified in paragraph (f) of this section. (3) The competency evaluation must be performed by a registered nurse in consultation with other skilled professionals, as appropriate. (4) A home health aide is not considered competent in any task for which he or she is evaluated as unsatisfactory. An aide must not perform that task without direct supervision by a registered nurse until after he or she has received training in the task for which he or she was evaluated as ''unsatisfactory,'' and successfully completes a subsequent evaluation. (5) The hospice must maintain documentation that demonstrates the requirements of this standard are being met.	
(d) *Standard: In-service training.* A home health aide must receive at least 12 hours of in-service training during each 12-month period. In-service training may occur while an aide is furnishing care to a patient. (1) In-service training may be offered by any organization except one that is excluded by paragraph (f) of this section, and must be supervised by a registered nurse. (2) The hospice must maintain documentation that demonstrates the requirements of this standard are met.	
(e) *Standard: Qualifications for instructors conducting classroom supervised practical training, competency evaluations and in-service training.* Classroom supervised practical training must be performed by or under the supervision of a registered nurse who possesses a minimum of two years nursing experience, at least one year of which must be in home health care. Other individuals may provide instruction under the general supervision of a registered nurse.	

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

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patient by a registered nurse or the appropriate qualified therapist. Written patient care instructions for a home health aide must be prepared by a registered nurse or other appropriate skilled professional (*i.e.*, a physical therapist, speech-language pathologist, or occupational therapist) who is responsible for the supervision of a home health aide as specified under paragraph (h) of this section. (2) A home health aide provides services that are: (i) Ordered by the physician or nurse practitioner; (ii) Included in the plan of care; (iii) Permitted to be performed under State law by such home health aide; and (iv) Consistent with the home health aide training. (3) The duties of a home health aide include: (i) The provision of hands-on personal care; (ii) The performance of simple procedures as an extension of therapy or nursing services; (iii) Assistance in ambulation or exercises; and (iv) Assistance in administering medications that are ordinarily self-administered. (4) Home health aides must report changes in the patient's medical, nursing, rehabilitative, and social needs to a registered nurse or other appropriate licensed professional, as the changes relate to the plan of care and quality assessment and improvement activities. Home health aides must also complete appropriate records in compliance with the hospice's policies and procedures.	
(h) *Standard: Supervision of home health aides.* i. A registered nurse or qualified therapist must make an onsite visit to the patient's home no less frequently than every 14 days to assess the home health aide's services. The home health aide does not have to be present during this visit. A registered nurse or qualified therapist must make an onsite visit to the location where the patient is receiving care in order to observe and assess each aide while he or she is performing care no less frequently than every 28 days.	**Reference: § 418.76(h)** **Issue:** As written, it is unclear whether this standard requires assessment of the home health aide's skills or the quality of the care and services actually provided. **Proposed Language:** Change first sentence as follows: A registered nurse or qualified therapist must make an onsite visit to the patient's home no less frequently than every 14 days to assess the **quality of the care and services provided by the home health aide**. **Rationale:** Presumably, this section requires that the quality of care being provided by the aide be assessed at least every 14

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ii. The supervising nurse or therapist must assess an aide's ability to demonstrate initial and continued satisfactory performance in meeting outcome criteria that include, but is not limited to— (i) Following the patient's plan of care for completion of tasks assigned to the home health aide by the registered nurse or qualified therapist; (ii) Creating successful interpersonal relationships with the patient and family; (iii) Demonstrating competency with assigned tasks; (iv) Complying with infection control policies and procedures; and (v) Reporting changes in the patient's condition. (3) If the hospice chooses to provide home health aide services under contract with another organization, the hospice's responsibilities include, but are not limited to— (i.) Ensuring the overall quality of care provided by an aide; (ii.) Supervising an aide's services as described in paragraphs (h)(1) and (h)(2) of this section; and (iii.)Ensuring that home health aides who provide services under arrangement have met the training and/ or competency evaluation requirements of this condition.	days. Competency assessment every 14 days would be onerous and excessive. Instead, an assessment of general competency should be conducted no more frequently than annually or bi-annually using the criteria in §418.76(c). Additionally, clarification is needed regarding where the assessment from the onsite visit is to be documented.
(i) *Standard: Individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit.* An individual may furnish personal care services, as defined in § 440.167 of the Code of Federal Regulations, on behalf of a hospice or home health agency. Before the individual may furnish personal care services, the individual must be found competent by the State to furnish those services. The individual only needs to demonstrate competency in the services the individual is required to furnish.	
(j) *Standard: Homemaker qualifications.* A qualified homemaker is a home health aide as described in § 418.76 or an individual who meets the standards in § 418.202(g) and	

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has successfully completed hospice orientation addressing the needs and concerns of patients and families coping with a terminal illness.	
(k) *Standard: Homemaker supervision and duties.* (1) Homemaker services must be coordinated by a member of the interdisciplinary group. (2) Instructions for homemaker duties must be prepared by a member of the interdisciplinary group. (3) Homemakers must report all concerns about the patient or family to the member of the interdisciplinary group who is coordinating homemaker services.	

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§ 418.78 Conditions of participation: Volunteers. The hospice must use volunteers to the extent specified in paragraph (e) of this section. These volunteers must be used in defined roles and under the supervision of a designated hospice employee.	
(a) *Standard: Training.* The hospice must maintain, document and provide volunteer orientation and training that is consistent with hospice industry standards.	
(b) *Standard: Role.* Volunteers must be used in day-to-day administrative and/or direct patient care roles.	
(c) *Standard: Recruiting and retaining.* The hospice must document and demonstrate viable and ongoing efforts to recruit and retain volunteers.	
(d) *Standard: Cost saving.* The hospice must document the cost savings achieved through the use of volunteers. Documentation must include— (1) The identification of each position that is occupied by a volunteer; (2) The work time spent by volunteers occupying those positions; and (3) Estimates of the dollar costs that the hospice would have incurred if paid employees occupied the positions identified in paragraph (d)(1) of this section for the amount of time specified in paragraph (d)(2) of this section.	**Reference: §418.78(d)(2)** **Issue:** The meaning of work time should be clarified. **Proposed Language:** The work time spent **(including training, orientation and travel time, in addition to time spent providing direct care and administrative services)** by volunteers occupying those positions; and **Rationale:** All time donated by volunteers should be included in determining their work time. State laws differ regarding the amount of training required and may be significant. In addition, travel time may be significant in rural areas. Time spent on all such activities should be recognized as part of the contribution made by volunteers.
(e) *Standard: Level of activity.* Volunteers must provide day-to-day administrative and/or direct patient care services in an amount that, at a minimum, equals 5 percent of the total patient care hours of all paid hospice employees and contract staff. The hospice must maintain records on the use of volunteers for patient care and administrative services, including the type of services and time worked.	**Reference: § 418.78(e)** **Issue:** The requirement that volunteer time represent 5 percent of total patient care hours by paid hospice staff should be satisfied by calculating all time contributed by volunteers. **Proposed Language:** Revise the first sentence of (e) as follows: Volunteers must provide services in an amount that, at a minimum, equals 5 percent of the total patient care hours of all paid hospice employees and contract staff. **Calculation of volunteer service hours include all work time as set forth in (d)(2) of this section.** **Rationale:** *See* rationale for comment to (d)(2).

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§ 418.100 Condition of participation: Organization and administration of services. The hospice must organize, manage, and administer its resources to provide the hospice care and services to patients, caregivers and families necessary for the palliation and management of terminal illness.	**Reference: Preamble to Proposed Rule, 70 Fed. Reg. 30853 (May 27, 2005) ("We believe that a well-managed hospice will be more likely to allocate resources so that patients maintain their highest functional capacity.")** **Issue:** It is unreasonable to expect that dying patients will maintain their highest functional capacity. **Proposed Language:** We believe that a well-managed hospice will be more likely to allocate resources so that patients maintain their highest functional capacity **consistent with the course of their terminal illness**. **Rationale:** The expectation is troubling and incongruent for patients who have been certified as expected to die within six months. However, hospice should assure that patients maintain their highest functional capacity consistent with the course of their terminal illness.
(a) *Standard: Serving the hospice patient and family.* The hospice must ensure— (1) That each patient receives and experiences hospice care that optimizes comfort and dignity; and (2) That each patient experience hospice care that is consistent with patient and family needs and desires.	**Reference: § 418.100(a)** **Issue:** Some patients and family members may have unreasonable or even inconsistent conflicting desires. **Proposed Language:** (2) That each patient experience hospice care that is consistent with patient and family needs **as identified in the plan of care. The needs and desires of the Patient, as expressed directly or through the Representative, shall be given primary consideration.** **Rationale:** Patient and family needs and desires should be carefully considered and incorporated into the plan of care as appropriate. However, the patient's needs and desires should be primary.
(b) *Standard: Governing body and administrator.* A governing body (or designated persons so functioning) assumes full legal authority and responsibility for the management of the hospice, the provision of all hospice services, its fiscal operations, and continuous quality assessment and performance improvement. A qualified administrator reports to the governing body and is responsible for the day-to-day operation of the hospice. The administrator must be a hospice employee and possess education and experience required by the hospice's governing body.	
(c) *Standard: Services.* (1) A hospice must be primarily engaged in providing the following care and services and must do so in a manner that is consistent within accepted standards of practice: (i) Nursing services. (ii) Medical social services. (iii) Physician services.	

