DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 418

[CMS-3844-F]

RIN 0938-AH27

Medicare and Medicaid Programs: Hospice Conditions of Participation

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule revises the existing conditions of participation that hospices must meet to participate in the Medicare and Medicaid programs. The final conditions address the comments that we received on the proposed rule published on May 27, 2005. This final rule focuses on the care delivered to patients and their families by hospices and the outcome of that care. The final requirements continue to reflect the unique interdisciplinary view of patient care and allow hospices flexibility in meeting quality standards. These changes are an integral part of the Administration's efforts to achieve broad based improvements in the quality of health care and our efforts to improve the quality of care furnished through the Medicare and Medicaid programs.

EFFECTIVE DATE: These regulations are effective on [180 days after the date of publication in the **Federal Register**]. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the **Federal Register** as of [OFR insert 180 days after date of publication in the Federal Register].

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SUPPLEMENTARY INFORMATION:

I. Background

Hospice care is an approach to caring for the terminally ill individual that provides palliative care rather than traditional medical care and curative treatment. Palliative care is an approach that improves the quality of life of patients and their families facing the problems associated with life-threatening illness through the prevention and relief of suffering by means of early identification, assessment and treatment of pain and other issues. Hospice care allows the patient to remain at home as long as possible by providing support to the patient and family, and by keeping the patient as comfortable as

possible while maintaining his or her dignity and quality of life. A hospice uses an interdisciplinary approach to deliver medical, social, physical, emotional, and spiritual services through the use of a broad spectrum of caregivers.

Section 122 of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA), Pub. L. 97–248, added section 1861(dd) to the Social Security Act (the Act) to provide coverage for hospice care to terminally ill Medicare beneficiaries who elect to receive care from a Medicare-participating hospice. Under the authority of section 1861(dd) of the Act, the Secretary has established the Conditions of Participation (CoPs) that a hospice must meet to participate in Medicare and/or Medicaid, and these conditions are set forth at 42 CFR part 418. The CoPs apply to a hospice as an entity as well as to the services furnished to each individual under hospice care. Under section 1861(dd) of the Act, the Secretary is responsible for ensuring that the CoPs, and their enforcement, are adequate to protect the health and safety of individuals under hospice care. To implement this requirement, State survey agencies conduct surveys of hospices to assess their compliance with the CoPs.

The hospice CoPs were originally published on December 16, 1983 (48 FR 56008) and were amended on December 11, 1990 (55 FR 50831) largely to implement provisions of section

6005(b) of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101– 239). However, many of the current CoPs have remained unchanged since their inception.

As the single largest payer for health care services in the United States, the Federal Government assumes a critical responsibility for the delivery and quality of care furnished under its programs. Historically, we have adopted a quality assurance approach that has been directed toward identifying health care providers that furnish poor quality care or fail to meet minimum Federal standards. These problems would either be corrected or would lead to the exclusion of the provider from participation in the Medicare or Medicaid programs. However, we have found that this problem-focused approach has inherent limits. Ensuring quality through the enforcement of prescriptive health and safety standards, rather than improving the quality of care for all patients, has resulted in our expending much of our resources on dealing with marginal providers, rather than on stimulating broad-based improvements in quality of care.

In order to take advantage of continuing advances in the health care delivery field, incorporate changes made to the Act, and incorporate recommendations made by various government agencies we are revising the Medicare hospice CoPs, which are also used by Medicaid. The revised CoPs

focus on a patient-centered, outcome-oriented, and transparent process that promotes quality patient care for every patient every time.

We have developed a set of core requirements for hospice services that encompass the following: Patient rights, comprehensive assessment, patient care planning and coordination by a hospice interdisciplinary group (IDG). Overarching these requirements is a quality assessment and performance improvement program that builds on the philosophy that a provider’s own quality management system is key to improved patient care performance. The objective is to achieve a balanced regulatory approach by ensuring that a hospice furnishes health care that meets essential health and quality standards, while ensuring that it monitors and improves its own performance.

We are revising the CoPs based on four main considerations. First, we considered the recommendations from the Secretary’s Advisory Committee on Regulatory Reform. In an effort to make regulations more predictable and responsive to relevant stakeholders, the Committee heard public testimony on a variety of hospice-related topics and developed recommendations to address key issues that were highlighted. The Committee recommended that we clarify the relationship between nursing facilities and hospices (found

in our final rule at §418.112); change the requirements for 24-hour nursing services for hospices providing respite care (§418.108 of the final rule); and clarify that all qualified individuals, including nurses, are permitted to furnish dietary counseling (§418.64(d)(2) of the final rule).

Second, we considered the Balanced Budget Act of 1997 (Pub. L. 105–33) because it made changes to the hospice statute that must now be incorporated into the CoPs. Specifically, the Balanced Budget Act of 1997 (BBA) permitted hospices to provide physician services, including those of a medical director, under contract (§418.64 and §418.102 of the final rule). It also allowed hospices located in non-urbanized areas to receive a waiver of the requirement that physical therapy, occupational therapy, speech-language pathology , and dietary counseling be available on a 24-hour as needed basis (§418.74 of the final rule). Additionally, the legislation allowed hospices located in non-urbanized areas to receive a waiver of the requirement that dietary therapy be provided by hospice employees (§418.74 of the final rule).

Third, we considered section 946 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). Section 946 of the MMA amended section 1861(dd) of the Act, to permit a hospice to

enter into an arrangement with another hospice to provide core hospice services or to provide the highly specialized services of a registered professional nurse, in certain circumstances (§418.64 of the final rule).

Finally, this revision is part of a larger effort to bring about improvements in the quality of care furnished to hospice patients and their families through an outcome-oriented approach to patient care. The revised CoPs focus on the core elements of hospice care that are necessary to achieve positive patient outcomes to meet the growing challenges associated with the changing hospice care environment such as increasingly diverse patient populations and care settings.

Before developing the proposed CoPs for hospices, published in the **Federal Register** on May 27, 2005, we analyzed our hospice survey data, and received advice and suggestions from the hospice industry, professional associations, practitioner communities, consumer advocates, and State and other governmental agencies with an interest in, or responsibility for, hospice regulation and oversight. Based on the data and suggestions, we developed the following principles:

- Focus on the continuous, integrated health care process that a patient/family experiences across all

aspects of hospice care, and on activities that center around patient assessment, care planning, service delivery, and quality assessment and performance improvement;

- Use a patient-centered, interdisciplinary approach that recognizes the contributions of various skilled professionals and other support personnel and their interaction with each other to meet the patient's needs;
- Incorporate an outcome-oriented quality assessment and performance improvement program;
- Facilitate flexibility in how a hospice meets performance expectations;
- Require that patient rights are ensured; and
- Use performance measurement systems to evaluate and improve care.

Based on these principles and the public comments that were submitted regarding the May 2005 proposed rule, we are setting forth this final rule.

II. Provisions of the Proposed Regulations and the Analysis and Responses to Public Comments

On May 27, 2005, we set forth proposed rules for hospices that choose to participate in Medicare and Medicaid. We proposed to revise all of the existing conditions of participation (CoPs), and to add several new

CoPs to address aspects of hospice care that we believe need attention. This section will briefly describe the content of each CoP in the proposed rule.

We proposed no changes to Subparts B (Eligibility, Election and Duration of Benefits), G (Payment for Hospice Care), or H (Coinsurance) of 42 CFR Part 418.

We received 205 timely items of correspondence that raised numerous issues. These comments, detailed below, came from accrediting bodies, consumer advocacy organizations, hospices, individuals, national health care provider organizations, State agencies, and State health care provider organizations.

1. Scope of the Part (§418.2)

We proposed to revise §418.2 to reflect the reorganization of the part and to include an introductory statement describing the purpose of the part. We did not receive any comments on this section. Therefore, we are adopting the provisions as proposed.

2. Definitions (§418.3)

We proposed to remove, revise, and add numerous definitions to this section in order to clarify the meaning of the proposed rule. We proposed to move the definitions of “physician” and “social worker” from the definitions section to the personnel requirements section at §418.114

because the definitions set forth the standards that these individuals must meet in order to function in a hospice. In addition, as it is not a condition of participation, and is only used for hospice payment purposes, we proposed to maintain the existing definition of the term “cap period.”

We proposed to revise the definitions of the terms “attending physician”, “bereavement counseling”, “employee”, “hospice”, “representative”, and “terminally ill”. Finally, we proposed to add definitions for the following terms: “clinical note”, “drug restraint”, “hospice care”, “licensed professional”, “palliative care”, “physical restraint”, “progress note”, “restraint”, “satellite location”, and “seclusion”.

We proposed to add nurse practitioners to the definition of “attending physician” because section 408 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) changed the statutory definition of “attending physician” to include nurse practitioners with respect to some (but not all) aspects of hospice services.

The terms “drug restraint”, “physical restraint”, and “seclusion” were presented for the first time in the proposed rule. Seclusion and restraint requirements were proposed because anecdotal evidence suggested that there are

occasions when hospice inpatient facilities must use seclusion and/or restraints for patient and/or staff safety. Moreover, Section 591 of the Public Health Service (PHS) Act, as added by the Children's Health Act (P.L. 106-310), prohibits the use of restraint and seclusion, except under specific circumstances, in any health care facility, that receives support in any form from any program supported in whole or in part with funds appropriated to any Federal department or agency.

We proposed to define the term "satellite location" to codify long-standing Medicare survey and certification policies that permit hospices to operate multiple locations under a single provider number. Multiple locations were not an issue when the hospice CoPs were originally implemented, and, as such, were not addressed. We believed that the proposed definition would help hospices determine when they do or do not need to obtain Medicare approval for a new location and what criteria would be used by Medicare in approving or denying a multiple location application.

Comment: Many commenters requested that changes be made to the proposed definition of "attending physician." Some of these commenters requested that, in addition to "nurse practitioner," we also add "advanced practice nurse," "clinical nurse specialist," and "physician's assistant" to

the definition of “attending physician” in order to broaden the category of individuals who could receive payment in that capacity. A single commenter suggested that we defer to the States to determine training, education and experience requirements for nurse practitioners. Another commenter suggested that the definition of “attending physician” should be divided into two definitions, one for physicians and one for nurse practitioners. Still another commenter requested that we delete the requirement that an attending physician must be legally authorized to practice surgery by the State in which he or she performs that function because surgery is not a specialty necessary to be considered qualified as an attending physician. Several other commenters requested that we specify in the definition of “attending physician” that a patient’s attending physician may be a hospice employee. Another commenter suggested that we add a statement that a nurse practitioner may cover for an attending physician in the attending physician’s absence.

Response: Section 408(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173) (MMA) amended the term “attending physician” at section 1861(dd)(3)(B) of the Act specifically for hospices to allow nurse practitioners to function as a patient’s

attending physician if the patient identifies the nurse practitioner as such. Following publication of the proposed rule, CMS published two final rules (70 FR 45144 and 72 FR 50214) on other matters that, among other things, modified the definition of the term “attending physician” to incorporate changes made by the MMA. We are deferring to these final rules. Furthermore, Section 1861(r)(1) of the Act specifically defines a physician as “a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action.” We believe that this statutory definition is appropriate for hospice providers, as well as for the many other health care providers for which it is used. We do not have the authority to delete the term “and surgery” from this definition.

