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# The new hospice Conditions of Participation: Changes in compliance focus

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The Medicare Hospice Conditions of Participation (CoPs), 42 C.F.R. Section 418, Subpart C, were revised and published in final by the Centers for Medicare and Medicaid Services (CMS) on June 5, 2008 [73 Federal Register 32088]. The effective date of the regulation changes is December 2, 2008, with the exception that providers must institute certain quality performance provisions by February 9, 2009. The proposed CoP rule changes, published a full three years previously, were notably a new direction for the hospice industry, and hundreds of comments were filed with CMS.

Many of the proposed provisions objected to by providers and commentators, have been removed or softened in the final rule. However, the general direction toward:

(1) increased quality outcomes measurable through a quality assurance and performance improvement matrix (QAPI); (2) increased credentialing and training for hospice care providers; and (3) the increased focus upon hospice services provided to nursing home residents, remain at the core of the new requirements. Additionally, strong emphasis is placed upon communications with patients at the start and throughout the care period, and heightened communication among the physicians who are involved in

hospice care, whether as the medical director of hospice, medical director of a skilled nursing facility (SNF), or the attending physician of the patient.

This article will emphasize certain particularly important CoP changes for compliance planning purposes, and is not an in-depth teaching tool on all of the CoP revisions, such as this author includes in a multi-hour training session.

Hospices must now use the new CoPs to fine-tune their overall compliance programming,<sup>1</sup> and nursing facilities should anticipate hospices will ask for new contract terms and understandings about the reciprocal requirements to care for their mutual patients. CMS policy personnel noted when the hospice CoPs were finalized that the SNF CoPs will also need to be amended to reflect these balanced responsibilities, according to Mary Rossi-Coajou of the United States Public Health Service.<sup>2</sup>

## Significant CoP changes

The National Hospice and Palliative Care Organization (NHPCO) hosted a two-day intensive conference<sup>3</sup> for state leaders, the organization's board and regulatory committee, and invited guests in Baltimore on June 4 and 5, 2008. The two-day event was carried out to NHPCO members throughout the country via live-streaming Internet broadcast; more than 650 programs audited the proceedings via the Web from their offices.

## Definitions

Although technically outside of the CoP section of the hospice regulation, the Definitions section at 42 CFR Section 418-3 necessarily affects all of its terms. CMS added new definitions of:

- bereavement counseling (which has always been viewed as a core service);
- clinical note;
- comprehensive assessment and initial assessment;
- dietary counseling (which is clarified as core service);
- employee (to include those detailed from one part of a complex organization to another);
- licensed professional;
- multiple location;
- palliative care;
- physician and physician designee;
- patient representative;
- restraint;
- seclusion; and
- terminally ill.

For compliance purposes, the inclusion of many of these specific definitions means that the policies and procedures of the hospice must be reviewed and revised to include the terms and their implications. Several definitions are incorporated from long-standing Medicare Benefit Policy Manual provisions, although some hospices were not aware of their impact. The multiple location definition is one of these, and is further discussed under the standard 418.100(f). A multiple-site location must offer all the services of the principal location, must be in compliance with all CoPs, and must be pre-approved by the Medicare program (not merely State licensure) before services are rendered to Medicare patients and billed to the program. Not all hospices today are functioning with approved multi-site locations, and they must

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definitely move promptly to address this problem.

Physician designee is defined as “a doctor of medicine or osteopathy designated by the hospice who assumes the same responsibilities as the medical director when the medical director is not available.” This definition, and the extensive discussion in the Preamble to the Final Rule about the Medical Director Section 418.102, as well as the comments by the CMS regulators at the June 4-5, 2008 NHPCO training session, underscore that CMS does not anticipate that hospices will have fragmented roles for a medical director played by multiple “medical directors,” but rather a single central physician authority taking responsibility for the whole of the hospice medical care. The Medical Director section at 418.102 also makes clear that if contracted for, medical director services contracts with a physician group must nonetheless be for a particular, named physician, not a rotating cast from the physician practice group.