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(iv) Counseling services, including spiritual counseling, dietary counseling, and bereavement counseling. (v) Home health aide, volunteer, and homemaker services. (vi) Physical therapy, occupational therapy and speech-language pathology therapy services. (vii) Short-term inpatient care. (viii) Medical supplies (including drugs and biologicals) and medical appliances. (2) Nursing services, physician services, and drugs and biologicals (as specified in § 418.106) must be made routinely available on a 24-hour basis 7 days a week. Other covered services must be available on a 24-hour basis when reasonable and necessary to meet the needs of the patient and family.	
(d) *Standard: Continuation of care.* A hospice may not discontinue or reduce care provided to a Medicare or Medicaid beneficiary because of the beneficiary's inability to pay for that care.	
(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	**Reference: § 418.100(e)** **Issue:** Overlapping responsibilities between hospice and other certified agencies could result in duplicate, inconsistent, uncoordinated efforts and enforcement responses by state survey agencies. **Proposal:** The standard should take into consideration obligations of other certified providers as well as program guidance regarding oversight and supervision for services provided "under arrangement." **Rationale:** The proposed language requires clarification when two certified providers, such as a hospice and a nursing home, have independent obligations to maintain program requirements for shared patients. Currently available guidance from CMS on "under arrangement" relationships speaks to oversight and accountabilities in a provider/supplier relationship but does not address the circumstance here when the arrangements are between two certified providers with independent duties and responsibilities to the Medicare program for continued participation. There is a need for clearer allocation of accountability and responsibility rather than leaving the two Medicare providers to guess which one is "under arrangement" with whom. **Reference: § 418.100(e)(2)** **Issue:**

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qualifications as hospice employees; and (3) Delivered in accordance with the patient's plan of care.	"Having at least the same qualifications as hospice employees" should be clarified. **Proposed Language:** Furnished in a safe and effective manner by personnel having at least the same qualifications as hospice employees **in comparable positions**; and **Rationale:** This section should be revised to clarify that vendors who provide care are held to the same qualifications as hospice employees, but that providers of non-care services are not required to meet unnecessary qualifications.
(f) *Standard: Hospice satellite locations.* (1) All hospice satellite locations must be approved by CMS before providing hospice care and services to Medicare patients. The determination that a satellite location does or does not meet the definition of a satellite location, as set forth in this part, is an initial determination, as set forth in § 498.3. (2) The hospice must continually monitor and manage all services provided at all of its locations to ensure that services are delivered in a safe and effective manner and to ensure that each patient and family receives the necessary care and services outlined in the plan of care.	
(g) *Standard: In-service training.* A hospice must assess the skills and competence of all individuals furnishing care, including volunteers furnishing services, and, as necessary, provide in-service training and education programs where required. The hospice must have written policies and procedures describing its method(s) of assessment of competency and maintain a written description of the in-service training provided during the previous 12 months.	

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§ 418.102 Condition of participation: Medical director. The hospice must designate a physician to serve as medical director. The medical director must be a doctor of medicine or osteopathy who is either employed by, or under contract with, the hospice. When the medical director is not available, a physician designated by the medical director assumes the same responsibilities and obligations as the medical director. The medical director and physician designee coordinate with other physicians and health care professionals to ensure that each patient experiences medical care that reflects hospice policy.	**Reference: § 418.102** **Issue:** Hospice rather than of the medical director should be responsible for designating a physician to cover the obligations of the medical director when she or he is unavailable. **Proposed Language:** The third sentence of §418.102 should be modified as follows: When the medical director is not available, a physician designated by the **hospice** assumes the same responsibilities.... **Rationale:** Hospice rather than the medical director has the ultimate responsibility for ensuring that qualified individuals provide hospice services. **Issue:** Hospice medical director may not be in the best position to ensure that a patient's medical care reflects hospice policy. **Proposed Language:** The medical director and physician designee coordinate with other physicians and health care professionals to **promote** medical care that reflects hospice policy **and is consistent with the plan of care**. . **Rationale:** Because of the number of health care professionals who may be involved in the patient's care, only some of whom are part of the hospice organization, the medical director is only in a position to coordinate with all of those professionals to promote compliance with hospice policy and specifically with the plan of care.
(a) *Standard: Initial certification of terminal illness.* The medical director or physician designee reviews the clinical information for each hospice patient and provides written certification that it is anticipated that the patient's life expectancy is 6 months or less if the illness runs its normal course. The physician must consider the following criteria when making this determination: (1) The primary terminal condition. (2) Related diagnosis(es), if any. (3) Current subjective and objective medical findings. (4) Current medication and treatment orders. (5) Information about the medical management of any of the patient's conditions unrelated to the terminal illness.	
(b) *Standard: Recertification of the terminal illness.* Before the recertification period for each patient, as described in § 418.21(a), the medical director or physician designee must review:	**Reference: § 418.102(b)** **Issue:** Consideration of the expectations and wishes of the patient's entire family may be improper and contrary to the

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(1) The patient's clinical information; and (2) The patient's and family's expectations and wishes for the continuation of hospice care.	patient's best interest. **Proposed Language:** (b) (2) The patient and**/or Representative's** expectations and wishes for the continuation of hospice care. **Rationale:** It should be recognized that when the wishes of a competent patient and the family are in conflict, the wishes of the patient are controlling. If the patient is incompetent, the decisions of the Representative must control.
(c) *Standard: Coordination of medical care.* The medical director or physician designee, and the other members of the interdisciplinary group are jointly responsible for the coordination of the patient's medical care in its entirety. The medical director or physician designee is also responsible for directing the hospice's quality assessment and performance improvement program.	**Reference: § 418.102(c)** **Issue:** The medical director may not be in a position to coordinate the patient's medical care in its entirety. **Proposed Language:** Revise first sentence as follows: The medical director or physician designee, and the other members of the interdisciplinary group are jointly responsible for the coordination of the patient's medical care **as it relates to the terminal illness and for collaboration with other caregivers.** **Rationale:** Because of the need to coordinate with caregivers unrelated to hospice, including the attending physician and nursing home medical director and staff, the hospice medical director and IDG may only be in a position to coordinate care as it relates to the terminal illness and to collaborate with other caregivers. **Issue:** The medical director or physician designee should be responsible for participating in the hospice's quality assessment and performance improvement program, but may not be the most appropriate person direct it. **Proposed Language:** Revise second sentence as follows: The medical director or physician designee is also responsible for **participating in** the hospice's quality assessment and performance improvement program. **Rationale:** The medical director may not have the time or expertise to direct the quality assurance program. The quality assurance program encompasses all aspects of the hospice operation, many of which the medical director may be unfamiliar with or which may be outside of his or her scope of practice. The hospice's governing body should be responsible for directing the program with participation by the medical director.

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§ 418.104 Condition of participation: Clinical records. A clinical record containing past and current findings is maintained for each hospice patient. The clinical record must contain accurate clinical information that is available to the patient's attending physician and hospice staff. The clinical record may be maintained electronically	**Clinical Records**
(a) *Standard: Content.* Each patient's record must include the following: (1) The plan of care, initial assessment, comprehensive assessment, and updated comprehensive assessments, clinical notes, and progress notes. (2) Informed consent, authorization, and election forms. (3) Responses to medications, symptom management, treatments, and services. (4) Outcome measure data elements, as described in § 418.54(e) of this subpart. (5) Physician certification and recertification of terminal illness as required in § 418.22 and described in § 418.102(a) and § 418.102(b) respectively. (6) Any advance directives as described in § 418.52(a)(3).	
(b) *Standard: Authentication.* All entries must be legible, clear, complete, and appropriately authenticated and dated. All entries must be signed, and the hospice must be able to authenticate each handwritten and electronic signature of a primary author who has reviewed and approved the entry.	
(c) *Standard: Protection of information.* The clinical record, its contents and the information contained therein must be safeguarded against loss or unauthorized use. The hospice must be in compliance with the Department's rules regarding personal health information set out at 45 CFR parts 160 and 164.	
(d) *Standard: Retention of records.* Patient clinical records must be retained for 5 years after the death or discharge of the patient, unless State law stipulates a longer period of time. If the hospice discontinues operation, hospice policies must provide for retention and storage of clinical records. The hospice must inform its State agency and its CMS Regional office where such clinical records will be stored and how they may be accessed.	