We do not believe that it is necessary to state in the definition that an attending physician may be an employee of the hospice. The decision as to who is or is not the attending physician belongs to the patient regardless of that individual’s employment relationship (or lack thereof) with the hospice. We do not prohibit attending physicians from being hospice employees as long as it is the patient’s choice to decide whether or not to have an attending physician and who that attending physician will be during

the patient's hospice care. In addition to consulting with the hospice interdisciplinary group (IDG) regarding the patient's hospice care, the attending physician retains responsibility for meeting the patient's needs that are not related to the terminal illness and that terminal illness's related conditions. The attending physician is typically someone with whom the patient had a relationship before electing to receive hospice care. The role of the attending physician is to provide a long term perspective on the patient and family that takes into account their medical and personal history. The attending physician is not typically an individual provided by the hospice to fill this role because a patient does not have an attending physician, although we recognize that this does occur at times.

We also do not believe that it is necessary to state that a nurse practitioner may act on behalf of the attending physician in the attending physician's absence. If the attending physician is unable to fulfill his or her duties, then the hospice physicians are responsible for fulfilling the attending physician's duties in his or her absence in accordance with §418.64(a)(3) of the final rule. Therefore, there is no need for the attending physician to designate another individual to cover his or her hospice patients. The role and function of the nurse practitioner is also

addressed in CMS hospice payment policies (see, for example, 42 CFR §418.304(e)).

Comment: A commenter requested that we revise the definition of “bereavement counseling” to reflect the fact that bereavement counseling begins before the patient dies. The commenter noted that the proposed rule even required the initial step of bereavement counseling to begin before the patient’s death by requiring that the initial bereavement assessment be completed at the time of the comprehensive assessment. Another commenter questioned the qualifications of persons providing bereavement counseling and indicated that we should consider adding language to address this question within the definition of “bereavement counseling.” Another commenter requested that we specify, in the definition of bereavement counseling, that the counseling only applies to the patient’s immediate family members as set out in the Act.

Response: We agree that effective bereavement counseling must begin before the patient’s death and that the proposed rule and this final rule reflect this practice by requiring a bereavement assessment early in the patient’s hospice stay. To clarify our intent, at section §418.3 of this final rule, we are revising the definition of “bereavement counseling” to specify that it occurs both

before and after the patient's death.

With respect to counseling immediate family members, current practice in many hospices is expanding this activity. Many hospice programs have extensive bereavement programs that extend beyond immediate family members to embrace other caregivers, friends, and the larger community. As the commenter pointed out, the statute at section 1861(dd)(2)(A)(i) of the Act mandates bereavement counseling for the immediate family of the terminally ill individuals, but does not explicitly limit counseling to only such family members. We believe that limiting counseling to immediate family members would disregard the work that many hospices do for other persons whose relationship with the patient is important. To restrict bereavement counseling to a select few would discourage hospices from providing this service, thus harming the bereaved and the larger community. Therefore, we did not insert language limiting the definition of "bereavement counseling" to immediate family members. Bereavement counseling is part of the hospice's bundled daily payment rate.

In order to facilitate bereavement counseling services beginning at an early time and being furnished to whomever the hospice assesses as needing services, we believe that it is necessary to allow hospices flexibility in deciding who

is qualified to provide bereavement services in accordance with their own policies, current standards of practice, and other applicable Federal, State, and local laws and regulations. In the proposed and final rule at §418.64(d), we require that counseling services, including bereavement counseling, are provided by or under the supervision of a qualified individual with experience in grief or loss counseling. Some hospices may use a social worker while other hospices may choose to use chaplains or volunteers to provide this service. This flexibility allows hospices to meet the needs of their patients and families in a manner that works best for their needs and resources. Therefore, we are not prescribing who may or may not furnish bereavement counseling services.

Thus, the revised definition for "bereavement counseling" is as follows:

"Bereavement counseling means emotional, psychosocial, and spiritual support and services provided before and after the death of the patient to assist with issues related to grief, loss, and adjustment."

Comment: Numerous commenters indicated that the proposed definitions for the terms "clinical note" and "progress note" were either unnecessary or redundant. The commenters suggested that these definitions either be

deleted or further clarified to distinguish their purpose. In addition, many commenters suggested that the terms “psychosocial” and “spiritual note” be added to the definition of “clinical note” to reflect the fact that individuals who furnish psychosocial and spiritual care such as social workers, counselors and chaplains also write notations in the patient’s clinical record.

Response: Notations in a patient’s clinical record by individuals furnishing services on behalf of a hospice are standard practice. They are a primary and crucial means of communication between various care providers who are in the patient’s home at different times while furnishing different services. Therefore, we believe that it is important to acknowledge their use in the hospice environment by requiring their presence in the patient’s clinical record. At the same time, we agree that having two separate definitions for notations is not necessary and may even be confusing. Therefore, at §418.3, we are using a single definition, “clinical note,” that addresses notations regarding both the patient and the family. We also added the terms “psychosocial” and “spiritual” to the definition to reflect the need for this important information in the patient’s clinical record. The condensed and revised definition is as follows:

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

We would like to point out that the term "clinical note" does not limit the notations only to those individuals who are clinicians. Clinical notes may be written by any individual furnishing care and services to a patient, including volunteers, homemakers, vendors, etc. Indeed, we would expect that clinical notes from all individuals would be included in the clinical record because the goal of the clinical note is to include as much information as possible to ensure that all hospice care providers have complete and correct information to use in making care decisions and furnishing care.

Comment: Many commenters were confused by the terms "initial assessment" and "comprehensive assessment" as they are used in §418.54, "Initial and Comprehensive assessment of the patient." The commenters requested definitions for these terms in order to help clarify the difference between the two assessment requirements to ensure that the proper

information was being gathered within the stated time frames.

Response: We agree that adding definitions of these two terms will help ensure that patients are being assessed in a timely fashion. We are clarifying that the initial assessment is to determine the patient's immediate care needs. Hospices must complete this abbreviated assessment in 48 hours. The comprehensive assessment must assess in-depth all of the patient's areas of need and will ensure that hospices are fully aware of the patient's current status. Hospices will be able to use these assessments to establish an individualized hospice plan of care that meets the patient's needs. We did not, as some commenters suggested, specify which disciplines must complete the comprehensive assessment. Hospices provide many different services and not every patient will require an assessment by a provider of each of those services. If, upon completion of the initial assessment, it is determined that a patient may benefit from physical therapy services, then we would expect a physical therapist to complete a physical therapy assessment as part of the comprehensive assessment. However, if there is no indication that the therapy services may benefit the patient, then a therapy assessment by a therapist would be unnecessary. The new definitions for

"initial assessment" and "comprehensive assessment" are added at §418.3 as follows:

"Initial assessment means an evaluation of the patient's physical, psychosocial and emotional status related to the terminal illness and related conditions to determine the patient's immediate care and support needs."

"Comprehensive assessment means a thorough evaluation of the patient's physical, psychosocial, emotional and spiritual status related to the terminal illness and related conditions. This includes a thorough evaluation of the caregiver's and family's willingness and capability to care for the patient."

Comment: A number of commenters asked us to define the terms "dietary counseling" and/or "dietitian" to help clarify what type of counseling hospices are required to provide to their patients, and who may furnish this service. A few commenters further suggested that we should differentiate between dietary counseling furnished by a dietitian and dietary counseling furnished by a qualified individual such as a nurse or nutritionist.

Response: Section 1861(dd)(1)(H) of the Social Security Act (the Act) requires hospice facilities to provide "counseling (including dietary counseling) with respect to care of the terminally ill individual and

adjustment to his death." However, the term "dietary counseling" has never been defined for hospices, and there is a great deal of confusion in the hospice industry regarding exactly what constitutes "dietary counseling." Therefore, we agree that a definition of "dietary counseling" is necessary. The definition at §418.3 reads as follows:

"Dietary counseling means education and interventions provided to the patient and family regarding appropriate nutritional intake as the patient's condition progresses. Dietary counseling is provided by qualified individuals, which may include a registered nurse, dietitian or nutritionist, when identified in the patient's plan of care."

We do not agree that we should prescribe what type of counseling must be provided by a dietitian. We would expect that, based on an assessment of the patient's dietary needs, a hospice would furnish dietary counseling services through an individual whose skills best meet the patient's identified needs. We believe that the needs of the individual patient, rather than preset rules, should be the determining factor relative to services and staff. We do not believe it is appropriate to define the term "dietitian" or establish personnel requirements for dietitians because

we believe that hospices should have the flexibility to employ an individual that would meet the needs of their patients in accordance with all other applicable Federal, State, and local laws and regulations.

Comment: A few commenters submitted suggestions for the proposed definition of the term “employee.” A single commenter asked that we replace the definition of the term “employee” with a definition of the term “staff.” Another commenter suggested that, through the definition of the term, hospice employees should be required to be appropriately trained in death and dying.

Response: The term “employee” is singular and is used throughout the regulation to refer to the direct relationship between the hospice and the individual in terms of furnishing services (that is, a direct employee), supervision, and lines of authority and responsibility. The term “staff,” on the other hand, is plural and may include individuals who are contracted through an outside entity, supervised by that outside entity, and primarily responsible to that outside entity. “Staff,” as a broader term, is not an appropriate substitution for the term “employee” in these definitions.

Additionally, it is not appropriate to require in the definition of the term “employee” that an employee must be

trained in issues related to death and dying. We agree that thorough training in issues related to death and dying is necessary for all individuals furnishing patient care services, including clinicians and patient care volunteers. In final §418.100(g)(1) we now require hospices to educate all hospice employees who have patient contact in the hospice philosophy. Education in the hospice philosophy would, we believe, encompass issues related to death and dying, as the commenter suggested. It is not necessary for office employees with no patient contact to be trained in issues relating to death and dying. To require the training for all employees, regardless of their role within the hospice organization, would unnecessarily burden hospices and divert resources from more critical patient care activities. Therefore, we are not requiring all hospice employees to receive such training.

Comment: A commenter suggested that, in the definition of "hospice care," we should specify that hospice care may be provided in the home, the community, or a facility.

Response: Hospice care is currently being furnished in a variety of settings, and we do not believe that it is necessary or appropriate to specify in this rule where hospice care may be provided. To do so may unintentionally preclude hospices from providing services in settings that

are appropriate but that are outside of an established definition.

Comment: Numerous commenters requested changes to the definition of “licensed professional.” Many of those commenters suggested that dietary therapy should be added to the list of examples of services that should be furnished by a licensed professional. Another commenter suggested deleting the list of examples because the examples may inadvertently limit the types of services that should be provided by licensed professionals. Yet another commenter suggested that medical social services should be deleted from the list of examples because not all States license social workers. Therefore, in those States where no State licensure for social workers exists, medical social services, CMS presumes, that the commenter is advocating that such services be furnished by a professional without a license.

Response: We agree that the proposed definition needs to be clarified. While the commenters are correct in suggesting that dietary therapy should be provided by a licensed professional, whether a nurse, dietitian or nutritionist, we agree with the commenter who suggested that the mere presence of the list of services is limiting. Therefore, while we agree that dietary therapy should be

provided by a licensed professional, we are not adding dietary therapy to the list of examples. Rather, at §418.3, we are deleting the entire list of examples because they are unnecessary and may be confusing. Deleting the list of examples also addresses the commenter's concern regarding the licensure status of social workers. We recognize that some States may not license social workers or other health care disciplines, and we do not intend to imply that States must provide licensure for all health care disciplines furnishing hospice services. Rather, our intent, as proposed at §418.116(a) and finalized at §418.114(a) is that if a State licenses a particular health care discipline, then any individual working within that discipline in the hospice environment must obtain and maintain that State license. If no State license exists for a particular discipline, and if that individual meets all other personnel and training requirements as required by this rule and any other applicable Federal, State, or local laws, regulations, policies, and requirements, then it is acceptable for that individual to furnish services to hospice patients absent a State license.