The definitions of restraint and seclusion of a patient, and their further development in the CoPs at sections 418.110(m),(n) and (o) concerning care in a hospice-owned inpatient facility, are new areas of concern identified by CMS. There are also provisions within the new Patient’s Rights section 418.52(b)(4) and (c)(6) about preventing violations involving mistreatment, neglect, and physical abuse, and the investigation and amelioration the hospice must take if such violations are suspected. Many hospices have never considered the issue of physical and chemical restraints of a terminally ill person within the context of abuse. This entire area must become a focus for hospice training, monitoring, and engagement, whether or not the hospice runs its own facility.

### Patient’s Rights

The Patient’s Rights section 418.52 of the

regulation is entirely new and can be considered a new “definition” of the relationship and role of the patient and hospice to each other. The clear message is that a hospice patient is not to be treated as out of the communication loop, or as merely an ancillary to the care planning. The central role of the patient in his/her own care and own end-of-life quality illustrate what the CMS staff have called the patient-centered changed focus of Medicare entitlement. Because the CoPs apply to all patients regardless of payer source or charity care, however, all patients’ rights are expanded in this section. During the CMS training, the CMS staff also emphasized that such details as the patients’ signatures on the rights document, the right to choose their own attending physician (which will be a change for some nursing facility resident patients), and the right to get pain managed well are fundamental, as are the scope and limitations of what the patient can expect to receive, tailored to his own individual coverage, if it is different from Medicare.

A current debate within the hospice industry is whether the admission of a patient can be done by a non-nurse, followed by the clinical work-up of a licensed registered nurse (RN). While the CMS staff did not answer questions about the “election” regulation (because it appears outside of the CoPs Subpart C), it is hard to see a non-clinician in the role of explaining patients’ rights which are so intrinsically intertwined with notions of quality of care and care planning.

### Timing and content of patient assessment

One of the two core features of the QAPI approach now mandated for hospices is the timing and content of the patient assessment. The new CoPs require that there be an initial assessment within 48 hours of the patient’s election of the hospice benefit. (The author assumes that this would be 48 hours from the

effective date of that election, but CMS staff said they had to “take back” this question to CMS benefits policy staff.)

Within five days, hospice RNs must perform and coordinate the components of a comprehensive assessment of the patient’s needs and goals in hospice care. The comprehensive assessment must be updated every 15 days, or more frequently if medically necessary, although the subsequent comprehensive assessments can be amalgamations of the intervening clinical notes, observations, interdisciplinary group (IDG) meetings, and so forth.

The purpose of the initial assessment, according to the CMS staff, was to make clear that a hospice had to “have hands on a patient prior to beginning care.” This suggests that the practice of some hospices to have standing orders for care commencement may be revisited or revamped. As for the timing of the five calendar days for the comprehensive assessment, CMS reported they had tried it in two demonstration sites and felt it could be done, although a “challenge” to some. Historically, many hospices have waited for a scheduled IDG meeting to occur to do the comprehensive assessment. When such meetings are weekly or every two weeks, the new CoP requirements will need to be met through other communications among concerned clinicians. CMS staff stated at the June 5th training that “checking boxes is not necessarily OK” and that the assessment and plan of care are the “two most important things you will do as a hospice.” CMS staff also offered that the comprehensive assessment is one of the areas that needs to be addressed and that an initial assessment can flow into a comprehensive one in the same visit, if input is received from the hospice clinical areas that need to be addressed. If there is not full agreement by staff about

how issues are to be addressed, the RN is to “document level of lack of agreement and some recommendation as to how to resolve this over time,” said Rossi-Coaju.

From a compliance standpoint, there will need to be direct links between the assessment and the sections of the care plan. CMS staff said that surveyors will look for this and that “flat standard care plans don’t work.” An additional compliance question will be the effect of a failure to have a comprehensive assessment within the five-day period.