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(e) *Standard: Discharge or transfer of care.* (1) If the care of a patient is transferred to another Medicare/ Medicaid-approved facility, the hospice must forward a copy of the patient's clinical record and the hospice discharge summary to that facility.	**Reference: § 418.104(e)** **Issue:** The patient's complete clinical record should not automatically be forwarded to a new facility. **Proposed Language:** If the care of a patient is transferred to another Medicare/ Medicaid-approved facility, the hospice must forward the hospice discharge summary to that facility **and such other clinical records as requested.** **Rationale:** It is unnecessary and potentially burdensome to transfer the patient's entire clinical record, but all records should be made available to the transfer facility on request.
(2) If a patient revokes the election of hospice care, or is discharged from hospice because eligibility criteria are no longer met, the hospice must provide a copy of the clinical record and the hospice discharge summary of this section to the patient's attending physician. (3) The hospice discharge summary must include— (i) A summary of the patient's stay including treatments, symptoms and pain management; (ii) The patient's current plan of care; (iii)The patient's latest physician orders; and (iv)Any other documentation that will assist in post-discharge continuity of care.	**Reference: § 418.104(e) (3)** **Issue:** The discharge summary should contain limited necessary information with the option to obtain additional information as requested. **Proposed Language:** The hospice discharge summary must include— (i) A summary of the patient's stay including treatments, symptoms and pain management; (ii)Any other documentation that will assist in post-discharge continuity of care, **as requested.** **Rationale:** *See* above.
(e) *Standard: Retrieval of clinical records.* The clinical record, whether hard copy or in electronic form, must be made readily available on request by an appropriate authority.	

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§ 418.106 Condition of participation: Drugs, controlled drugs and biologicals, medical supplies, and durable medical equipment. Medical supplies and appliances, as described in § 410.36 of this chapter; durable medical equipment, as described in § 410.38 of this chapter; and drugs and biologicals related to the palliation and management of the terminal illness and related conditions, as identified in the hospice plan of care, must be provided by the hospice while the patient is under hospice care.	**Drugs, Supplies & DME**
(a) *Standard: Administration of drugs and biologicals.* (1) All drugs and biologicals must be administered in accordance with accepted hospice and palliative care standards of practice and according to the patient's plan of care. (2) The interdisciplinary group, as part of the review of the plan of care, must determine the ability of the patient and/or family to safely self-administer drugs and biologicals.	
(b) *Standard: Controlled drugs in the patient's home.* The hospice must have a written policy for tracking, collecting, and disposing of controlled drugs maintained in the patient's home. During the initial hospice assessment, the use and disposal of controlled substances must be discussed with the patient and family to ensure the patient and family are educated regarding the uses and potential dangers of controlled substances. The hospice nurse must document that the policy was discussed with the patient and family.	**Reference: § 418.106(b)** **Issue:** Hospice has limited ability to control drugs maintained in a patient's home. **Proposed Language:** Modify the first two sentences as follows: The hospice must have a written policy for **monitoring** and disposing of controlled drugs maintained in the patient's home. The use and disposal of controlled substances must be discussed with the patient and family to ensure the patient and family are educated regarding **safe** uses of medication and their management. **Rationale:** It is unreasonable to expect the hospice to take responsibility for drug safety in the patient's home beyond educating the patient and family regarding drug safety and proper disposal. In addition, the initial assessment may not be the most appropriate time to conduct that education. Also, variations in state law regarding controlled substances will affect the degree of control that hospice has over handling of these drugs.
(c) *Standard: Use and maintenance of equipment and supplies.* (1) The hospice must follow manufacturer recommendations for performing routine and preventive maintenance on durable medical equipment. The equipment must be safe and work as intended for use in the patient's environment. Where there is no manufacturer recommendation for a piece of	**Reference: § 418.106(c)(1)** **Issue:** Hospice does not generally own or have the expertise to perform maintenance on durable medical equipment. **Proposed Language:** The hospice must **ensure that contracted vendors** follow manufacturer recommendations for performing routine and

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equipment, the hospice must develop in writing its own repair and routine maintenance policy. The hospice may use persons under contract to ensure the maintenance and repair of durable medical equipment.	preventive maintenance on durable medical equipment. **The hospice shall require that contracted vendors** develop in writing **their** own repair and routine maintenance policy where there is no manufacturer recommendation for a piece of equipment,. The equipment must be safe and work as intended for use in the patient's environment. The hospice may use persons under contract to ensure the maintenance and repair of durable medical equipment. **Rationale:** Because it is typical for hospices to lease DME from outside vendors, it is more appropriate to require the hospice to ensure that the vendors properly maintain the equipment. The IDG is not required to include a DME specialist and hospice staff does not typically have the expertise to undertake this responsibility directly.
(2) The hospice must ensure that the patient, where appropriate, as well as the family and/or other caregiver(s), receive instruction in the safe use of durable medical equipment and supplies. The patient, family, and/or caregiver must be able to demonstrate the appropriate use of durable medical equipment to the satisfaction of the hospice staff.	

EVERCARE HOSPICE COMMENTS

July 26, 2005

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§ 418.108 Condition of participation: Short-term inpatient care. Inpatient care must be available for pain control, symptom management, and respite purposes, and must be provided in a participating Medicare or Medicaid facility.	
(a) *Standard: Inpatient care for symptom management and pain control.* Inpatient care for pain control and symptom management must be provided in one of the following: (1) A Medicare-approved hospice that meets the conditions of participation for providing inpatient care directly as specified in § 418.110. (2) A Medicare-participating hospital or a skilled nursing facility that also meets the standards specified in § 418.110(b) and (f) regarding 24-hour nursing services and patient areas.	**Reference: § 418.108(a)(1) and (2)** **Issue:** The standard for inpatient care should include psychosocial needs. **Proposed Language:** Inpatient care for pain control, symptom management and **psychosocial needs** must be provided in one of the following: **Rationale:** Many times the need for respite care is associated with mental health issues of the patient. Inclusion of psychosocial issues in general, short-term inpatient care coverage will help hospices meet these needs more effectively.
(b) *Standard: Inpatient care for respite purposes.* Inpatient care for respite purposes must be provided by one of the following: (1) A provider specified in paragraph (a) of this section. (2) A Medicare/Medicaid approved nursing facility that also meets the standards specified in § 418.110(b) and (f).	**Reference: §418.108(b)** **Issue:** 24-hour RN services are often unnecessary for respite services. **Proposed Language:** Delete entire section. **Rationale:** Need for respite care is generally associated solely with the caregiver rather than the medical needs of the patient. Not only is a 24-hour RN not required, but the care may well be performed in an assisted living facility or other appropriately licensed residential care facility. This will become increasingly important and more logical as our population ages and more people require respite services.
(c) *Standard: Inpatient care provided under arrangements.* If the hospice has an arrangement with a facility to provide for short-term inpatient care, the arrangement is described in a legally binding written agreement that at a minimum specifies— (1) That the hospice supplies the inpatient provider a copy of the patient's plan of care and specifies the inpatient services to be furnished;	

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(2) That the inpatient provider has established patient care policies consistent with those of the hospice and agrees to abide by the palliative care protocols and plan of care established by the hospice for its patients; (3) That the hospice patient's inpatient clinical record includes a record of all inpatient services furnished, events regarding care that occurred at the facility, and that a copy of the inpatient clinical record and discharge summary is available to the hospice at the time of discharge; (4) That the inpatient facility has identified a individual within the facility who is responsible for the implementation of the provisions of the agreement; (5) That the hospice retains responsibility for arranging the training of personnel who will be providing the patient's care in the inpatient facility and that a description of the training and the names of those giving the training is documented; and (6) That a way to verify that requirements in paragraphs ©(1) through ©(5) of this section have been met is established.	
(d) *Standard: Inpatient care limitation.* The total number of inpatient days used by Medicare beneficiaries who elected hospice coverage in a 12month period in a particular hospice may not exceed 20 percent of the total number of hospice days consumed in total by this group of beneficiaries.	
(e) *Standard: Exemption from limitation.* Before October 1, 1986, any hospice that began operation before January 1, 1975, is not subject to the limitation specified in paragraph (d) of this section.	

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§ 418.110 Condition of participation: Hospices that provide inpatient care directly. A hospice that provides inpatient care directly must demonstrate compliance with all of the following standards:	
(a) *Standard: Staffing.* The hospice is responsible for ensuring that staffing for all services reflects its volume of patients, their acuity, and the level of intensity of services needed to ensure that plan of care outcomes are achieved and negative outcomes are avoided.	
(b) *Standard: Twenty-four hour nursing services.* The hospice facility must provide 24-hour nursing services that meet the nursing needs of all patients and are furnished in accordance with each patient's plan of care. Each patient must receive all nursing services as prescribed and must be kept comfortable, clean, well groomed, and protected from accident, injury, and infection.	
(c) *Standard: Physical environment.* The hospice must maintain a safe physical environment free of hazards for patients, staff, and visitors. (1) *Safety management.* (i) The hospice must address real or potential threats to the health and safety of the patients, others, and property. The hospice must report a breach of safety to appropriate State and local bodies having regulatory jurisdiction and correct it promptly. (ii) The hospice must take steps to prevent equipment failure and when a failure occurs, report it appropriate State and local bodies having regulatory jurisdiction and correct it promptly. (iii) The hospice must have a written disaster preparedness plan in effect for managing the consequences of power failures, natural disasters, and other emergencies that would affect the hospice's ability to provide care. The plan must be periodically reviewed and rehearsed with staff (including non-employee staff) with special emphasis placed on carrying out the procedures necessary to protect patients and others. (2) *Physical plant and equipment.* The hospice must develop procedures for managing the control, reliability, and quality of— (i.) The routine storage and prompt	