Comment: Numerous commenters requested clarification on the definition of the term "satellite location." Specifically, hospices requested that the definition

include: concrete criteria that hospices must meet in order to be considered satellite locations, information about the approval and survey process, and information about the type of services furnished by satellite locations.

Response: The term “satellite location” is now referred to as “multiple locations,” and §418.3 has been modified to reflect this change. We believe that this new terminology more accurately describes those entities that furnish a full array of services from two or more locations. We have also clarified our intent by stating that multiple locations are those locations “from which the hospice provides the same full range of hospice care and services that is required of the hospice issued the certification number.” We note that the term “certification number” is now used in place of the term “provider number.” This change reflects a change in the terminology used by CMS to describe the number issued to a hospice to identify it in certain Medicare systems.

We believe that clarifying that a multiple location provides the same full array of services as the hospice location originally issued the certification number will alleviate commenter concerns that convenience sites where staff stop in to complete paperwork or check messages, or warehouse sites where equipment is stored would need to be

approved by Medicare as multiple locations. We note that although we do not require hospices to obtain approval for warehouse and other single function sites, States may still require hospices to receive approval from State or local authorities. The requirement that multiple locations must share administration, supervision, and services with the hospice that was issued the certification number is relocated from the definition of the term at §418.3 to the paragraph addressing multiple locations at §418.100(f)(1)(ii). We continue to believe that it is the level of control and supervision exercised by the hospice that was issued the certification number over the multiple location, rather than mileage limitations or staffing levels, which determines whether or not a site is a multiple location of an existing hospice or a completely separate hospice.

We do not believe that it is appropriate to add specific criteria or procedures for the approval of multiple locations in the regulatory definition because this level of specificity may reduce our ability to adapt to rapid changes in the hospice industry related to the use of multiple locations. Rather, we will continue to address specific criteria and procedures for multiple locations in sub-regulatory guidance such as the State Operations Manual.

Comment: A commenter requested clarification about the definition of “palliative care” and its relationship to the requirement that, in order for a Medicare beneficiary to qualify for the Medicare hospice benefit, the beneficiary must be certified as being terminally ill. Specifically, the commenter asked if palliative care could be provided by a hospice to individuals who are not terminally ill or who have not elected the Medicare hospice benefit.

Response: Hospice care is a very specific type of care provided within a defined timeframe at the end of life. Palliative care, on the other hand, can be provided at any time of life when there is a need to anticipate, prevent and treat suffering to optimize a patient’s quality of life. Hospices have a long history of providing palliative care and are often in a position to provide the care either on a direct or contract basis to patients who either do not qualify for the Medicare hospice benefit (or another health care insurer’s hospice benefit) or who do not choose to forgo curative treatment in order to elect the Medicare hospice benefit. We do not prohibit hospices from providing these palliative care services to patients that do not elect or qualify for hospice care, as long as the hospices are primarily engaged in furnishing hospice care as required by section 1861(dd) of the Act.

Comment: A few commenters requested that we define the term "physician designee" as it was proposed in §418.102, "Medical director." The commenters believed that a definition would help to clarify this individual's role.

Response: We agree that defining this term will help clarify what responsibilities this individual has as well as when those responsibilities are assumed. The purpose of the physician designee role is to ensure that, if the medical director is unavailable, there is a predetermined, qualified individual who can assume all of the medical director's responsibilities. Having a predetermined individual who is ready and able to assume the medical director responsibilities will help to ensure that patients receive high quality hospice care even when the usual medical director is not available to perform his or her duties. With this in mind, we are adding a definition for "physician designee" at §418.3 to read as follows:

"Physician designee means a doctor of medicine or osteopathy designated by the hospice who assumes the same responsibilities and obligations as the medical director when the medical director is not available."

Comment: Several commenters asked us to clarify the definition of the term "representative" by recognizing case law, common law, and health care powers of attorney in

determining whether or not an individual is a patient's representative.

Response: The proposed definition of "representative" states that a representative is an individual who has the authority under State law to authorize or terminate care on the patient's behalf. In the context of this definition, we are deferring to State law in its entirety, including statutes, agency regulations, and binding court rulings. Since designations of health care powers of attorney are deemed to appoint legal representatives by most, if not all states, our proposed definition would include individuals granted health care powers of attorney. Thus, case law, common law, and health care powers of attorney are subsumed within the definition of the term "representative", and there is no need to amend it.

Comment: A majority of commenters requested that we revise the proposed definition of "drug restraint" to remove the stigma associated with the term "drug." A minority of commenters requested that we delete the definition of "drug restraint" completely, and suggested that the hospice industry at large or hospices individually should be allowed to determine a definition.

Response: Drugs have long played a prevalent role in hospice care. They are used to relieve pain, calm anxiety,

improve breathing and support the patient. However, the idea of drugs used as restraints is relatively new in hospice care and has provoked much anxiety in the hospice industry. We understand that hospices are concerned about an overly restrictive definition of the term “drug restraint.” We also understand that hospices are concerned about State surveyors applying the drug restraint regulations applicable to other health care providers to hospices. We believe that these regulations clearly apply only to hospice inpatient facilities (hospice programs do not have outpatient facilities). Deleting the definition of “drug restraint” will not resolve providers’ uncertainty, and will only leave hospices and patients in the untenable position of not knowing what is and is not a drug restraint; and simply renaming the definition as “chemical restraint” will not resolve the ambiguity either. While we acknowledge that the term “drug” may have a negative connotation among patients, we are not requiring hospices to use this term when discussing medications or chemicals with patients. Hospices are free to refer to drugs used for any purpose within the hospice in a manner that suits their patients and their representatives, families, other caregivers, and the hospice. Moreover, section 591(d)(1)(B) of the PHS Act prohibits the use of drugs “used as a restraint to control

behavior or restrict the resident's freedom of movement that is not a standard treatment for the resident's medical or psychiatric condition." This provision of the Act applies to any health care facility that receives any financial support from any program receiving Federal dollars.

Comment: Many commenters suggested that we narrow the definition of "drug restraint" to tailor it to the hospice environment. Specifically, commenters requested that we indicate, in the definition, that a drug is only considered a restraint if it is not an accepted treatment within a hospice program. The commenters expressed concern that drugs that may be considered restraints in other health care settings (for example, long term care facilities) are not restraints in hospice care because those drugs are used to treat distressing symptoms (for example, terminal restlessness). A single commenter requested that we not consider a drug to be a restraint if that drug is requested by the patient or the patient's representative while another commenter suggested that drugs should only be considered restraints if they are used inappropriately.

Response: Narrowing the definition of "drug restraint" by specifying that a drug is not a restraint if it is a "standard treatment within a hospice program" may hinder hospices from adopting new symptom management drugs in the

future because they may have not yet met the “standard treatment within a hospice program” criteria. Our final language states that drugs used as a restraint are drugs that are not standard treatment or dosage for the patient’s condition, and we believe that this will afford adequate protection to the hospice patient population. Therefore, we are not adding this additional limitation to the definition.

Similarly, narrowing the definition by adding a provision that a drug is not a restraint if it is requested is not appropriate. Requesting a drug does not alter its status as a restraint. In fact, there are times when a patient, representative or family member may request that a drug be administered to protect a patient from his or her own behavior. The requestor would, in essence, be asking for a restraint. Once the drug is administered, the patient would require the increased level of supervision required by this rule in order to ensure the patient’s safety and well being at all times. Therefore, we are not adding a provision to exclude drugs from the definition of “drug restraint” if those drugs are requested by the patient or family.

Furthermore, narrowing the definition of “drug restraint” to those drugs that are used inappropriately is not suitable. There are drugs commonly used in the hospice

environment for symptom management that can also be used appropriately as drug restraints under limited circumstances when warranted by the patient's condition and needs as documented in the patient's clinical record.

Comment: A few commenters suggested that we should use the same definition of "chemical restraint" for hospices as we do for other provider types.

Response: We agree that using the same definition will help to ensure that hospice patients receive the same level of care and protection regardless of where they receive health care services. In addition, we agree that using the same definition will help to ensure that employees moving from another provider type to the hospice setting will more likely be familiar with the regulatory requirements. Therefore, at §418.3, we are adopting the same definition and definitional format for drug restraints as is used in the Hospital Conditions of Participation. We are deleting the definitions of "drug restraint" and "physical restraint" in favor of a more expansive definition of "restraint" that encompasses both drug and physical restraints. We believe that having a single definition, rather than three separate definitions, will simplify the regulation and increase the public's understanding of the requirements. The specific section of the new "restraint" definition that applies to

drug restraints is as follows:

"A drug or medication when it is used as a restraint to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition."

Comment: Many commenters suggested changes for the definition of "physical restraint" ranging from a suggestion to delete the definition to a suggestion that devices adjacent to the patient's body also be considered physical restraints.

Response: As with "drug restraints," we understand that there is a great deal of apprehension and uncertainty regarding physical restraints. In the preamble to the proposed rule we asked for public comments regarding instances when physical restraints may or may not be appropriate and necessary. We heard from a few commenters that bedrails and positional devices are used for patient safety, and for assisting patients in functioning independently. No commenters described a single instance where physical restraints have been, or to their knowledge, are now used, whether appropriately or inappropriately, for patient safety, behavior management or any other purpose. The lack of specific comments leads us to conclude that this is an issue that most hospices choose not to discuss.

Without this input, we are unable to gauge the level of physical restraint utilization in the hospice industry or the purposes of that utilization.

The Children's Health Act (CHA) requires us to promulgate regulations concerning the use of restraints in hospices. Deleting the definition of "physical restraint" would be in conflict with the requirements of the CHA and will not alleviate the concern about the safe and proper use of physical restraints. Indeed, deleting the definition will only leave hospices wondering whether their practices constitute physical restraint and what precautions should be taken to ensure patient safety and well being. We do not believe that this is in the best interest of patients or hospices; therefore we are including a definition to address physical restraints. Moreover, section 591 of the PHS Act sets forth a statutory definition, which is the basis for enforcing regulations on the use of restraints.

At the same time, however, we are sensitive to commenters' concerns that the definition of "physical restraint," as was proposed, could include bedrails and positional devices. Bedrails and positional devices may have the effect of restraining one patient but not another, depending on the individual patient's condition and circumstances. For example, a partial bedrail may assist one

patient to enter and exit the bed independently while acting as a restraint for another patient. Patients who attempt to exit a bed through, between, over, or around bedrails are at risk of injury or death. The potential for serious injury is more likely from a fall from a bed with raised bedrails than from a fall from a bed where bedrails are not used. Bedrails also potentially increase the likelihood that the patient will spend more time in bed and fall when attempting to transfer from the bed. To address these potential hazards, many long term care facilities have replaced the use of bedrails with lower beds, perimeter mattresses, alarms, and sitters for restless individuals. We encourage hospices to have a dialogue with their long term care facility colleagues about the safe and appropriate use of bedrails for hospice patients, as we believe that both parties can learn from their successes. To reflect the fact that it is the function and effect of a device, rather than a device itself, that determines whether or not the device is a physical restraint, we have revised the definition at §418.3 as follows:

"Restraint means: (a) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely, not including devices, such as

orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).”