Hospices will need compliance tools to track for this marker, notices to the billing office of the dates of the assessment, and procedures to handle the possible effect of timing failure by making the first billable Medicare day the date of the comprehensive assessment itself. (This is comparable to the Medicare regulatory requirements for certification of terminality within two days of admission. If that standard is missed, all days prior to the actual late certification are arguably non-billable because they are not covered.)

Serious staffing issues may occur around the CMS requirement that only an RN can coordinate the comprehensive assessment, do the initial assessment, and “advocate” for the patient through the IDG process. The CMS staff on June 5th said it had to be a single (i.e., specific) RN per patient, which could wreck havoc on hospices with tight RN staffing. However, the language of the CoP regulation itself does not say a specific RN per patient is required, and CMS would be unlikely to prevail in that interpretation unless the regulation was changed.

### **The QAPI program**

The hospice industry has been deeply engaged in working towards recommended quality assurance standards and procedures; NHPCO has worked collaboratively with CMS on the

underlying concepts of this activity. The result in the CoPs is a condition which takes less than two thirds of a Federal Register page to lay out, but has pages of commentary and a growing legion of consultants aimed at supporting this effort. In summary, hospices are now required to create their own individual on-going, company-wide quality assurance and improvement program that is data-driven and touches all parts, all staff, all contracted persons, and all levels of hospice care. It will be individually crafted but must be capable of demonstrating to CMS’s satisfaction that the hospice knows how to identify, prioritize, staff, and resolve issues affecting patient care. The focus must be on “high risk, high volume, or problem-prone areas” by considering the frequency, prevalence and severity of problems in multiple aspects of the hospice’s functioning. Routine tracking of adverse events is required, with reporting to external authorities where appropriate. A well-organized performance improvement project process must be established to address the problems that the Quality Assurance system identifies. Documentation, in depth and with sophistication, is required of the QAPI program. Finally, the governing body rather than senior management is made “responsible” for seeing that there is an annual evaluation of the quality improvement and patient safety aspects of the program, that all improvement actions are evaluated for effectiveness, and that there are point people to run this internally in the hospice.<sup>4</sup>

Many compliance experts may question how realistic and how appropriate it is to keep the governing body this closely involved in the operational side of a QAPI, and comments were filed to this effect. However, the hospice industry was only successful in getting the medical director out of the central position of responsibility, which is a very good thing in light of how ill suited and trained hospice

physicians are for this role. It is reflective of the physician-centric thinking of CMS in so many of its regulatory actions, to say nothing of how little it seems the hospice industry’s day-to-day work was understood.

It is gratifying to learn that CMS appreciates that performance improvement projects anticipate that some approaches may not work, and that the documentation will necessarily reflect this. Of course, it is imperative that CMS make this clear in its training of state and federal surveyors, and in the Interpretive Guidelines which will have such importance in the first years of this new regulation’s enforcement. CMS staff on June 5th made a point of saying “Participating in a national project does not absolve you” if the project is not focusing on the issues the individual hospice actually faces. That is a rather discouraging (albeit off-hand) comment, when hospice as an industry could benefit from knowing how all sorts of hospices fare under a common set of standards or procedures with a sophisticated analysis system that creates large data pools.

### **Contracting for core services**

To the extent it can do so under the currently statutory language, CMS has attempted to relax prior strict interpretations of the ability of hospices to contract for nursing and counseling services from outside the hospice. (The ability to have physician independent contractors was established by statute and regulation some years ago.) Generally, hospices must employ those who provide core services of nursing, counseling and medical social services as W-2 employees, but there are certain exceptions.<sup>5</sup> The new CoPs incorporate the existing waivers permitting hospices to contract for core services when unexpected staff demands occur. The CoPs also now include reference to the ability of rural

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hospices to apply for long-standing waivers when attempts to hire nurses have been unsuccessful and the efforts are documented through advertising and other outreach mechanisms.<sup>6</sup>

During the CMS June 5th NHPCO training, CMS staff suggested that if a hospice had several patients on continuous care, that in itself could cause a “peak patient load” for which there are exceptions to the employees-only core service requirement. CMS staff said they “do not want to see routine contracted care for continuous care.” Continuous care is defined as eight or more hours of RN and aide hospice services provided to a patient being treated in a personal residence, due to acuity of symptoms. It is reimbursed at a higher level by Medicare than routine home care, which has a per diem reimbursement structure.