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disposal of trash and medical waste; (ii.) Light, temperature, and ventilation/air exchanges throughout the hospice; (iii.) Emergency gas and water supply; and (iv.) The scheduled and emergency maintenance and repair of all equipment	
(d) *Standard: Fire protection.* (1) Except as otherwise provided in this section— (i) The hospice must meet the provisions applicable to nursing homes of the 2000 edition of the Life Safety Code (LSC) of the National Fire Protection Association The Director of the Office of the Federal Register has approved the NFPA 101 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal register/code of federal regulations/ibr locations.html.* Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in the edition of the Code are incorporated by reference, CMS will publish a notice in the **Federal Register** to announce the changes. (ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the LSC does not apply to hospice. (2) In consideration of a recommendation by the State survey agency, CMS may waive, for periods deemed appropriate, specific provisions of the Life Safety Code which, if	

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rigidly applied would result in unreasonable hardship for the hospice, but only if the waiver would not adversely affect the health and safety of patients. (3) The provisions of the adopted edition of the Life Safety Code do not apply in a State if CMS finds that a fire and safety code imposed by State law adequately protects patients in hospices. (4) Beginning March 13, 2006, a hospice must be in compliance with Chapter 9.2.9, Emergency lighting. (5) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to hospices. (6) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a hospice may place alcohol-based hand rub dispensers in its facility if— (i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities; (ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls; (iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and (v)The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore MD and at the Office	

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of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this amendment, CMS will publish notice in the **Federal Register** to announce the changes.	
(e) *Standard: Patient areas.* The hospice must provide a home-like atmosphere and ensure that patient areas are designed to preserve the dignity, comfort, and privacy of patients. (1) The hospice must provide— (i) Physical space for private patient and family visiting; (ii) Accommodations for family members to remain with the patient throughout the night; and (iii) Physical space for family privacy after a patient's death. (2) The hospice must provide the opportunity for patients to receive visitors at any hour, including infants and small children.	
(f) *Standard: Patient rooms.* (1) The hospice must ensure that patient rooms are designed and equipped for nursing care, as well as the dignity, comfort, and privacy of patients. (2) The hospice must accommodate a patient and family request for a single room whenever possible. (3) Each patient's room must— (i) Be at or above grade level; (ii) Contain a suitable bed and other appropriate furniture for each patient; (iii) Have closet space that provides security and privacy for clothing and personal belongings; (iv) Accommodate no more than two patients; (vi)Provide at least 80 square feet for each residing patient in a double room and at least 100 square feet for each patient residing in a single room; and (vii) (vi) Be equipped with an easily-activated, functioning device	

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accessible to the patient, that is used for calling for assistance. (4) For an existing building, CMS may waive the space and occupancy requirements of paragraphs (f)(2)(iv) and (f)(2)(v) of this section for a period of time if it determines that— (i) Imposition of the requirements would result in unreasonable hardship on the hospice if strictly enforced; or jeopardize its ability to continue to participate in the Medicare program; and (ii) The waiver serves the needs of the patient and does not adversely affect their health and safety.	
(g) *Standard: Toilet/bathing facilities.* Each patient room must be equipped with, or conveniently located near, toilet and bathing facilities.	
(h) *Standard: Plumbing facilities.* The hospice must— (1) Have an adequate supply of hot water at all times; and (2) Have plumbing fixtures with control valves that automatically regulate the temperature of the hot water used by patients.	
(i) *Standard: Infection control.* The hospice must maintain an infection control program that protects patients, staff and others by preventing and controlling infections and communicable disease as stipulated in §418.60.	
(j) *Standard: Sanitary environment.* The hospice must provide a sanitary environment by following current standards of practice, including nationally recognized infection control precautions, and avoid sources and transmission of infections and communicable diseases.	
(k) *Standard: Linen.* The hospice must have available at all times a quantity of clean linen in sufficient amounts for all patient uses. Linens must be handled, stored, processed, and transported in such a manner as to prevent the spread of contaminants.	
(l) *Standard: Meal service and menu planning.* The hospice must furnish meals to each patient that are— (1) Consistent with the patient's plan of care, nutritional needs, and therapeutic diet; (2) Palatable, attractive, and served at the proper temperature; and (3) Obtained, stored, prepared, distributed, and served under sanitary conditions.	
(m) *Standard: Pharmaceutical services.* Under the direction of a qualified pharmacist, the hospice must	

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provide pharmaceutical services such as drugs and biologicals and have a written process in place that ensures dispensing accuracy. The hospice will evaluate a patient's response to the medication therapy, identify adverse drug reactions, and take appropriate corrective action. Drugs and biologicals must be obtained from community or institutional pharmacists or stocked by the hospice. The hospice must furnish the drugs and biologicals for each patient, as specified in each patient's plan care. The use of drugs and biologicals must be provided in accordance with accepted professional principles and appropriate Federal, State, and local laws.	
(n) *Pharmacist.* A licensed pharmacist must provide consultation on all aspects of the provision of pharmaceutical care in the facility, including ordering, storage, administration, disposal, and record keeping of drugs and biologicals. (1) *Orders for medications.* (i) A physician as defined by section 1861(r)(1) of the Act, or a nurse practitioner in accordance with the plan of care and State law, must order all medications for the patient. (ii) If the medication order is verbal or given by or through electronic transmission— (a) The physician must give it only to a licensed nurse, nurse practitioner (where appropriate), pharmacist, or another physician; and (b) The individual receiving the order must record and sign it immediately and have the prescribing physician sign it in accordance with State and Federal regulations. (2) *Administration of medications.* Medications must be administered by only the following individuals: (i) A licensed nurse, physician, or other health care professional in accordance with their scope of practice. (ii) An employee who has completed a State-approved training program in medication administration. (iii) The patient, upon approval by the attending physician. (3) *Labeling of drugs and biologicals.* Drugs and biologicals must be labeled in accordance	

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with currently accepted professional practice and must include appropriate accessory and cautionary instructions, as well as an expiration date (if applicable). (4) *Drug management procedures.* (i) All drugs and biologicals must be stored in secure areas. All drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1976 must be stored in locked compartments within such secure storage areas. Only personnel authorized to administer controlled medications may have access to the locked compartments. (ii) The hospice must keep current and accurate records of the receipt and disposition of all controlled drugs. (iii) Any discrepancies in the acquisition, storage, use, disposal, or return of controlled drugs must be investigated immediately by the pharmacist and hospice administrator and where required reported to the appropriate State agency. A written account of the investigation must be made available to State and Federal officials. (5) *Drug disposal.* Controlled drugs no longer needed by a patient must be disposed of in compliance with the hospice policy and in accordance with State and Federal requirements.	
(o) *Standard: Seclusion and restraint.* (1) The patient has the right to be free from seclusion and restraint, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. The term restraint includes either a physical restraint or a drug that is being used as a restraint. A physical restraint is any manual method or physical or mechanical device, material or equipment attached or adjacent to the patient's body that he or she cannot easily remove, that restricts free movement of, normal function of, or normal access to one's body. *A drug used, as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard treatment for a patient's	**Reference: §418.110(o)** **Issue:** The proposed standard adds are overly restrictive or inappropriate for Hospice. **Proposal:** Similar to comments raised above for investigations of alleged abuse, the final regulations should support the relationships between hospice and nursing home providers and clarify for both the assignment of accountability under their respective regulations for appropriate use of restraint and seclusion for shared patients. The regulation should also take into account the reality of hospice care in the home as it relates to restraint and seclusion. **Rationale:** This is a very restrictive definition and as applied in the hospital and nursing home context requires a comprehensive assessment of need, risk benefit analysis

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medical or psychiatric condition. Seclusion is the confinement of a person alone in a room or an area where a person is physically prevented from leaving.	and evidence of informed consent before any such device or practice meeting this definition is applied to a resident. Clarification of accountability is needed on the crossover enforcement implications for hospice if a deficient practice by the facility is identified or, alternatively, if hospice but not the nursing home decides a device is indicated for some reason. While the Hospice can provide education on patient safety issued related to bedrails and other devices, it is not possible to police the use of such devices in the home setting.
(2) Seclusion and restraint can only be used in emergency situations if needed to ensure the patient's or others' physical safety, and only if less restrictive interventions have been tried, determined and documented to be ineffective.	
(3) The use of restraint and seclusion must be—	**Reference: § 418.110(o)(3)**
(i) Selected only when less restrictive measures have been found ineffective to protect the patient or others from harm;	**Issue:** The degree of required of physician involvement is impracticable for the hospice setting. **Proposal:** The requirement of physician involvement should reflect the reality of the physician's role in hospice care. **Rationale:** Unlike Hospitals, Hospice providers and their patients do not have consistent presence of physicians at home or in the nursing home setting, making the timing of the physician oversight requirements overly burdensome and impractical in most instances.
(ii) Carried out in accordance with the order of a physician. The following will be superseded by more restrictive State laws: (a) Orders for seclusion or restraints must never be written as a standing order or an as needed basis (that is, PRN). (b) The hospice medical director or physician designee must be consulted as soon as possible if restraint or seclusion is not ordered by the hospice medical director or physician designee.	**Reference: § 418.110(o)(3)(ii)** **Issue:** A restraint or seclusion order may be given by a non-hospice physician. **Proposal:** Orders made by a nursing facility or a non-hospice physician for seclusion or restraint should be reviewed as soon as possible by the IDG. **Rationale:** The hospice should not be responsible for orders made by non-hospice personnel.
(c) A hospice medical director or physician designee must see the patient and evaluate the need for	**Reference: § 418.110(3)(ii)(c)** **Issue:** It is frequently infeasible for the hospice medical director or physician designee to see the patient and evaluate the