This language almost precisely tracks 591(d)(1)(A) of the PHS Act, and matches the definition in the Hospital Conditions of Participation. As a commenter suggested, physical restraint applies to any device that has a restrictive effect, regardless of whether the device is attached to or adjacent to a patient’s body. It is the effect of the device, rather than its location, that makes it a restraint. Using the same definition for hospices as is used for other provider types will help ensure that patients are consistently provided the same quality of care and supervision when restraints are used, regardless of whether those patients are in a hospital or a hospice inpatient facility. At the same time, using the same definition will make staff transitions between different provider types easier because the same set of restraint rules will apply to some other provider types. This may be particularly helpful to hospices that have occasion to

furnish services under contract where a nurse or other practitioner may be more familiar with the rules governing restraints in hospitals. Having the same definition will help to ensure that there is no conflict between the practitioner's previous background and training and the applicable hospice rules.

Comment: Several commenters noted that the proposed definition of the term "seclusion" implies that any placement of patients in private rooms would constitute seclusion. One commenter suggested that the term should be completely removed.

Response: While it was not our intent, we agree that the proposed definition of "seclusion" could embrace private rooms. Therefore, at §418.3, we have revised the definition of "seclusion" by adding the term "involuntary." Patients who request private rooms do so voluntarily, and therefore would not be in seclusion. However, if a patient is placed alone in a private room against his or her will and is not permitted visitors or egress from that room, then the patient would be considered to be in seclusion. We also believe that it is essential for the term "seclusion" to remain in this rule. Seclusion, as defined in section 591(d)(2) of the PHS Act, may only be used under circumstances described at 591(b). Deleting the term

"seclusion" will not assist hospices in complying with the statutory requirement, and will only leave hospice facilities and patients in the untenable position of not knowing what situations do and do not qualify as "seclusion" and whether they may be in violation of the Children's Health Act. We do not believe that this is in the best interest of hospices or their patients.

Comment: A few commenters requested that we delete the definition of the term "terminally ill" because it is a term that may discourage patients from accepting hospice care.

Response: Section 1861(dd) of the Act establishes the Medicare hospice benefit for beneficiaries who are terminally ill with a prognosis of 6 months or less if the illness runs its normal course. The definition that we proposed is the same definition that is used in the Act. We believe that this is necessary to maintain the definition in this rule because this term is used in the hospice payment rules.

Comment: A number of commenters requested that we define the term "family" using a very broad, patient-directed approach that allows the patient to identify those who are considered to be his or her "family."

Response: We do not believe that a single definition of the term "family" would benefit beneficiaries or

hospices. The meaning of “family” can change depending on circumstances and availability of persons close to the patient. While allowing the patient to identify his or her “family” would be ideal, this may not be possible for patients who cannot communicate and who do not have written information available for the hospice. We have decided that it would be most appropriate to allow each hospice to establish its own policy on what “family” means in its community and with its own patients.

Comment: A single commenter requested that we add a definition for the term “unnecessary drugs” to include drugs used in excessive dosages, for excessive durations, without adequate monitoring, without adequate indications for use, or in the presence of adverse events.

Response: The term “unnecessary drugs” did not appear within the proposed rule. The concept is very interesting and may be useful to hospices when assessing a patient’s drug therapy regimen as required by §418.54(c), Content of the comprehensive assessment. We have incorporated some of the commenter’s concerns in our final rule at section 418.54(c)(6). This section requires hospices to review a patient’s prescription and over-the-counter drugs in use at the time of the assessment, including, but not limited to, an identification of the effectiveness of the drug therapy

regimen, any potential or existing drug side effects, any potential or existing drug interactions, any duplicate drug therapies, and any drug therapy requiring laboratory monitoring. Excessive dosages or durations, or inadequate monitoring would likely lead to effectiveness and side effect issues that will be assessed during the comprehensive assessment and subsequent updates. The IDG, in conference with an individual who has specialized education and training in drug management, such as a pharmacist, will be required to address these issues in the patient's individualized hospice plan of care.

Comment: A commenter suggested that we should define the term "adverse event" using the Joint Commission patient safety event taxonomy. Another commenter suggested that we should define the term as an, "unanticipated, non-therapeutic response or injury".

Response: While we agree that using the Joint Commission patient safety taxonomy or suggested definition may be helpful for some hospices, we do not believe that a single definition of "adverse event" would meet the needs of all hospices at this time. In general, an adverse event would be any action or inaction by a hospice that causes harm to a hospice patient. We believe that hospices are capable of determining what is or is not an adverse event

based on the characteristics and needs of their patient populations and staff. We recognize that hospices are seeking further guidance on this issue, and we plan to provide such guidance in future sub-regulatory guidance, such as the State Operations Manual and Interpretive Guidelines.

Comment: A few commenters requested that we define the term “homemaker services” with specific references to the Medicaid personal care benefit that many states offer to Medicaid beneficiaries. Commenters asked for clarification about the role of homemakers in hospice care, their relationship to Medicaid personal care aides, and the qualifications for individuals who furnish homemaker services.

Response: Section §418.202(g) in subpart F of the current hospice regulations states, “[h]omemaker services may include assistance in maintenance of a safe and healthy environment and services to enable the individual to carry out the treatment plan.” We believe that this language adequately describes the role that homemakers play in hospice care, and we are making no changes to it in this final rule.

Each State establishes its own Medicaid personal care aide benefit, pursuant to our regulations at 42 CFR 440.167,

including its own eligibility criteria, scope of services to be provided, and personnel qualifications. Medicaid regulations impose only minimal restrictions on the state's discretion regarding these services. Hospice care is meant to supplement the care provided by the patient's caregiver. If the individual(s) furnishing Medicaid personal care services is functioning as the patient's caregiver, then the hospice would not be expected to replace the Medicaid personal care providers with its own homemaker services on a round-the-clock basis. The Medicare hospice benefit is not meant to be a caregiver benefit and should not be expected to function as such. Hospices should work with their respective State Medicaid agencies if they have questions about who pays for services provided to patients eligible for both Medicare and Medicaid.

With regard to who is qualified to furnish homemaker services on behalf of a hospice, we proposed in §418.76(j) that a homemaker must have either completed home health aide training requirements or must have successfully completed a hospice's orientation addressing the needs and concerns of patients and families coping with a terminal illness. We continue to believe that either home health aide (now referred to as a hospice aide) training or hospice orientation provides sufficient knowledge for an individual

to function as a homemaker under the supervision of the IDG, and our final requirements at §418.76(j) and §418.76(k) reflect this.

Comment: Several commenters requested that we define the term "nursing services." Most of these commenters defined the term to include those services furnished by a registered nurse, licensed practical nurse (LPN), licensed vocational nurse (LVN), nurse practitioner or other advanced practice nurse. However, the commenters were divided on whether or not services should be allowed to be delegated by a nurse to a hospice aide and whether these delegated services should be considered nursing services.

Response: The intent of section 1861(dd) of the Act has always been to require hospices to furnish nursing services to their patients as part of the Medicare hospice benefit. Hospices have complied with this requirement for the past two decades using the services of a variety of different categories of nurses ranging from nurse practitioners to licensed vocational nurses to registered nurses. Hospices have not, to our knowledge, had any difficulty in determining what constitutes nursing services and we see no reason to establish a definition for the term at this time.

It is important to point out that if we had included

delegated services in the definition of the term “nursing services,” then the inclusion would effectively prohibit hospices from contracting for hospice aide services. We believe that this de facto prohibition would occur because those contracted hospice aides would routinely be furnishing delegated nursing services, and section 1861(dd) of the Act requires that substantially all nursing services should be furnished by direct hospice employees. We do not think that the commenters intended to establish this de facto prohibition on contracting for hospice aide services.

Comment: A commenter asked us to define the term “covering physician” as a physician acting on behalf of the attending physician.

Response: The term “covering physician” did not appear in the proposed rule. If the patient’s attending physician is not available to care for his or her patients, then a hospice physician would assume care responsibilities. In accordance with the proposed and final rule at §418.64(a)(3), a hospice is responsible for providing an alternate physician to meet the medical needs of the patient in the attending physician’s absence.

Comment: A few commenters asked us to add a definition for the term “social worker.” Some commenters proposed

maintaining the current definition as an individual with a Bachelors degree in Social Work from an accredited university. Others suggested raising the requirement to a Masters degree in Social Work from an accredited university.

Response: We believe that the commenters raise important issues, which are discussed in a subsequent portion of the preamble. We are relocating the credential requirements for social workers from the definitions section to the new personnel requirements section (§418.114). We believe that this new, central location for all credentialing requirements is the appropriate location for the social work credentialing requirements as well. Therefore, we are addressing these suggestions in the personnel qualifications section of this rule.

Comment: Several commenters asked us to add definitions for the four levels of care provided in hospice (routine home care, continuous home care, respite care, and general inpatient care). A few commenters even provided their own definitions for these levels of care.

Response: These “levels of care” are payment rather than health and safety issues, and therefore we are not addressing them in this rule. These terms are used specifically in reference to our hospice payment rules found at 42 CFR 418 Subpart F “Covered Services” and Subpart G

"Payment for Hospice Care." In these two subparts, specific criteria for these payment levels are detailed, and these criteria constitute the definitions for these payment terms.

Comment: Some commenters asked us to define the term "plan of care," and suggested the plan of care should be defined as a written document that addresses the patient and family needs identified in the comprehensive assessment and is updated as needed.

Response: We agree with the commenters that the plan of care must be a written document and that it must address the status of the patient and family as identified in the comprehensive and updated assessments. We also agree that the plan of care should be updated as frequently as necessary based on changing status and needs. We do not believe that it is necessary to define "plan of care" because pertinent issues are being specified in this final rule at §418.56, "Interdisciplinary group, care planning, and coordination of services." Section 418.56 requires that a hospice IDG "prepare a written plan of care for each patient. The plan of care must specify the hospice care and services necessary to meet the patient and family-specific needs identified in the comprehensive assessment as such needs relate to the terminal illness and related conditions." In addition, §418.56(d) will require that the

plan of care be updated by the IDG “as frequently as the patient’s condition requires, but no less frequently than every 15 calendar days.” We believe that these requirements adequately address the commenters’ concerns.

Comment: A commenter requested that we define the term “spiritual assessment” to ensure that these assessments address more than a person’s religious affiliation.

Response: Our inclusion of “spiritual assessments” in hospices should not be solely related to religious affiliation (or lack thereof). These assessments might focus on a patient’s sense of peace, purpose, beliefs, etc., but may not be warranted for all patients, particularly if they already have an available spiritual/emotional support system. Therefore, we do not believe that it is in the best interest of hospice patients and hospice providers to prescribe exactly what constitutes a spiritual assessment. A definition may unintentionally interfere with the individualized, patient-centered hospice care that we require hospices to furnish. We do not intend for this regulation to suggest that any spiritual counseling or services be provided to a hospice patient or family against their wishes.

Comment: Many commenters asked us to define the phrase “patient’s home” or “patient’s residence” as a house,

apartment, SNF/NF, ICF/MR, assisted living facility, adult home, shelter, foster home or any other place where a patient lives.

Response: We are unable to develop a single definition of the terms “home” or “residence” at this time. We will consider these suggestions for future rulemaking.

Comment: Many commenters requested a definition of the term “facility” as it is used in proposed and final §418.112.