The use of specialist nurses under contract, rather than permanently employed, is also approved in the published regulation.<sup>7</sup> Because hospices seldom have large pediatric populations, CMS staff affirmed, during the teaching session, that it would be appropriate to contract for pediatric nursing services.

In a decision strongly opposed by the hospice industry, CMS has tightened the credentials for the social work staff who can serve as the core service professionals for that service area. The regulation will require either that those who perform medical social work services have Masters in social work (MSW) degrees, or else that others who are not Masters-prepared but have degrees in behavioral health, must work under an MSW’s supervision and have a year’s work experience in social work in a health setting other than hospice.<sup>8</sup> The one exception is those persons with Bachelor’s degrees in social work, who are already employed by a given hospice prior to the effective date of the regulation, may continue

in that specific position unsupervised by a MSW. But, if they move to a different hospice, they lose that independence and must be directly supervised by an MSW. This is a particularly onerous new requirement that does not appear to have a strong factual base from CMS’s response to comments in the Preamble, does not seem founded upon any indication of lack of quality in care provided to hospice patients at present, and does not seem internally consistent (the non-MSW gets to stay in place, but can not move to another hospice.) The MSW-trained professional is a particularly scarce commodity in community-based health care these days, so the full impact of this provision could be to limit access to hospice care in geographic regions of the country. This prospect is not addressed in the impact analysis CMS prepared for the regulation.

CMS is requiring the Medicare-certified hospice to have an individual trained in and knowledgeable about pharmacy information (although not necessarily a licensed pharmacist) to participate in the care planning for all hospice patients. Although many hospices have utilized pharmacist consultants, this requirement for input is at a higher level, and higher cost, for hospices. The Preamble also warns that such pharmaceutical products-knowledgeable individuals must be screened for conflicts of interest to prevent their recommending products for which they receive rebates or financial incentives. This is a new area for hospice compliance planning concern; monitoring and spot-checking audits must be designed and implemented.

Aides who deliver personal care and assistive supportive care for hospice patients are now termed “hospice aides” and will be required to be trained at a comparable level to a home health aide under the Medicare home health agency CoPs. These are replicated within the

hospice CoPs at Section 418.76. This section can be satisfied by meeting a state-standard of training that meets or exceeds the new CoP or by qualifying as an aide trained to satisfy the nurse aide standard of the Medicare CoPs for nursing facilities. Although some hospices may need to do considerable training of staff to meet this new requirement, it was anticipated by industry and largely well endorsed. Unlike the home health aide (HHA) CoPs, if a hospice which trains its own aides should receive a survey deficiency at the conditional level, it will not be disqualified from training its aides.

An additional burdensome requirement of the new CoPs is that there be background criminal checks done on all individuals who have any direct care relationship to patients or who have access to their clinical or financial files. This requirement is being instituted without any parallel in any other health industry segment, and also without any findings back yet from CMS demonstrations projects now underway to test the feasibility and cost of such broadened criminal background check provisions. CMS again appears to have leapt ahead of the facts and ahead of the reasonableness balance. It is a provision which will have to be abided by, but hospice industry leaders should seek reconsideration of its being actualized before better expense data becomes available. The CoP also expects hospices to ensure the same level of criminal background checks are done by any vendors of services to the hospice which fall within the clinical and fiscal broad descriptors. This measure can be satisfied by an assurance of compliance by the vendor in its contracts with hospices, according to statements made by the CMS staff during the June 5th training session. On July 28, 2008, in a CMS online forum for hospice and home health providers, CMS affirmed that a criminal background check is required for all vendors that have

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contact with the patient or the patient's clinical record.