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restraint or seclusion within 1 hour after initiation of this intervention.	need for a restraint within 1 hour after initiation of the intervention. **Proposal:** The standard should allow flexibility for a nurse to handle "on the spot" needs with follow up by a physician. **Rationale:** The proposed alternative is more achievable in a real world clinical scenario. Hospices do not have physicians available to see a patient within one hour because the majority of hospices have contracted physicians who are part-time and have their own active practices.
(d) Each order for a physical restraint or seclusion must be in writing and limited to 4 hours for adults; 2 hours for children and adolescents ages 9 through 17; or 1 hour for patients under the age of 9. The original order may only be renewed in accordance with these limits for up to a total of 24 hours. After the original order expires, a physician must reassess the patient's need before issuing another seclusion and restraint order. (iii) In accordance with the interdisciplinary group and a written modification to the patient's plan of care; (iv) Implemented in the least restrictive manner possible not to interfere with the palliative care being provided; (v) In accordance with safe, appropriate restraining techniques; (vi) Ended at the earliest possible time; and (vii) Supported by medical necessity and the patient's response or outcome, and documented in the patient's clinical record. (4) A restraint and seclusion may not be used simultaneously unless the patient is— (i) Continually monitored face to face by an assigned staff member; or (ii) Continually monitored by staff using video and audio equipment. Staff must be in immediate response proximity to the patient.	**Reference: § 418.110(3)(ii)(d)** **Issue:** Time limitations for restraint and seclusion are too restrictive. **Proposal:** Delete this section. **Rationale:** This section should be deleted to allow for the flexibility and judgment of the clinician in collaboration with the hospice IDG who is actively involved in the care planning of the patient.

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(5) The condition of the patient who is in a restraint or in seclusion must continually be assessed, monitored, and reevaluated by an assigned staff member.	**Reference: § 418.110(5)** **Issue:** The meaning of "continual" monitoring is unclear. **Proposal:** The monitoring requirement should be clearly stated and consistent with state law. **Rationale:** "Continually" could be interpreted inappropriately and excessively as constantly.
(6) All staff who have direct patient contact must have ongoing education and training in the proper and safe use of seclusion and restraint application and techniques and alternative methods for handling behavior, symptoms, and situations that traditionally have been treated through the use of restraints or seclusion.	
(7) The hospice must report to the CMS regional office any death that occurs while the patient is restrained or in seclusion, within 24 hours after a patient has been removed from restraint or seclusion.	**Reference: § 418.110(7)** **Issue** A patient may die from the terminal illness within 24 hours of being removed from restraint or seclusion. **Proposed language:** Delete: "within 24 hours after a patient has been removed from restraint or seclusion." **Rationale:** The death should not be reported if there is no reason to believe that it is related to the use of restraint or seclusion.

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§ 418.112 Condition of participation: Hospices that provide hospice care to residents of a SNF/NF, ICF/MR, or other facilities. In addition to meeting the conditions of participation at § 418.10 through § 418.116, a hospice that provides hospice care to residents of a SNF/NF, ICF/MR, or other residential facility must abide by the following additional standards.	
(a) *Standard: Resident eligibility, election, and duration of benefits.* Medicare patients receiving hospice services and residing in a SNF, NF, or other facility must meet the Medicare hospice eligibility criteria as identified in § 418.20 through § 418.30.	
(b) *Standard: Professional management.* The hospice must assume full responsibility for professional management of the resident's hospice care, in accordance with the hospice conditions of participation and make any arrangements necessary for inpatient care in a participating Medicare/Medicaid facility according to §418.100.	
(c) *Standard: Core services.* A hospice must routinely provide all core services. These services include nursing services, medical social services, and counseling services. The hospice may contract for physician services as stated in § 418.64(a). A hospice may use contracted staff provided by another Medicare certified hospice to furnish core services, if necessary, to supplement hospice employees in order to meet the needs of patients under extraordinary or other non-routine circumstances, as described in § 418.64.	
(d) *Standard: Medical director.* The medical director and physician designee of the hospice must provide overall coordination of the medical care of the hospice resident that resides in an SNF, NF, or other facility. The medical director and physician designee must communicate with the medical director of the SNF/NF, the patient's attending physician, and other physicians participating in the provision of care for the terminal and related conditions to ensure quality care for the patient and family.	**Reference: § 418.112(d)** **Issue:** Medical directors often rely on other professional members of the IDG to communicate with the staff of the facilities. **Proposed Language:** The medical director, physician designee **or other health care professional member of the IDG** must communicate with the medical director of the SNF/NF, the patient's attending physician, and other physicians participating in the provision of care for the terminal and related conditions to ensure quality care for the patient and family. **Rationale:** Timely communication can be facilitated by allowing other qualified members of the IDG, in addition to the medical director and physician designee, to carry out this responsibility.
(e) *Standard: Written agreement.* The hospice and the facility must have a written agreement that specifies the provision of hospice services in the facility. The	

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agreement must be signed by authorized representatives of the hospice and the facility before the provision of hospice services. The written agreement must include at least the following: (1) The written consent of the patient or the patient's representative that hospice services are desired. (2) The services that the hospice will furnish and that the facility will furnish. (3) The manner in which the facility and the hospice are to communicate with each other to ensure that the needs of the patient are addressed and met 24 hours a day. (4) A provision that the facility immediately notifies the hospice if— (i) A significant change in the patient's physical, mental, social, or emotional status occurs; (ii) Clinical complications appear that suggest a need to alter the plan of care; (iii) A life threatening condition appears;	**Ref.: § 418.112(e)(4)(iii)** **Issue:** The patient has a life threatening illness when he or she enters the facility. **Proposed Language:** A life threatening condition **unrelated to the terminal illness** appears; **Rationale:** Because hospice patients, by definition, have one or more life threatening conditions, it is only reasonable to require the facility to notify hospice if a new or unrelated life threatening condition appears.
(iv) A need to transfer the patient from the facility and the hospice makes arrangements for, and remains responsible for, any necessary continuous care or inpatient care necessary related to the terminal illness; or (v) The patient dies. (5) A provision stating that the hospice assumes responsibility for determining the appropriate course of care, including the determination to change the level of services provided. (6) An agreement that it is the facility's primary responsibility to furnish room and board. (7) A delineation of the hospice's responsibilities, which include, but are not limited to, providing medical direction and management of the patient, nursing, counseling (including spiritual and dietary	

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counseling), social work, bereavement counseling for immediate family members, provision of medical supplies and durable medical equipment, and drugs necessary for the palliation of pain and symptoms associated with the terminal illness, as well as all other hospice services that are necessary for the care of the resident's terminal illness. (8) A provision that the hospice may use the facility's nursing personnel where permitted by law and as specified by the facility to assist in the administration of prescribed therapies included in the plan of care only to the extent that the hospice would routinely utilize the services of a hospice resident's family in implementing the plan of care.	
(f) *Standard: Hospice plan of care.* A written plan of care must be established and maintained for each facility patient and must be developed by and coordinated with the hospice interdisciplinary group in consultation with facility representatives and in collaboration with the attending physician. All care provided must be in accordance with this plan. The plan must reflect the hospice's policies and procedures in all aspects and be based on an assessment of the patient's needs and unique living situation in the facility. It must include the patient's current medical, physical, social, emotional, and spiritual needs. Directives for management of pain and other symptoms must be addressed and updated as necessary to reflect the patient's status. (1) The plan of care must identify the care and services that are needed and specifically identify which provider is responsible for performing the respective functions that have been agreed upon and included in the plan of care. (2) The plan of care reflects the participation of the hospice, the facility, and the patient and family to the extent possible. (3) In conjunction with representatives of the facility, the plan of care must be reviewed at intervals specified in the plan but no less often than every 14-calendar day. (4) Any changes in the plan of care must be discussed among all caregivers and must be approved by the hospice before implementation.	**Reference: § 418.112(f)(4)** **Issue:** It is unrealistic to require changes in the plan of care to be discussed among all caregivers before implementation. **Proposed Language:** Any changes in the plan of care must be coordinated by the hospice IDG, with the facility and communicated to caregivers, as appropriate, before implementation. **Rationale:**