Response: The general term “facility” has been removed from this condition of participation (CoP) in favor of a more specific list of the facility types to which §418.112 applies. As the general term no longer appears in the rule in the context of §418.112, it is no longer necessary to define it.

Comment: A commenter suggested that we define the term “hospice patient” as a patient who has been certified as being terminally ill and who has accepted the care of a hospice agency.

Response: There is no single definition of “hospice patient” that can encompass all types of patients treated by a hospice and all eligibility criteria for all payment sources. Certifying a patient’s terminally ill status is a Medicare and Medicaid payment requirement that does not

necessarily apply to other health insurance or private pay patients. To say that un-certified patients are not “hospice patients” by excluding them from the definition would be inappropriate. However, “hospice patients” for Medicare payment purposes are those Medicare beneficiaries certified under §418.22 and electing hospice services under §418.24. Furthermore, we note that the term “hospice patient” does not appear in statute or regulation, and, as such, we do not believe that it requires a definition in this rule.

3. Condition of Participation: Patient’s rights (Proposed §418.52)

We proposed to replace the existing CoP, Informed consent, at §418.62, with a new patient rights CoP. The proposed patient rights CoP was divided into five standards. The first standard,”(a) Notice of rights,” would have required hospices to develop a notice of rights, including information about advance directives and the hospice’s controlled drug policies. Under the proposed requirement, hospices would have been required to present the notice of rights verbally (meaning spoken) and in writing to patients and families in a language and manner that they are able to understand. This would have occurred before the hospice furnished care to a patient and family. Hospices would also

have been required to document the patient's or representative's understanding of the notice of rights.

In standard (b), "Exercise of rights and respect for property and person," we proposed that the patient would be able to exercise his or her rights, be respected, voice grievances, and not be subjected to discrimination or reprisal. We also proposed that hospices would investigate and report all alleged violations of patient rights, and take appropriate corrective action where necessary.

The third standard, "(c) Pain management and symptom control," proposed that patients would have the right to receive effective pain management and symptom control from the hospice.

Standard (d), "Confidentiality of clinical records," proposed that hospices would be required to maintain the confidentiality of clinical records in accordance with the Privacy Rule published in the **Federal Register** on December 28, 2000 (65 FR 82461) as amended on August 14, 2002 (67 FR 53182) and set out at 45 CFR parts 160 and 164.

Finally, the fifth standard, "(e) Patient liability," proposed that patients would be informed about the extent to which payment may be expected from the patient, Medicare or Medicaid, third-party payers, or other sources, verbally and in writing in a language that the patient was able to

understand. This standard proposed that this information would be provided to patients before care was furnished. The intent of this standard was to ensure that patients were aware of their potential out-of-pocket costs for hospice care, such as co-payments, so that they would not be surprised by financial concerns at this stressful time.

Comment: A majority of commenters on this issue expressed concern about the proposed requirement that hospices provide a notice of the patient's rights and responsibilities verbally, as well as in writing, in a language and manner that the patient would understand. Many of these commenters requested that hospices not be required to furnish written notices in obscure or otherwise uncommon languages. Other commenters requested that the choice of language(s) used to communicate be left to the discretion of each hospice or that the communication be done in accordance with guidance issued by the Department of Health and Human Services (HHS) related to Title VI of the Civil Rights Act of 1964, Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons. Still other commenters requested that we specifically recognize in the regulation that interpreters, family or otherwise, be permitted to facilitate communication of the notice of rights to patients and families.

Response: We recognize that this is an area of concern for hospices, as it may be challenging for hospices to communicate with patients who speak languages other than English. However, ensuring that patients are aware of their rights and how to exercise them are vital components of improving overall hospice quality and patient satisfaction. If patients are unaware of their rights or the methods and protections available for exercising those rights, then hospices cannot expect to receive valid feedback from patients on ways to improve their services. Without the valid feedback, true quality measurement and improvement cannot exist. Therefore, we believe it is in the interest of patients and hospices to ensure that all patients, regardless of their communication needs, are informed of their patient rights.

Even so, we are sensitive to the concerns of hospice providers. The HHS guidance on Title VI (August 8, 2003, 68 FR 47311) applies to those entities that receive federal financial assistance from HHS, including hospices. This guidance presents four areas for hospices to consider when developing and implementing strategies to meet the needs of limited English proficient persons. The guidance recognizes the role of professional translation services, as well as family and friends of the patient, in communicating

important information to patients, including the notice of rights. Hospices are already expected to comply with the HHS guidance, and doing so will enable them to comply with the requirements of the proposed rule.

Using family and friends as translators should not be the communication plan of choice for the hospice for its patients who do not speak English, unless the patient specifically requests this approach. Hospices should make all reasonable efforts to secure a professional, objective translator for hospice-patient communications, including those involving the notice of patient rights. Furthermore, hospices should make all reasonable efforts to have written copies of the notice of rights available in the language(s) that are commonly spoken in the hospice's service area. For those patients who speak uncommon languages in areas where professional translators for those languages are not readily available, using family and friends of the patient is an acceptable option.

Comment: A commenter asked that we explicitly specify in §418.52(a)(2) that patients have the right to refuse to formulate advance directives.

Response: Under this final rule, hospices are required to comply with 42 CFR Part 489 Subpart I, "Advance directives." Patients may choose to develop advance

directives in accordance with applicable State requirements. Likewise, they may choose to not formulate advance directives. We believe that 42 CFR 489 adequately addresses all aspects of advance directives, including patient choice. Therefore, we are not adding the commenter's suggestion.

Comment: Some commenters asked that we clarify what type of documentation would be necessary to demonstrate that the hospice provided patients with a notice of rights and that the patient or representative demonstrated an understanding of the rights. A majority of commenters noted that language in the proposed rule, "demonstrated an understanding of," was imprecise and difficult to measure. Additional commenters suggested that language from the home health agency CoPs at 42 CFR 484.10 should be used in the hospice CoPs. Section 484.10 states that "the HHA must maintain documentation that it has complied with the requirements of this section." This language, commenters noted, would allow hospices to determine in their own policies how the documentation would be handled. Several other commenters suggested that hospices be required to obtain the patient's or family's signature, confirming that they received the notice of rights.

Response: We agree that a more precise requirement will help hospices ensure that patients and families are

fully informed about the notice of rights. Furthermore, we agree that more precise language will help hospices ensure that they are in compliance with our documentation requirements. Therefore, this final rule at §418.52(a)(3) states, “The hospice must obtain the patient’s or representative’s signature confirming that he or she has received a copy of the notice of rights and responsibilities.”

Comment: Some commenters noted that State practices and laws may govern a legal representative’s exercise of a patient’s rights as described in §418.52(b)(3). The commenters requested that we add the phrase “and practice” at the end of this requirement so it would read: “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 and practice.”

Response: Without more specific information from the commenters regarding what practices states may unofficially have in place, we do not believe that it is appropriate for us to add the phrase “and practice” to the requirement at this time. If more specific information is made available at a future time, we will reconsider this suggestion.

Comment: Many commenters had concerns about the scope

of the responsibilities of hospices when investigating and reporting violations of patient rights by hospice staff. In addition, the commenters had concerns about the proposed timeframes for investigating and reporting alleged violations to local authorities and State survey agencies. Specifically, the commenters noted that it would not be necessary to notify State and local bodies having jurisdiction about unverified violations. The commenters also noted that alleged violations may occur several days before the hospice becomes aware of them, and indicated that the reporting timeframe should not begin before a hospice even becomes aware of the alleged violation. Numerous commenters suggested that the patient rights requirement in the home health agency regulations at §484.10 might be more appropriate, while others suggested that the investigation and reporting requirements be deleted in their entirety.

Response: Requiring hospices to investigate potential violations of patient rights by hospice staff (including contracted or arranged services) will protect patients and their families. Reporting violations (when verified in accordance with hospice policies and procedures and any applicable State and local laws and regulation) is an integral part of improving the quality of hospice care provided to Medicare beneficiaries. At the same time,

adopting regulations more in line with those currently in the home health agency rules would not, we believe, be appropriate for the hospice industry because hospices typically care for more fragile patients and families in a wider variety of patient care settings, such as private homes, long term care facilities, and hospice inpatient units. The home health agency requirements are narrower than what we are requiring. We believe that a broader framework in these hospice regulations, coupled with a hospice's own policies and procedures, will allow hospices to adapt the requirements to the particular needs and concerns of their patient populations now and in the future.

However, we agree that further clarifications are warranted to ensure that a hospice assumes full responsibility for its staff, while not overwhelming the hospice with responsibilities beyond its control. To that end, we are requiring hospice staff that discover alleged violations to immediately report such allegations involving anyone furnishing services on behalf of the hospice, including contracted and arranged services, to the hospice's administrator. The hospice administrator must investigate violations involving anyone furnishing services on behalf of the hospice and, if verified, the hospice must report the violation to State and local bodies having jurisdiction

within 5 working days of any member of the hospice staff (including those furnishing contracted or arranged services) becoming aware of the violation in accordance with the hospice's own policies and procedures. We would expect that significant violations, such as illegal actions by hospice staff, would be reported to State and local bodies. We believe that these modifications will ensure that violations are fully addressed while not overburdening hospices.

Comment: A single commenter requested that we defer to State requirements for violation reporting.

Response: If State requirements for reporting violations are stricter than our Federal requirements, then those stricter State requirements would take precedence. Stricter State requirements may be those that require violations to be reported regardless of whether they are verified or not, or requirements that verified violations be reported in less than 5 days. However, if State requirements are less stringent than Federal requirements, then the Federal requirements will take precedence. We believe that the scope and timeframes contained in this final rule are the minimum health and safety requirements with which facilities could reasonably be expected to comply.

Comment: Several commenters specifically focused their

concerns on the implementation of proposed §418.52(b)(4) in the context of the dual and possibly overlapping responsibilities of hospices that provide services to residents of long term care facilities. In particular, commenters suggested that hospices should only be held responsible for those individuals functioning on behalf of the hospice and that concerns pertaining to individuals functioning on behalf of the long term care facility should be the responsibility of that facility.

Response: We agree that hospices should only be held responsible for investigating and reporting violations pertaining to their own employees and contractors. To address this comment, at §418.112(c)(8), we are setting forth a requirement that the written agreement between the hospice and the SNF/NF or ICF/MR must contain a provision whereby the hospice must report all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property by anyone unrelated to the hospice to the facility administrator within 24 hours of the hospice becoming aware of the alleged violation.

This requirement will assure that the SNF/NF or ICF/MR is made aware of the alleged violation in a timely manner so that it can begin its own investigation and implement its

own intervention(s). A hospice may also want to consider incorporating a provision in the contract to require a SNF/NF or ICF/MR to notify the hospice if any of its staff become aware of a potential patient rights violation involving hospice staff. Such a provision may enhance hospice-facility communication and cooperation. In addition, we will consider this issue when developing complementary regulations for long term care facilities.

Comment: A few commenters asked that we define the term “immediately” as it applies to the timeframe for reporting alleged violations to the hospice’s administrator. The commenter recommended that the timeframe for reporting alleged violations be based on an assessment of the patient’s needs.

Response: It is in the patient’s best interest to involve the hospice administrator at the time that the potential violation is noted to assure that the situation is adequately and expeditiously dealt with. Once notified, it is up to the hospice’s policies and procedures and the hospice administrator’s judgment, in accordance with this rule, to handle the allegation. The hospice administrator is the designated leader of the hospice and assumes responsibility for the care and services furnished by the hospice, whether directly or under contract. This is a 24-

hour a day responsibility, and it applies to incidences of alleged violations.