Certain aspects of the relationships between hospices and nursing facilities are significantly affected by the new hospice CoPs, in ways discussed below. But with regard to the role the nursing facility staff play as surrogates for a hospice patient's family or friends, the patient in a private home, the hospice CoPs, and the Preamble language make clear that SNF staff are to do what they otherwise would have done for a patient in a nursing home under room-and board with supportive nursing, and not less. And the hospice is to train the SNF staff, provide bereavement services to them if requested, and call upon them to handle a patient's care in the same manner as a family would. This helps clarify the government's expectations of the level of care for a person who is institutionally housed and cared for, and also lays the ground work for the parallel regulatory sections which will be enacted for the SNF CoPs in the near term. It is also responsive to the concerns expressed by the OIG which has reviewed care provided to hospice patients in SNFs and in private homes and concluded that fewer services are provided by hospices to the institutional setting patients. The hospice industry might well now posit that the SNF is the surrogate for the "best practices" private home, because in fact there are people present at all times, who pay attention to the patient and deal with assistance in daily living needs which may go unattended by the absent or busy family member of an individual living at home. In such a "best practices" SNF arrangement, patients may need fewer hospice interventions because stability is greater. The opposite may be true; but at present, there is little research in this area.

Additionally, hospice compliance staff can rely upon CMS's interpretations and call upon SNFs to meet the expectations of

continuation of services on their part with regard to the patients.

### **The changing role of the hospice medical director**

CMS has underscored the importance of the medical director's (MDir's) role in hospice care by speaking to the need for a central medical quality oversight by the director and the hospice, in collaboration. The MDir cannot in future be a sometime presence, little connected, and utilized for the "sign off" function of the certification forms on terminality. The MDir's or physician designee, as chosen by the hospice, not the doctor, "has responsibility for the medical component of the hospice's patient care program."<sup>9</sup> The hospice, however, must ensure that the MDir is doing the job, is oriented to the hospice's work, and is competent.

Although CMS retreated from the proposed CoP standard of making the MDir the principal leader of the QAPI function, the MDir still must supervise all physician employees and contractors to the hospice, must administratively lead the hospice in developing and improving medical care, and must actively work in facilitating communication with inpatient facilities where hospice patients may reside. In the new area of regulation of restraints and isolation, the CoPs in effect eliminate standing orders by stating physician "orders based on future contingencies are not acceptable."<sup>10</sup>

The fraud and abuse anti-kickback concerns about hospices' financial relationships with physicians have not diminished with the new CoPs. To the contrary, the regulations call for written documentation of the relationships, and the CoPs recite the concerns about referral arrangements between hospices and SNFs which, in the past, have often been driven by relationships between physicians serving as medical directors of SNFs (and in the dual role

as attending to such patients in many cases). However, CMS declines to forbid the SNF medical director from serving as medical director of a hospice by saying there is nothing in the CoPs which would prohibit the relationship.<sup>11</sup>

### **Hospice services to residents of SNF**

The new CoPs establish a regulatory, and thus a compliance standard, for hospice care to patients who reside in nursing facilities at any facility which is or could be licensable as a Medicare/Medicaid certified facility. CMS chose in the final regulation not to require similar standards for hospice care to patients who reside in those assisted living facilities (ALFs) which are not Medicare/Medicaid certified. However, compliance officers should note that some ALFs are Medicare/Medicaid-certified, or have sections of their facilities which are so certified, therefore compliance analysis must be on a matrix which fits the factual circumstances.