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	Because of the great number of facility staff and variation in their work hours, it would be impossible to discuss a change in the plan of care with all of them before the change is implemented.
(g) *Standard: Coordination of services.* The hospice must designate a member of its interdisciplinary group to coordinate the implementation of the plan of care with the representatives of the facility. The hospice must provide the facility with the following information: (1) Plan of care. (2) Patient or patient's representative hospice consent form and advance directives. (3) Names and contact information for hospice personnel involved in hospice care of the patient. (4) Instructions on how to access the hospice's 24-hour on-call system. (5) Medication information specific to the patient (6) Physician orders.	
(h) *Standard: Transfer, revocation, or discharge from hospice care.* Requirements for discharge or revocation from hospice care, § 418.104(e), apply. Discharge from or revocation of hospice care does not directly impact the eligibility to continue to reside in an SNF, NF, ICF/ MR, or other facility.	
(i) *Standard: Orientation and training of staff.* Hospice staff must orient facility staff furnishing care to hospice patients in the hospice philosophy, including hospice policies and procedures regarding methods of comfort, pain control, symptom management, as well as principles about death and dying, individual responses to death, patient rights, appropriate forms, and record keeping requirements.	**Reference: § 418.112(i)** **Issue:** It is not always practical or necessary for hospice to train facility staff. **Proposal:** Hospice should train facility staff when requested to do so by the facility. It should make educational and training resources, including hospice contacts, available to facility staff. **Rationale:** Although hospice may act as a resource, the facility should be responsible for ensuring that its staff receives training. Making hospice responsible for training facility staff would create potential liability for hospice that should remain with the employer. In addition, training may be duplicative or inconsistent if more than one hospice operates in a facility.

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§ 418.114 Condition of participation: Personnel qualifications for licensed professionals. (a) *General qualification requirements.* Except as specified in paragraph (c) of this section, all professionals who furnish services directly, under an individual contract, or under arrangements with a hospice, must be legally authorized (licensed, certified or registered) to practice by the State in which he or she performs such functions or actions, and must act only within the scope of his or her State license, or State certification, or registration. All personnel qualifications must be kept current at all times.	
(b) Personnel qualifications for physicians, speech-language pathologists, and home health aides. The following qualifications must be met: (1) *Physicians.* Physicians must meet the qualifications and conditions as defined in section 1861(r) of the Act and implemented at § 410.20 of this chapter. (2) *Speech language pathologists.* Speech language pathologists must meet the qualifications specified in section 1861(ll)(1) of the Act. The individual must have a master's or doctoral degree in speech-language pathology and must— (i) Be licensed as a speech-language pathologist by the State in which the individual furnishes such services, or, (ii) In the case of an individual who furnishes services in a State which does not license speech-language pathologists, must: (a) Have successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating such supervised clinical experience), (b) Have performed not less than 9 months of supervised full-time speech language pathology services after obtaining a master's or doctoral degree in speech-language pathology or a related field, and successfully completed the Praxis National Examination in Speech-Language	

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Pathology. (3) *Home health aides.* Home health aides must meet the qualifications required by section 1891(a)(3) of the Act and implemented at § 484.75.	
(c) *Personnel qualifications when no State licensing, certification or registration requirements exist.* If no State licensing laws, certification or registration requirements exist for the profession, the following requirements must be met: (1) *Occupational therapist.* An occupational therapist must— (i) Be a graduate of an occupational therapy curriculum accredited by the American Occupational Therapy Association, and be eligible for the National Registration Examination of the American Occupational Therapy Association; or (ii) Have 2 years of appropriate experience as an occupational therapist, and have achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapist after December 31, 1977. (2) *Occupational therapy assistant.* An occupational therapy assistant must— (i) Meet the requirements for certification as an occupational therapy assistant established by the American Occupational Therapy Association; or (ii) Have 2 years of appropriate experience as an occupational therapy assistant, and have achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapy assistant after December 31, 1977. (3) *Physical therapist.* A person who— (i) Has graduated from a physical	

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therapy curriculum approved by— (a) The American Physical Therapy Association; (b) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association; or (ii) Prior to January 1, 1966— (a) Was admitted to membership by the American Physical Therapy Association; (b) Was admitted to registration by the American Registry of Physical Therapists; or (c) Has graduated from a physical therapy curriculum in a 4-year college or university approved by a State department of education; or (iii) Has 2 years of appropriate experience as a physical therapist, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking qualification as a physical therapist after December 31, 1977; or (iv) Was licensed or registered prior to January 1, 1966, and prior to January 1, 1970, had 15 years of full-time experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy; or (v) If trained outside the United States— (a) Has graduated, since 1928, from a physical therapy curriculum approved in the country in which the	

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curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy; (b) Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy. (4) *Physical therapist assistant.* A person who— (i) Has graduated from a 2-year college-level program approved by the American Physical Therapy Association; or (ii) Has 2 years of appropriate experience as a physical therapy assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that these determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as a physical therapy assistant after December 31, 1977. (5) *Registered nurse.* A graduate of a school of professional nursing. (6) *Licensed practical nurse.* A person who has completed a practical nursing program. (7) *Social worker.* A person who has a baccalaureate degree from a school of social work accredited by the Council on Social Work Education.	
(d) *Standard: Criminal background checks.* The hospice must obtain a criminal background check on each hospice employee and contracted employee before employment at the hospice.	

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§ 418.116 Condition of participation: Compliance with Federal, State, and local laws and regulations related to health and safety of patients. The hospice and its staff must operate and furnish services in compliance with all applicable Federal, State, and local laws and regulations related to the health and safety of patients. If State or local law provides for licensing of hospices, the hospice must be licensed.	
(a) *Standard: Licensure of staff.* Any persons who provide hospice services must be licensed, certified, or registered in accordance with applicable Federal, State and local laws.	
(b) *Standard: Multiple locations.* Every hospice must comply with the requirements of § 420.206 of this chapter regarding disclosure of ownership and control information. All hospice satellite locations must be approved by CMS and licensed in accordance with State licensure laws, if applicable, before providing Medicare reimbursed services.	
(c) *Standard: Laboratory services.* (1) If the hospice engages in laboratory testing other than assisting a patient in self-administering a test with an appliance that has been approved for that purpose by the FDA, the hospice must be in compliance with all applicable requirements of part 493 of this chapter. (2) If the hospice chooses to refer specimens for laboratory testing to a reference laboratory, the reference laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the applicable requirements of part 493 of this chapter.	

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§ 418.200 [Amended] 6. Section 418.200 is amended by revising the reference "§ 418.58" to read "§418.56".	

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§ 418.202 [Amended] 7. In § 418.202, paragraph (e) is amended by revising the reference ''§ 418.98(b)'' to read ''§ 418.108(b)'' and paragraph (g) is amended by revising the reference ''§ 418.94'' to read ''§ 418.76''.	

WDC 372069v1

Submitter : Joyce Alexa **Date:** 07/26/2005

Organization : VNA Hospice Homecare of Porter Co., IN

Category : Hospice

Issue Areas/Comments

Issues 1 - 10

Personnel Qualifications

418.76 Supervision of Home Health Aides: I disagree with the changes to 418.94 and believe that you should continue with the current rule that refers to Sec. 484.36 especially as it relates to the supervision of the home health aide. This rule should not be changed unless you have strong rationale for the change. For hospices that are part of a certified home health agency, the changes recommended will cause a great deal of confusion and additional staff resources will need to be added to track and schedule the separate supervision requirements between home health and hospice. I have not heard of any hospice problems or concerns that have been related to the current rule for supervision of Home Health Aides, therefore it seems that adding additional expense and complexity is not warranted. Thank you.

Inpatient Care

418.110 Hospices that provide Inpatient Care Directly: I disagree with the deletion of the requirement that "each shift must include a registered nurse who provides direct patient care." A patient that qualifies for General Inpatient Care needs the skills of a registered nurse onsite to consult with the physician/IDT to change the plan of care during each shift to assure that pain and symptoms are managed. While a LPN/LVN may be able to assist in RN in porviding care, they world not have the skills to work independently without RN onsite supervision. Many states have limitations on the role of the LPN especially as it relates to assessing patients and obtaining physician orders. Another area of limitation for the LPN is in the initiation of IV infusions. The acuity of the patient who would qualify for the General Inpatient Level of Care would require the hospice to assign an RN to be onsite to both deliver and supervise the patient's care. If you remove this requirement, you will create situations where some hospices will provide the RN care/onsite supervision in order to meet Nurse Practice Act requirements, and others will possibly provide this care with the use of LPN/LVN's only. This will create potential conflict between state and federal laws and conflict, unfair competition and confusion between hospices who view their responsibility and liability differently. Please do not delete the requirement for an RN to be onsite on each shift who provide direct patient care for patients at the General Inpatient Level of Care. Thank you.

Short Term Inpatient Care

418.108 1). Short term inpatient care at the General Inpatient Level of Care should be available for psychosocial/family crises. 2). I disagree with the change that removes the requirement for a Registered Nurse to be on each shift to provide direct patient care for SNF hospice patients who require General Inpatient Level of Care for the same reasons that were sited in my comments for 418.110 above. 3). I agree that a LPN/LVN would be appropriate for the patient in the SNF who is there for Inpatient Respite. In these cases, it is appropriate for the LPN to work without an RN onsite because in these cases, the care plan is not under continual revision, rather the care is routine in nature. Thank you.