Comment: Some of commenters expressed concern regarding the manner in which the terms “mistreatment” and “injury” are used in the proposed patient’s rights CoP. They believe the terms to be vague and too difficult to judge objectively.

Response: The terms “mistreatment” and “injury” encompass two important areas that affect patient safety and satisfaction. While other terms such as “abuse” and “neglect” imply actual harm to a patient, “mistreatment” is a broader term that encompasses quality of life issues that are crucial as patients and families cope with death and dying. We understand that the broad nature of the term makes it difficult to judge. This judgment difficulty is exactly why we are requiring hospices to conduct their own internal investigation into the potential patient rights violation. We are leaving these terms mostly undefined so that hospices may determine whether “mistreatment” or “injury” have occurred on a case-by-case basis. State tort liability laws may serve as a guide for hospices in determining whether “mistreatment” or “injury” have occurred. Through a thorough investigation, hospices can determine, in accordance with their own policies and

procedures, whether mistreatment occurred and what steps need to be taken to resolve the mistreatment and prevent future occurrences.

The presence of the term “injury” is also important in this standard because it addresses other issues that may not constitute “abuse” or “neglect” but that nonetheless impact a patient’s well-being. We understand that some relatively minor injuries such as skin tears may be perceived as injuries. By maintaining the term “injury” in this standard, hospices are required to fully investigate incidents of minor injuries (like skin tears) to determine if they constitute a violation of a patient’s rights. If the internal investigation reveals that all appropriate steps were taken to prevent the minor injury, then the hospice may determine that the injury is not a violation of a patient’s rights. However, if the investigation reveals that reasonable precautions were not taken, then the hospice may determine that the injury is a violation of patient rights. In setting forth a standard in the final rule that requires hospices to report patient injuries to the hospice administrator, hospices have the opportunity to conduct a self assessment to determine if care processes need to be changed to improve the consistent delivery of quality care.

Comment: Some commenters asked for clarification

regarding proposed §418.52(c), which reads, “The patient has a right to receive effective pain management and symptom control from the hospice.” While the commenters supported the intent of this standard, they questioned its scope. One commenter wanted to know whether this standard would require hospices to furnish continuous home care, while another questioned if hospices were supposed to be responsible for pain and symptom management unrelated to the terminal and related conditions. Still another commenter suggested that hospices should be allowed to refer patients to other providers for pain and symptom management.

Response: Effective pain and symptom management have long been the hallmark of hospice care, and we appreciate that the commenters recognized the importance of this patient right. We agree that hospices are required to furnish pain and symptom management for the terminal illness for which the patient is receiving hospice care and conditions related to the terminal illness. We have revised this standard and clarified this point at §418.52(c)(1). The continuous home care level of care described in the payment and coverage sections at 42 CFR 418.204 and 418.302 may or may not be the most effective way to provide effective pain management and symptom control while maintaining a patient at home.

It is acceptable for hospices to refer pain and symptom control issues unrelated to the terminal illness and related conditions to other providers. If a hospice were to make a referral, we would expect the hospice to coordinate its efforts with the other provider to avoid duplicative or contradictory therapies in accordance with final §418.56(e)(5). The goal of this coordination is to ensure that the patient's hospice plan of care is implemented, and that the hospice care is furnished in concert with other care sources to ensure that all patient needs are met. In accordance with §418.100(c) hospices are responsible for pain and symptom management related to the terminal illness and related conditions and should not refer patients to other providers for these issues. If a hospice does not have the expertise to handle pain and symptom management issues related to the terminal and related conditions, it is responsible for procuring the expertise for the patient as part of its regular hospice services.

Comment: Many commenters suggested that we should add provisions stating that patients have the right to refuse treatment and the right to be involved in developing their plans of care.

Response: We agree that these are important patient rights that should be included in this final rule. We

believe that including these rights, at new §418.52(c)(2) and §418.52(c)(3) respectively, will help to ensure that the patient's goals and needs are consistently reflected in the hospice's plan of care and actions.

Comment: A few commenters requested that we add a provision requiring hospices to provide patients with a written statement of the scope of care and services that will and will not be provided. One commenter requested that we add a provision stating that patients have the right to receive information about the services covered under the hospice benefit.

Response: We agree that providing a patient with general information about his or her hospice benefit is an important step in ensuring that hospice patients are educated about their rights. Therefore, we are establishing section 418.52(c)(7), which requires hospices to provide this general benefit information.

We also agree that providing a patient with general information about the scope of services that the hospice provides, as well as any limitations on those services, will further empower hospice patients and their caregivers to take an active role in hospice care planning. Providing the patient and family a list of services that the hospice may provide gives the patient and family an opportunity to

request specific services that the IDG had not considered. Simply knowing that help is available may lead patients and families to reach out for it. For this reason, we are establishing section §418.52(c)(8), which requires hospices to provide information about the scope of services that the hospice will provide to its patients, and specific limitations on those services.

Comment: A single commenter requested that we add a specific provision stating that patients have the right to continue to maintain a relationship with their attending physician once they elect the hospice benefit.

Response: It is understood and widely accepted throughout the health care community, including in the hospice industry, that patients should be allowed, even encouraged, to continue to work with their attending physicians as they transition from one health care provider or setting to another. The goal of this practice is to enhance continuity and quality of care by actively including the attending physician, who knows that patient's medical and family history, in planning and delivering the patient's hospice care. We believe that this is in the best interest of patients and providers. Explicitly identifying a patient's right to choose his or her attending physician without undue influence from a hospice will help ensure that

hospices and patients continue to benefit from the knowledge of attending physicians. Therefore, we have added this patient right at §418.52(c)(4).

Comment: A commenter requested that we add a provision stating that patients have the right to access, request amendments to, and receive an accounting of disclosures regarding their health information.

Response: Patient rights regarding their health information are explicitly addressed in the HIPAA regulations at 45 CFR 164.502(a)(2)(i) and 164.524. Hospices are already required to comply with these extensive regulations, and we see no need to duplicate the HIPAA patient rights requirements in this rule. Therefore, we are not adding this suggested provision.

Comment: Many commenters expressed confusion and concern about our proposed requirement that hospices notify patients of the extent to which payment may be expected from the patient before care is initiated. Commenters sought clarification on how this requirement would dovetail with the Advanced Beneficiary Notice (ABN), long term care facility payments, and private health insurance payment rules. In addition, commenters wanted to know if, before care is initiated, hospices would be required to advise patients of those services that would not be covered by the

hospice because those items would not be in the plan of care, even though the plan of care had not yet been formulated. Some commenters suggested that, rather than providing exact dollar amounts for patient liability, we should require a more general description about co-pays, Medicaid spend down requirements, etc. Other commenters requested that this notice not be in writing or that it be provided at the time of the initial assessment rather than before any care is provided. A single commenter requested that the requirement be phased in over a period of time.

Response: The original intent of this proposed standard was to educate patients and families about their potential liability in consideration of all available payment sources. Patients and families often come to hospice after long illnesses with pressing financial concerns. In requiring hospices to provide information when services are first provided (particularly on Medicare's comprehensive benefit with minimal co-pays) we sought to alleviate some of those financial worries. However, as many commenters noted, hospices regularly provide this payment overview as part of their patient intake process when patients are choosing whether or not to elect the hospice benefit. We encourage hospices to continue this practice. Furthermore, commenters noted that financial liability for

long term care facility residents becomes very complicated and uncertain because of the patient's residential status. Information provided before the start of care is likely to be inaccurate because hospices do not control the resident's long term care facility liability. The proposed timing of the notification and its all-encompassing nature make it impractical for hospices to implement and would likely not increase the benefit of hospice services to patients and families. Therefore, we are deleting this requirement. We believe that the existing ABN requirements at 42 CFR 411.404, which require hospices to notify patients should a particular service or item potentially not be covered by Medicare, provide the most timely and accurate information to patients and families. The ABN should be delivered far enough in advance that the patient or representative has time to consider the options and make an informed choice. The ABN should be verbally reviewed with the patient or representative and any questions raised during that review should be answered before it is signed.

Comment: A commenter requested that we add a provision to the patient's rights CoP stating that patients have the right to refuse to participate in experimental research.

Response: Ethical research practices dictate that patients must choose to participate in experimental research

and that their participation or lack thereof may not negatively impact their well-being. In addition, although we acknowledge that it may occur at times, experimental research in palliative care is not, to our knowledge, a common occurrence. We believe that the existing patient opt-in research standard, combined with the rarity of the situation, does not warrant us issuing a new standard within this CoP.

Comment: A few commenters suggested that we should add a provision, either in the “Patient’s rights” requirement or other requirements, that ensures that long term care facility residents are provided a choice of which hospice furnishes their care.

Response: We are aware of concern within the hospice industry about long term care facilities that choose to not contract with hospice providers, or to only contract with a single hospice provider to furnish hospice services to residents. However, authority to govern long term care facilities’ actions is not contained in the hospice regulations found in 42 CFR part 418. Therefore, we are not adding the suggested requirement. We will however, take these comments into consideration as we review the long term care CoPs for possible future revisions that would address this aspect of long term care facility responsibility

relative to the care of residents.

Comment: Some commenters requested that we require hospices to recognize board-certified chaplains as advocates for patient rights in hospices.

Response: We expect that all hospice employees and contractors should be patient rights advocates with the best interest of the patients in mind at all times. We are not requiring that hospices use patient advocates. However, if hospices choose to designate specific patient rights advocates, they are free to do so, and are free to select those individuals who are best suited for the task. Board-certified chaplains may serve well in the patient rights advocate capacity, and hospices are free to explore this option.

Comment: Another commenter requested that we add a provision stating that patients should not be denied hospice care based on the cost of their reasonable and necessary palliative care.

Response: Decisions about admission to hospice fall outside of the purview of this rule, which focuses on ensuring the safe and effective provision of quality care to patients and their families once the patient is admitted to a hospice. Although we take this issue very seriously, we are not incorporating the suggested provision in this rule.

We note that providers, in general, cannot be required to provide services to Medicare patients (see Section 1802(a) of the Social Security Act).

Comment: A single commenter suggested that patients should be required to demonstrate their willingness to comply with the plan of care.

Response: We understand that patient noncompliance is occasionally an obstacle for hospices in providing safe and effective hospice care. However, we have no authority to mandate patient compliance. It is the hospice's responsibility to fully educate the patient and family regarding hospice care, as well as hospice policies and procedures for handling plan of care disagreements, emergencies and other situations that may prompt patient noncompliance. For these reasons we are not adding a patient compliance provision.

Comment: A single commenter suggested that hospices be required to comply with any additional State reporting requirements for elder abuse.

Response: We agree that hospices should be required to comply with all health and safety related Federal, State and local laws and regulations, which would include reporting requirements for elder abuse. This rule finalizes §418.116, "Compliance with Federal, State and local laws and

regulations related to the health and safety of patients," which requires hospices to comply with State elder abuse reporting requirements.

4. Condition of participation: Initial and Comprehensive assessment of the patient (Proposed §418.54)

The proposed assessment requirement identified the general areas that would be included in a patient assessment and the time frames for completing the assessments to help hospices ensure that they were identifying needs in all areas in a timely fashion.