The significant change is that the relationship between a certified nursing facility and the hospice now must be governed by a written contract affecting all aspects of hospice service and partitioning responsibilities between the two organizations.<sup>12</sup> The contractual relationship components should be reviewed and audited by the compliance officer of the hospice. These components include:

- An agreed-upon method to develop a single, detailed care plan for the hospice-participating SNF resident, which will govern both the facility's and the hospice's actions.
- Full coordination and participation of the hospice and SNF clinical staff in a patient's care.
- Dominance of the hospice medical director in the medical care planning for the SNF resident.
- Responsibility of the hospice for ensuring the SNF staff are trained in hospice protocols (which could be done by another hospice) as well as the new CoPs

for hospice. It is the responsibility of the hospice to provide bereavement services to the SNF staff, if requested or desired.

- Prompt and appropriate notice to the hospice staff by the SNF staff when changes of patient status occur pertaining to the terminal illness.
- Responsibility of the SNF staff to function on a continuing basis in the capacities which would parallel the roles of a family or community lay caregiver to a hospice patient in a private home. This includes the provision of skilled services by the SNF in circumstances when a lay caregiver would be taught such skills (e.g., injections, medication management, turning the patient, dressing wounds, dietary management and specialized feedings, etc.)

In instituting broad changes to the hospice CoPs and articulating the nature of the relationship between hospices and SNFs where patients reside, CMS has underscored that this is necessary, due to the quality-of-care protections that hospices must institute. But, CMS has also stated in strong Preamble language, that the relationship between hospices and nursing facilities is under great scrutiny by OIG, the MedPac reimbursement analysts, the CMS senior policy offices, and others, because of the risk of fraudulent relationships, kickbacks, and “handoffs” of patients with questionable terminal status for whom hospices assume the costs of care and SNFs are financially rewarded.<sup>13</sup>

### Multi-site hospices

In the final CoPs, CMS has incorporated what it refers to as long-standing regulatory practice<sup>14</sup> that requires hospices with multiple geographic sites of staffing and IDT teams to be centrally organized, supervised, and monitored. CMS has also reiterated that these locations are not “satellite” work stands, but rather locations from which and to which

hospices dispatch care and receive referrals. They may function under a single Medicare provider number, thus averting the often delayed and expensive process of establishing a start-up new Medicare provider location. However, these multi-site hospices must have their locations approved by the CMS/Medicare program office, not merely be licensed by a state or surveyed by state agencies. All hospice compliance officers must identify all locations from where services are being provided and ensure that these are duly Medicare-approved prior to any billings for services from those locations. This inventory is often missing or supervision and controls loosely maintained. From December 2008 onwards, regular surveys of these ancillary sites will be possible from state or deemed accreditation agencies.

### Conclusion

The final, revised hospice Medicare CoPs will be a challenge for most hospices to implement in the focal areas of QAPI, contractual relationships with SNFs, and credentialing of service professionals and training of hospice aides. Compliance officers would do well to read through the voluminous Preamble of the Final Rule to get the full flavor of CMS’s urgency about high quality, well controlled hospice care. Good auditing around the principal CoPs, and active training for hospice employees and contractors are two areas in which the compliance officer should have a central role. ■

1 See Randall, D. “Compliance and the Hospice Conditions of Participation,” *Compliance Today*, June 2007, p 52.  
2 Statements of Mary Rossi-Coajou, USPHS, at the National Hospice and Palliative Care (NHPCO) training sessions on the new CoPs, June 5, 2008, Baltimore, MD.  
3 For further information, see <http://www.nhpco.org/j4a/pages/index.cfm?pageid=5624>  
4 See detailed language at 418.58, and 418.58(e) concerning the governing body.  
5 42 CFR 418.64  
6 42 CFR 418.66(a)  
7 42 CFR 418.64(b)(3).  
8 42 CFR 418.113(b)(5)  
9 42 CFR 418.102(d)  
10 CoP Preamble at 73 Fed.Reg. 32150  
11 73 Fed.Reg. at 32159, column one  
12 42 CFR 418.118  
13 See Preamble at 73 Fed Reg  
14 I referred to this policy area as a “missing CoP” in “Compliance and the Hospice Conditions of Participation” *Compliance Today*, June 2007, p 52.

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