Submitter : Mr. David Giese **Date:** 07/26/2005

Organization : Minnesota Department of Health

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3844-P-144-Attach-1.DOC

MINNESOTA
MDH
DEPARTMENT OF HEALTH

Protecting, Maintaining and Improving the Health of Minnesotans

July 26, 2005

Attachment #144

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

Re: Proposed Hospice Rules, 42 CFR Part 418, File Code CMS-3844-P

To CMS Administrator:

Thank you for the opportunity to comment on the new proposed hospice rule. In our opinion the rules appear to focus on a patient-centered outcome-oriented process to improve the quality of care and provide adequate safe guards for consumers receiving hospice services. We offer a few comments for your consideration.

418.3 Definitions:

Drug Restraint
We recommend additional guidance on the use of unnecessary drugs at end of life. Medications used in hospice need to be assessed in order to determine if they are considered a chemical restraint, using the same standards set forth for nursing homes, as stated in Appendix PP, CFR 483.13 (a) F222, Chemical Restraints. Additionally, we recommend adding a statement such as *"if using for purposes that are not standard of treatment, must give indications for use and explain in medical record".*

We recommend using the same drug language as contained in Appendix PP, for SNF/NF providers under 483.25(1) F329, Unnecessary Drugs, which states the following:

An unnecessary drug is any drug when used:
(i) In excessive dose (including duplicate therapy); or
(ii) For excessive duration; or
(iii) Without adequate monitoring; or
(iv) Without adequate indications for its use; or
(v) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or
(vi) Any combinations of the reasons above.

Rationale: We recommend this language in order to be consistent with current standards of practice and for the quality of life for terminally ill patients.

Palliative Care
We recommend expanding the definition of palliative care to clarify it further. Does this mean that hospice providers may only provide palliative care to those patients who have elected the hospice benefit? How does the state survey those patients who receive palliative care, but have not been declared terminal by a physician or elected the hospice benefit? Can those patient records be included in the sample for review?

Subpart C
418.52 PATIENT RIGHTS

(a) (4) (b) *Standard: Exercise of rights and respect for property and person.*
Although it's implied under 418.56 (c) (6) content of plan of care, we recommend expanding the language in this section to include that the patient has the right to participate in the development of the plan of care, as they are able.

We also recommend that you include language stating that the patient has the right to refuse treatment and refuse to participate in experimental research.

(b) (4) (i)
We recommend that you define "immediately", as it relates to notifying the administrator of alleged violations. If an alleged violation occurred during the night hours, would it be the expectation that staff call the administrator during the night or would within 24 hours be acceptable? We recommend that the time frame for notification be based on patient's individualized assessment and identified needs.

Rationale: The word "immediately" is vague and non-specific. This same language is in the nursing home and ICF/MR regulations with different interpretations. The nursing home regulations allows for a 24-hour notification. The ICF/MR regulations require notification to occur at the time of the incident.

(4) (e) *Standard: Patient liability.*
We recommend that you delete the word *"in writing"* in the requirement that states "Before care is initiated, the patient must be informed verbally and in writing in, and in a language that he or she can understand, of the extent to which payment may be expected from the patient, Medicare or Medicaid, third party payers, or other resources of funding known to the hospice".

Rationale: We believe that requiring that the patient must be informed of payment terms "in writing" and in a language that he or she can understand, will present a hardship for some hospices, especially those in rural areas.

418.54 Comprehensive assessment of the patient.
ASSESSMENT TIME FRAMES.

(c) *Standard: Content of the comprehensive assessment.*

We recommend adding language to make it clear that the comprehensive assessment is individualized to the patient and subsequent goals are patient centered. The care provided is also based on patient needs and not what services the provider can provide.

418.56 Interdisciplinary group care planning and coordination of services.

(a) *(i) Standard: Approach to service delivery.*
We recommend that you delete the following: ... "(who is not the patients attending physician)".

Rationale: Including that language would present a hardship for some hospices, especially in rural areas. In rural areas, the hospice medical director may be the attending physician.

(c) (6) *Standard: Content of the plan of care.*
We recommend clarifying that "agreement of the plan of care" may not always be possible.

Rationale: A patient may agree with the plan of care, but not necessarily all the family members will agree.

418.76 Home health aide and homemaker services.

(d) Standard: In-service training.
We recommend including the same requirement for an annual performance evaluation that is included in the Home Health regulations under 484.36(b)(2)(ii) G214.

Rationale: Requiring an annual performance evaluation would help to assure that the home health aides remain competent.

(g) (2) (i) *Standard: Home health aide assignments and duties.*
We recommend that you state that the home health aide services are ordered by the interdisciplinary group or team, not the physician or nurse practitioner. The physician and/or nurse practitioner are members of the IDG.

(h) (1) *Standard: Supervision of home health aides.*
We recommend that you clarify if the supervisory visits by a qualified therapist is to be provided when the home health aide is providing only delegated therapy services (e.g. PT services supervised by a PT). Please refer to language in Home Health regulations 484.36(d)(l),G228.

(h) (2) We recommend that you add the word "qualified" to the following sentence "The supervising nurse or *"qualified"* therapist must assess an aide's ability to . . .".

Rationale: The supervising therapist needs to be qualified.

418.104 Clinical records.

(e) (2) *Standard: Discharge or transfer of care.*
We recommend that you clarify what portion of the clinical record, in addition to the discharge summary, is required in the proposed rules.

Rationale: The proposed rules indicate that the entire record needs to be copied. This would be a burden for the hospice provider.

418.106 Drugs, controlled drugs and biologicals, medical supplies, and durable medical equipment.

(b) Standard: *Controlled drugs in the patient's home.*
We question whether the hospice can demand the destruction of controlled drugs of patients that are being served in their private homes, because the medications are considered personal property.

418.110 Hospices that provide inpatient care directly.

(b) Standard: 24 hours nursing services.
We recommend defining "respite care" and "inpatient care" based on acuity of the care needed by the patients, with "respite care" being at a lower level of care. The respite care would not require 24-hour nursing services and the inpatient care would require the 24-hour nursing services. We feel strongly that patients needing acute care require higher nursing services 24-hours a day.

(n) *(2) Administration of medications.*

We recommend including the language that is in the current regulations.

Rationale: The proposed administration of medications language does not include the administration of medications by a family member. We recommend that you include the language that is in the current regulations.

418.114 Personnel qualifications for licensed professionals.
We recommend placing this section in the beginning of the rule, after definitions.

Rationale: We believe that by placing this section in the beginning of the rule, it would make the rule more user-friendly.

(c) (5) This requirement should include the language under the definitions 484.3 (2) Licensed Professional.

Rationale: This would maintain consistency throughout the regulations and clearly define that an RN is more than a graduate nurse.

(d) *Standard: Criminal background checks.*
Please clarify if the provider must receive the completed background study prior to allowing employees to provide direct care.

Rationale: Minnesota recently changed their law regarding this issue, because they were finding that people were working without being prior approved and later found to be disqualified based on the completed criminal background study. Minnesota also had a provision that if they were under direct supervision, they could work. Direct supervision would need to be defined.

418.116 Compliance with Federal, State, and local laws and regulations related to health and safety of patients.

(b) *Standard: Multiple locations.*
We question whether providers will have to submit requests for approval of satellites upon the adoption of the new CoPs. A provider may not be surveyed for a few years after adoption of the new CoPs.

If you have any questions regardding our comments, please contact Kay Herzfeld of my staff. Ms. Herzfeld may be reached at (651) 215-8726 or kay.herzfeld@health.state.rnn.us.

Thank you for your thorough efforts in developing these rules. We look forward to their adoption.

Sincerely,

David J. Giese, Director
Division of Compliance Monitoring

Submitter : Ms. J Lenz **Date:** 07/26/2005

Organization : Crawford County Home Health, Hospice

Category : Hospice

Issue Areas/Comments

Issues 1 - 10

Social Work

The Conditions of Participation should allow for state licensure as a qualifier for a bachelor level position in a medicare certified hospice. At present, BSW's are not required to hold a license and are really not held accountable for things that they do. The license provides credence, ethics training, and accountability for social workers who work with vulnerable populations including hospice patients. In order for a license to have value, it must go beyond the mere attainment of a CSWE approved degree. Many BSW's have not completed any continuing education or ethics training, and are held to a much lesser standard then people who hold the LBSW license. In reality, the wording of the law makes it sound like the approved degree is so much more valuable. Currently in Iowa, there are many LBSW's who are very qualified to provide hospice care and may hold a degree which is not approved by the CSWE. The LBSW license in the state of Iowa should in fact be a leveler for people doing social work in this state. To disregard the state license and all that goes with it is truly a devaluation of those of us who hold the license. There are huge inconsistencies in the licensure of social workers and if BSW's want credence for the mere attainment of their degree, then the LBSW license should be mandated.