The proposed comprehensive assessment requirement was divided into five standards. The first standard, (a), "Initial assessment," would require a registered nurse to make an initial assessment visit within 24 hours of receiving a physician's admission order for care, unless ordered otherwise by the physician. The purpose of this initial assessment was to determine the patient's immediate care and support needs. In the proposed rule we differentiated this initial assessment from the hospice's evaluation of a patient's appropriateness for hospice care. We stated that visiting a patient to determine his or her appropriateness for hospice care does not constitute an initial assessment.

The second standard, (b), "Time frame for the

completion of the comprehensive assessment," proposed that the hospice IDG and the patient's attending physician complete the comprehensive assessment no later than four calendar days after the patient elected the hospice benefit. The four day time frame was proposed because many hospice patients are admitted to hospice late in their terminal illness and often require intensive hospice services at the beginning of their hospice stay. A hospice must assess a patient to identify his or her needs before it can develop and implement a plan of care to meet those needs. Therefore, a timely assessment is necessary to properly care for a patient.

In the third standard, (c), "Content of the comprehensive assessment," we proposed that hospices identify the physical, psychosocial, emotional, and spiritual needs of the patient related to the terminal illness and related conditions. As proposed, the comprehensive assessment would include information about the terminal condition, complications and risk factors, an initial bereavement assessment, a drug profile review, and any further referrals or evaluations, as appropriate. We did not propose that hospices use a specific assessment form or tool.

Under proposed standard (d), "Update of the

comprehensive assessment," the hospice IDG would be required to update each patient's comprehensive assessment no less frequently than every 14 days and at the time of each recertification. The proposed comprehensive assessment update would document changes that had occurred since the last assessment, including the patient's progress toward desired outcomes and the patient's response to the care furnished by the hospice. We proposed these update time frames because the condition of a hospice patient is expected to change over the course of hospice care, and often does so quite rapidly, considering that the median length of a hospice stay is about 26 days.

The final standard in this proposed CoP, (e), "Patient outcome measures," would require hospices to include, as part of the information gathered by the comprehensive assessment, data elements to allow hospices to measure patient outcomes. This standard proposed that the data elements would be collected and documented in the same manner for all patients in order to ensure the accuracy and consistency of the data. Hospices would be required to use the data in individual care planning and the quality assessment and performance improvement program described in proposed §418.58. We did not propose to require hospices to use any specific patient outcome measures or data elements.

Comment: Many commenters requested that we clarify in the opening paragraph of the CoP that hospices are not required to assess a patient's condition beyond the patient's need for hospice care and services related to the terminal illness and related conditions. Commenters suggested that we delete the phrase "but is not limited to" because it implies that hospices are required to assess and address areas beyond the boundaries of the terminal illness and related conditions.

Response: The Medicare hospice benefit covers all care provided by hospices for the palliation and management of an individual's terminal illness and related conditions. Hospices are required to furnish these services; however, they are not required to furnish services for needs unrelated to the terminal illness and related conditions. Our intent in specifying that hospices are not limited to assessing the patient's status and needs associated with the terminal and related conditions was to explicitly permit hospices to look beyond the terminal and related conditions to gain a complete picture of the patient. We did not intend to imply that hospices would be required to provide care for those issues that are outside of the scope of hospice care under the hospice benefit. In order to clarify our intent in the second sentence of the CoP, we have

removed the phrase “but is not limited to” and we have replaced the word “care” with “assessment”. The final sentence of the introductory paragraph at 418.54 now reads, “This assessment includes all areas of hospice care related to the palliation and management of the terminal illness and related conditions.”

Modifying the requirement does not mean that hospices are prohibited from identifying and/or addressing issues and areas of patient need outside of the hospice benefit, even though hospices are not responsible for providing services for these issues. Indeed, not gathering the information may make it more difficult for hospices to effectively plan to care for a patient because important information would not be available when making care planning decisions.

Comment: The majority of commenters who submitted comments in this section expressed concern about the timing of the initial assessment. Commenters seemed unclear about the proposed requirement that hospices would have 24 hours from the time that a physician order is received to make the assessment. Additionally, commenters were concerned that the proposed rule, as written, would not allow hospices to adjust the initial assessment timeframe based upon patient and family wishes. Many commenters specifically requested that we replace the term “physician’s order for care” with

“physician’s certification”, which would require the assessment to be completed after the physician has certified that the patient is terminally ill and thus an appropriate candidate for hospice care. A few commenters explicitly disagreed with this suggestion. Several other commenters questioned the role that the patient’s election to receive hospice care played in determining when to begin the time frame for completing the assessment.

Response: We agree that a more definitive time point needs to be established and that patient and family wishes should be taken into account when establishing this time frame. We recognize that some patients are self-referred and therefore may not have a physician’s order for hospice care. These patients could create uncertainty in hospices because hospices would not know when to begin the 24 hour period for completion of the initial assessment. This uncertainty could lead to situations of non-compliance that are out of the hospice’s control. We do not believe that this would be in the best interest of patients or hospices; therefore, we are revising the timeframe language as requested by many commenters.

In order to clarify the length of time that hospices have to complete the initial assessment, we have referenced language used in Subpart B, Eligibility, election and

duration of benefits, of the existing hospice regulations, into the initial assessment requirement at §418.54(a). Once a hospice has obtained an election statement for a particular Medicare or Medicaid patient in accordance with the requirements of Subpart B, the hospice has 48 hours to complete the initial assessment, unless the patient, his/her representative, and/or physician request an expedited time frame. Since election requirement is particular to the Medicare and Medicaid hospice benefits, hospices are free to establish a similar starting point for non-Medicare and Medicaid patients in their own policies, based on the needs of the hospice, its community, and any applicable State and local laws and regulations.

We also agree that the needs of patients or their representatives should be taken into consideration when completing the initial assessment. There are times when patients or representatives may want to expedite the initial assessment, and their wishes, along with the health status of the patient, should be taken into account when scheduling and completing the initial assessment. For example, a patient’s representative may request that the hospice complete the initial assessment in a shortened timeframe because the patient is in acute distress and requires immediate hospice assistance. We would expect the hospice

to consider the patient's or representative's request for a change in the initial assessment timeframe when scheduling the necessary visit(s) to complete the initial assessment. Therefore, we have modified the language to state that the patient or representative may request that the initial assessment be completed in less than 48 hours.

If a patient or representative wishes to delay the completion of the initial assessment, it would not be appropriate to have that patient or representative elect the hospice benefit. When a patient elects the hospice benefit she waives the right to receive all other Medicare covered services for the terminal illness and related conditions. If the patient may not receive all other Medicare covered services for the terminal illness and related conditions, and that patient cannot receive hospice services because she has not received an initial assessment to determine her immediate care needs, then the terminally ill patient is effectively without health care for the intervening time period. We do not believe that this is an acceptable situation.

Standard (a), "Initial assessment," now states, "The hospice registered nurse must complete an initial assessment within 48 hours after the election of hospice care in accordance with §418.24 is complete (unless the physician,

patient, or representative requests that the initial assessment be completed in less than 48 hours)."

Comment: A few commenters expressed support for separating the initial assessment from the comprehensive assessment.

Response: We agree that separating the assessment requirements will enable hospices to quickly assess the most critical areas of need and begin furnishing appropriate care while ensuring that all areas of need are assessed by the appropriate disciplines in a timely manner.

Comment: Some commenters requested that we replace the requirement that hospices complete initial assessments within 24 hours with a requirement that hospices make or make available an initial patient contact within 24 hours of receiving a referral. In addition, commenters requested that any hospice employee, or at least an RN or social worker, be permitted to make this initial contact.

Response: We understand there may be some confusion in the hospice community about the purpose of the initial assessment. The purpose of the initial assessment is to gather the critical information necessary to treat the patient's immediate care needs. The initial assessment is not a "meet and greet" visit whereby the hospice introduces itself to the patient and begins to evaluate the patient's

interest in and appropriateness for hospice care. As the commenters stated, the initial patient contact takes place before the hospice assumes responsibility for the patient's care. Hospices may choose the time frame and appropriate individual for completing this initial contact.

It is not appropriate to substitute an initial contact for an initial assessment. Merely requiring an initial contact within 24 hours would not be sufficient to meet the needs of critical patients. Patients often come to hospice in moments of crisis. An initial contact when a patient is in need of timely assistance would be a disservice to the patient and family and would not lead to effective, high quality care. Hospices may choose to send a social worker or other discipline to complete the initial assessment along with the RN, and this may lead to better patient outcomes and satisfaction. Because other disciplines do not have the skills necessary to independently complete the initial assessment, we are not incorporating the commenters' suggestions.

Comment: Several commenters suggested that we change the phrase "RN must make an initial assessment visit" to "RN must complete an initial assessment." Similarly, another commenter suggested that we require that "the hospice registered nurse must perform and document an initial

assessment visit." The commenters stated that their proposed revised language would clarify our intent that, rather than simply making a visit to begin the initial assessment, the initial assessment must be fully complete within the specified timeframe.

Response: The commenters are correct in their assertion that the initial assessment must be completed, not just started, within the timeframe. Completing the initial assessment, which means that it is both performed and documented, enables the hospice to determine the patient's immediate care and support needs in a timely manner. An accurate determination of care and support needs cannot be made until the initial assessment is complete; therefore, we agree that it is necessary that it be completed within 48 hours. We have clarified the requirement to read, "The hospice registered nurse must complete an initial assessment within 48 hours… ."

Comment: A few commenters questioned the role of the hospice physician in completing the initial assessment.

Response: The initial assessment completed by hospice staff must address the patient's critical physical, psychosocial and emotional status related to the terminal and related conditions. It is likely not the most efficient use of a physician's time to complete a task (the initial

assessment) that can be fully handled by a registered nurse. Therefore, we continue to require that a registered nurse complete the initial assessment. This requirement in no way prevents a hospice from using the knowledge and skills of both a registered nurse and a physician to complete the initial assessment. A physician who is employed by or under contract with a Medicare hospice cannot bill separately for the initial and comprehensive assessments.

Comment: Several commenters requested that we revise the time frame for completing the initial assessment. Suggestions included 48 hours, 72 hours, the close of the day following the day the patient is referred, and 24 hours "when reasonably possible." Other commenters requested that the time frame be deleted completely.

Response: Establishing a clear and consistent time frame for completing the initial assessment is essential to ensuring that patients benefit from hospice care early in their stay. Completing the initial assessment within 48 hours will help hospices gather the essential information to begin a plan of care that addresses the patient's needs before those needs escalate and become extremely difficult to address.

Overall, many commenters stated that the 24 hour timeframe for the initial assessment, as we proposed, was

too restrictive. In this final rule we have effectively increased the length of the time frame by changing its starting point from the time the physician's order is received to the time that the election statement is complete in accordance with the applicable requirement of Subpart B. Under the proposed rule, hospices would have been required to complete the initial assessment within 24 hours of the physician's order to begin hospice care, even if the hospice was unable to schedule a visit with the patient and family within that timeframe. Under the revised final rule language, hospices have 48 hours after the patient elects the hospice benefit to complete the initial assessment. At times, a patient, representative, or physician may request that the comprehensive assessment be completed in a time frame less than 48 hours, and we expect hospices to accommodate such requests when they are made.

Comment: Many commenters questioned the role of the patient's attending physician in completing the comprehensive assessment. Some commenters explicitly requested that hospices should not be required to involve attending physicians. Other commenters requested that a provision be added permitting attending physicians to "opt out" of participating in the assessment. Still others indicated that we should require attending physicians to

approve, in writing, the content of the comprehensive assessment.