Submitter : Mr. David Schulke **Date: 07/26/2005**

Organization : American Health Quality Association

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3844-P-146-Attach-1.DOC

Attachment #146
July 26, 2005

THE AMERICAN HEALTH QUALITY ASSOCIATION

Mark McClellan, MD
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

File Code: CMS-3844-P

Dear Dr. McClellan:

The American Health Quality Association (AHQA), representing the national network of Medicare Quality Improvement Organizations (QIOs), is pleased to provide comments on the proposed rule for "Hospice Conditions of Participation (COPs)" published in the *Federal Register* of May 27, 2005.

"QAPI"

QIOs have assisted providers under recent CMS initiatives to report quality data and improve health care in nursing homes, home health agencies and hospitals. During that time, local and national partnerships in quality improvement have flourished, and early results show that key indicators of care are improving. Further, providers that work most closely with their QIOs are improving care delivery faster.

Unlike other Medicare providers, hospice organizations do not have formalized access to technical assistance through the QIO contracts with Medicare. CMS performance data and customer satisfaction surveys conclusively show that Medicare providers are benefiting greatly from QIO services, yet hospice currently is denied the opportunity to work with QIOs. After reviewing the proposed COPs and consulting with national representatives of hospice organizations, we are confident that hospice providers could capitalize on QIO expertise and services to support their efforts "to develop, implement, and maintain an effective data driven quality assessment and performance improvement program (QAPI)." We believe that partnering with QIOs would help hospice organizations comply with the revised COPs and enhance their internal quality improvement efforts.

Recommendation #1: CMS should include language in its final rule explicitly recognizing the value of hospice organizations working with QIOs and directing the QIOs to support hospice organizations that volunteer to work with them in order to comply with the revised COPs under §418.58.

Recommendation #2: The implementation date of such a QIO assignment should be made contingent upon the availability of QIO funding commensurate with the level of activity associated with providing quality improvement assistance and support to hospice organizations.

QIOs have limited experience providing targeted technical assistance to hospice providers on specific clinical issues in end-of-life care. However, after discussing the proposed COP requirements with QIOs and hospice representatives, we believe that QIO expertise in the field of quality measurement and systems improvement would be greatly valued by hospice care providers as they strive to better measure and improve quality.

Specifically, QIOs have the capacity to instruct and assist hospice organizations' efforts to collect and analyze data and systematically develop interventions where areas for improvement are identified. This assistance could include using root cause analysis to address adverse events.

QIOs also have vast experience helping providers in other care settings collect, monitor, and utilize performance data to set priorities for improvement and achieve performance goals. In recent years, the organizations also have enhanced their ability to engage senior administrative and clinical leadership in making performance measurement and improvement a core goal in their health care organizations.

Finally, provision of quality improvement services in other provider settings (hospital, home care, nursing homes and physician offices) would allow QIOs to facilitate bridges to enhance critical issues of care coordination among people receiving end-of-life care. We are confident QIOs could provide valuable aid to hospice organizations developing programs to "show measurable improvement in indicators that are linked to improving palliative outcomes and end-of-life support services."

Recommendation 3: CMS should conduct a special study in the QIO 8th Statement of Work, to perform a pilot project that involves a QIO/hospice organization partnership to increase awareness and use of quality improvement principles and strategies as a mechanism to assess and improve their care delivery systems, thereby improving end-of-life care.

"Outcome-Based Performance Measures"

QIOs have significant experience helping hospitals with the collection and submission of quality data to a central warehouse. This experience would be useful for hospice organizations that seek to collect and submit quality data to NHPCO to satisfy recommendations of the COP. We agree that collecting and submitting quality data is an essential element of quality improvement; however, experience tells us that this activity can be complex and burdensome.

Currently, less than half of hospice organizations are submitting data to the National Hospice and Palliative Care Organization. We believe QIO assistance should be available to increase the number of hospice organizations submitting data by minimizing difficulties associated with data collection and submission, as well as beginning to apply this data for quality improvement purposes.

Recommendation 4: CMS should provide funding for and explicitly include language directing QIOs to assist hospice organizations with data collection and submission activities associated with §418.54(e). The implementation date of this new responsibility should be made contingent upon the availability of funding for this work.

AHQA appreciates the opportunity to comment on this important matter. Please contact myself or Dave Adler (dadler@ahqa.org; 202-261-7572) with any questions regarding these comments.

Sincerely,

David G. Schulke

Executive Vice President

Submitter : **Ms. Janis Bivins** **Date: 07/27/2005**

Organization : **IntegriCare, Inc.**

Category : **Hospice**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-3844-P-147-Attach-1.DOC

CMS-3844-P-147-Attach-2.DOC

HOSPICE PROPOSED CoP COMMENTS General-
Please take this opportunity to make the words of the Conditions directive and descriptive and not so subject to interpretation by external entities. At the same time use caution that they are not too prescriptive. If an agency is making a great attempt to read, interpret and follow the regulations they should not be subject to federal contractors making different interpretations (perhaps based on their personal bias) and penalizing the agency when good patient outcomes are obtained and appropriate processes are followed.

You also have to recognize the number of hospices that are small to medium/intermediate size that utilize a Medical Director with responsibilities other than the Hospice (i.e. private practice). The ultra large organizations cannot be used to dictate hospice care parameters for all- and are not the indicator of any better care or outcomes than smaller organizations.

RIGHTS
Good statement of the rights that have been in use for years.

ASSESSMENT- TIME FRAMES
418.54(d) Time Frame- comprehensive assessment updated no less than every 14 days. The term 'updated' needs to be more specific, as it could be interpreted as having current assessment entries or re-completion of a comprehensive assessment instrument/tool. When the Hospice is assessing the different parameters of the patient/caregiver/family's needs on a concurrent basis- they should not be penalized by an interpretation for completion of something that can add nothing to the patient/family care or meeting their needs.

OUTCOMES MEASURES
It is important that you protect the agency's right to determine and compare their outcomes against prioritized internal measures- agency specific and or peer agency performance within a group or extended company.

PLANS OF CARE COORDINATION OF SERVICES
418.54(4)
This addition is excellent to add the perceived but never included evaluation and coordination of patient care at no less than every 14 days.

The 'attending collaboration'- needs to be worded clearly enough to allow for the different levels of participate of the attending without penalty to the hospice organization. It would be counter productive to leave the interpretation to an external entity that could penalize the agency inappropriately when every effort has been made to include the attending to the extent they desire.

QAPI
It is good that the agency is allowed to define their own measures.

The direction to track adverse events is too loosely worded to adequately direct appropriate responses. In Hospice there are no current adverse events defined. If you mean occurrences at variance with the outcome goals- then state it clearly.

Define past history- how far past, to what extent should this affect the direction of the care and processes being followed currently by the organization. WE learn form the past, but we also put it behind us!

INFECTION
Acknowledge the limitations of the agency in determining the outcomes for patients that are immuno-suppressed, terminal, with extensive co morbidities- even when every effort is made to instruct, provide, and support appropriate care protecting the patient from avoidable infections. Some are not- it is often known that infection will most likely be the instrument of their demise.

CONTRACT SERVICES
The directions should allow for a greater (but not exclusive) use of contracted hours for supporting continuous care needs of the patient. This meets some of the same parameters mentioned for the specialized care. It is unpredictable, cannot be anticipated, or if so would be cost prohibitive to keep the agency staffed to the level required for the occasional needs for the small/medium sized agency.

AIDES 418.76(h)
The concept of requiring every other supervisor visit to be made with the Aide in attendance is unrealistic and cost prohibitive, and a scheduling nightmare, without a correlating benefit to the patient.

The written approval of clergy providing care as a volunteer is excellent.

ORGANIZATION/SERVICES
I fully support acknowledging and defining the satellite requirements.

The responsibility of the Medical Director assessment of patient every 14 days- is not realistic for the small and intermediate size hospices. It is the other professionals who keep the assessments current, and then in discussion with the physician the strategy is developed for the Plan of Care. This is realistic and must not be interrupted..

Directing the Discharge Summary documentation is consistent with common practices.

The requirement for the Medical Director to be responsible for the quality assurance/performance improvement of the agency is not realistic for the small/medium hospice without a fulltime Medical Director. It should remain the responsibility of the IDG with the Medical Director being a part of that organization. This remains consistent with the other responsibilities placed on the IDG- professional management of care etc.

The requirement that a copy of the patient chart be sent to the facility to which the patient is transferred must be more specifically defined- to adequately direct the intent- that the receiving facility be equipped to provide appropriate care at the time of admission. The definition might address a summary of the care provided the patient and their response to date, and the current POC.

MEDS, DME

The prescriptive statement that the agency nurses must cover the controlled med management , and disposal and document it in the patient chart- is too prescriptive. For the families with intent to divert, it will have no impact which is the intent I am assuming.

SHORTTERM INPATIENT CARE

Bravo, for making the requirement of 24 hour direct RN care be more related to the appropriative response to the patient needs.

RESIDENTS RESIDING IN A FACILITY

Good definition of the requirements previously addressed in the Survey and Certification letter.

SOCIAL SERVICES

I think we should readdress the use of the BSW practicing without the supervision/direction of the MSW- when the responsibilities are much more comprehensive than in Home health where the MSW supervision is required.