Response: The scope of public comments submitted regarding the role of the attending physician in hospice care suggested that there is no single model that applies. Some commenters indicated that community-based attending physicians provide a leading role in hospice care, actively participating in the IDG, writing orders, and even making visits. Some commenters, however, indicated that community-based attending physicians preferred to step back once a patient has elected hospice, typically transferring their patients to the hospice physician's care. While we are pleased to know that there are many attending physicians who wish to stay involved in caring for their patients, these physicians should not assume that their attending physician service role is part of the hospice benefit. Likewise, while we are pleased to know that hospices are fully prepared to care for all of their patients needs, including those needs unrelated to the terminal illness and related conditions that the attending physician would be responsible for, it would be inappropriate for a hospice to influence a patient to relinquish his or her attending physician.

At the same time, we are sensitive to the concerns expressed by the hospices. Some patients do not have

attending physicians. Some patients do not want to continue seeing their attending physicians. Some attending physicians may be unresponsive to, or uncooperative with, the hospice. We do not want to place patients in a position where they must choose between receiving services from their attending physician and their hospice, nor do we want to place hospices in a position where they are forced to handle difficult attending physicians who disrupt their operations.

In light of these considerations, we are maintaining the requirement that hospices consult with the patient's attending physician when completing the comprehensive assessment. Involving the attending physician to the extent possible will allow hospices to gain additional information about the patient. Attending physicians can often provide a lengthy history of the patient's disease process and family dynamics can help the hospice make better care planning decisions that result in improved patient outcomes. In recognition of the fact that not all patients have willing attending physicians, we have added a caveat that this consultation need only occur if there is an attending physician to consult with. In this way, attending physicians may, with the patient's agreement, opt out of following the patient's care through the patient's hospice stay. We are not, as some commenters suggested, requiring

that the attending physician sign a document approving the content of the comprehensive assessment. Rather, we leave it to hospices to define in their own policies and procedures how they will document that they have conferred with the attending physician. We believe that this will give hospices the ability to structure their communication and coordination system in a way that meets their needs for timely information sharing and documentation.

Comment: Several commenters wanted to know if the consultation with the attending physician to complete the comprehensive assessment could be accomplished over the telephone or through electronic communication methods.

Response: A hospice would need to consult with willing attending physicians in accordance with its own policies and procedures. If a hospice's policies and procedures permitted it to consult with attending physicians on the telephone or through electronic communications, then that would be an acceptable practice. Rather than dictate what is or is not an acceptable communication method, this rule seeks to ensure that these communications occur. Effective communication between the hospice and attending physician in completing the comprehensive assessment will enable a hospice to develop a more complete understanding of the patient and family in order to develop a plan of care that

addresses all areas of need related to the terminal illness and related conditions.

Comment: A majority of commenters addressed the issue of the length of time necessary to complete the comprehensive assessment. As with the initial assessment, some commenters questioned the exact time that the time frame began. Some commenters expressed strong support for the proposed four day time frame, with a few commenters even suggesting that, in the future, we should move to a two or three day time frame. Other commenters suggested that the time frame should be lengthened to five, seven, eight, or even 14 days. Some suggested that no timeframe be established at all. Still other commenters suggested that we should add a caveat that completion of the comprehensive assessment should be dependent upon the patient's condition.

Response: Completing the comprehensive assessment is an integral step in hospice care. The information gathered in the comprehensive assessment is the basis for completing the plan of care. If the information is not gathered in a timely manner, then completing the plan of care is delayed. This results in patients and families not receiving all of the services they need in order to maximize comfort and dignity and achieve the patient's and family's hospice care goals. Comprehensive assessment plays an important role in

hospice care and a reasonable time is needed for its completion. The time frames suggested by the commenters varied greatly, with some being so short as to potentially preclude hospices from conducting a truly thorough assessment and some being so long as to virtually ensure that hospices would never be required to complete comprehensive assessments for more than 30 percent of their patients. Neither extreme would successfully meet the needs of patients and hospices.

In the middle are the commenters who suggested maintaining the four day requirement, lengthening it to five days, or lengthening it to seven days. While we appreciate the support from commenters who agreed with the proposed four day time frame, we agree with those commenters who suggested that a longer time frame would be more appropriate due to the scheduling demands of hospice providers. We have lengthened the time frame from four days to five days. Allowing hospices another day to complete the comprehensive assessment will allow more time to schedule the necessary contacts.

While we have lengthened the time frame, we note that it is a maximum, a length of time that should not be exceeded. The time frame should not be misinterpreted to prevent hospices from completing the comprehensive

assessment earlier than five days after the patient or representative elects the hospice benefit. Indeed, we encourage hospices to complete comprehensive assessments in less than five days if at all possible. This is particularly true for patients who enter hospice in crisis. While the initial assessment will provide the necessary information to begin the plan of care for these critical patients, it is the comprehensive assessment that will fill in important pieces of information to be used to maximize the patient and family's physical, emotional and spiritual comfort. While we recognize that a portion of patients enter hospice at the end stage of the disease process and may die in less than five days after electing the hospice benefit, their physical condition does not necessarily absolve hospices of the responsibility to comprehensively assess these patients. The hospice is still responsible for taking all appropriate steps to complete the comprehensive assessment as that assessment is tailored to the patient's areas of need. The ability of hospices to tailor the exact content of the comprehensive assessment, and the individuals who complete it, to the needs of patient and families addresses concerns about extremely short stay patients who may not be contacted by all disciplines before death. We do not expect or require designated disciplines to complete

assessments if those assessments are not indicated as being necessary during the initial assessment and any subsequent contacts.

Comment: A few commenters suggested that we eliminate certain areas from the comprehensive assessment. In particular, commenters suggested that we eliminate the requirement that hospices assess spiritual or potential bereavement issues as part of the comprehensive assessment. Commenters noted that eliminating either of these areas from the comprehensive assessment would make it easier to complete the comprehensive assessment within the required time frame. The commenters acknowledged that these areas would still need to be assessed, and stated that completing the assessments by the time of the first IDG meeting would be sufficient.

Response: As discussed above, we agree that fully assessing all areas may require more than the four days we initially proposed for this process. For this reason, we have extended the timeframe from four days to five days. We believe that this approach, rather than carving out certain sections of the comprehensive assessment, best meets the flexibility needs of hospices and the care needs of patients. In maintaining both the spiritual and bereavement assessment requirements, hospices will be required to ensure

that patient and family specific information about these important areas is gathered in a timely manner to inform the care planning decisions. At the same time, allowing hospices more time to schedule the necessary contacts to gather this information will ensure that hospices have the flexibility to incorporate new patients into existing workloads and schedules. We believe that this solution accommodates the concerns of the commenters without separating these two key areas from the comprehensive assessment.

Comment: Some commenters requested that the final sentence of the introductory paragraph of standard (c) be revised. The commenters stated that characterizing the comprehensive assessment as a description does not fully capture the role of the comprehensive assessment. Commenters suggested that we use either the phrase, “[t]he comprehensive assessment must take into consideration the following factors,“ or the phrase, “[f]actors that must be considered in developing the individualized care plan interventions include“ in its place.

Response: We agree that more expressive language is useful in introducing the elements that the comprehensive assessment must contain. Since both of the suggested phrases achieve the same goal, we chose to incorporate the

more concise statement because it will likely lead to less confusion. Therefore, the final sentence of the introductory paragraph at §418.54(c) states, "[t]he comprehensive assessment must take into consideration the following factors."

Comment: Several commenters suggested that we should add a new element to standard 418.54(c), "Content of the comprehensive assessment," which would address the issue of the patient's functional status and the impact of that status on the patient's ability to understand and participate in care planning and implementation.

Response: We agree that the functional status of the patient, both physically and mentally, impacts the patient's ability to participate in his or her own care and the hospice's ability to furnish that care. Furthermore, we agree that this information should be collected as part of the comprehensive assessment. Therefore, we have added a new element at §418.54(c)(3) that requires hospices to assess the patient's "[f]unctional status, including the patient's ability to understand and participate in his or her own care."

Comment: Several commenters suggested that we add a new element to standard 418.54(c), "Content of the comprehensive assessment," which would address the issue of the imminence

of death.

Response: We agree that assessing the imminence of the patient's death is an important part of the comprehensive assessment. A certain portion of hospice patients have extremely short hospice stays of three days, and sometimes less than that. The imminence of a patient's death will often drive the type and frequency of services provided to a patient. Published studies and reports (Medpac, "Report to the Congress: Increasing the Value of Medicare," Chapter 3, June 2006; Huskamp, H., Buntin, M.B., Wang, V., and Newhouse, J., "Providing Care at the End of Life: Do Medicare Rules Impede Good Care?", Health Affairs, 2001) have noted that hospice per-patient expenditures are highest in the last few days of life. This indicates that the pattern of care for a patient in the last days of life will likely be different than for a patient who is expected to receive hospice services for several weeks or months. Identifying the imminence of death as part of the comprehensive assessment will allow hospices to more accurately tailor the plan of care to the patient's status. We are adding this element as new §418.54(c)(4).

Comment: Numerous commenters suggested that we add a new element to the comprehensive assessment standard (c), which would address severity of symptoms.

Response: We agree that the severity of a patient's symptoms is an important aspect of the comprehensive assessment that should be assessed for all patients, and we have added this requirement as new §418.54(c)(5). Gathering accurate information about symptom severity will allow hospices to make more accurate care planning decisions. We are not prescribing how hospices must assess symptom severity. There are numerous pain and distress scales available for use and we do not endorse one scale over another. Hospices have the discretion to identify the manner in which they will assess and document symptom severity for their patients. We anticipate, over time, that useful tools for patient assessment will emerge, and that the hospice industry will select the most effective and efficient assessment tools to use as part of a standard patient assessment practice. We may revisit the patient assessment requirements in the future to ensure that the requirements reflect current standards of practice.

Comment: Many commenters supported our proposed requirement that hospices complete a medication review for each patient as part of the comprehensive assessment. The commenters suggested that further clarification was needed with regard to the requirement that hospices include a review of a patient's prescription and over-the-counter

drugs. Commenters suggested that this review should included all drugs and alternative therapies, even those unrelated to the terminal illness and related conditions. Furthermore, some commenters suggested that hospices should be required to differentiate in their documentation of this review which drugs were and were not related to the terminal illness and related conditions. Some commenters noted that hospices should not be held responsible for not being aware of drugs that they were not informed of by the patient, family, physician, or other health care provider.

Response: We thank the commenters for their support and agree that the drug profile review should include all drugs, herbal remedies and other alternative treatments that could affect drug therapy, whether those drugs and remedies are related to the terminal illness and related conditions or not. This thorough review must document all substances which the patient is using. While we understand that patients and families may be unwilling to disclose the use of certain substances, we expect hospices to use all available and appropriate methods to develop a complete list. These efforts may include asking the patient, family, attending physician, and any other health care providers. Efforts may also include asking to look at all medications in the home, being attentive to tell-tale odors, and looking

for medication-specific equipment in the home. Hospices may choose how to document the drug profile review and the efforts made to complete it in the manner that best suits their individual needs. While we agree that it may be helpful for hospices to note the relationship of a drug and therapy to the terminal illness and related conditions, we do not believe that it is necessary to prescribe this level of documentation detail in regulation.

Comment: A few commenters suggested that we restructure the comprehensive assessment standard to de-emphasize the bereavement and drug therapy sections of the comprehensive assessment. The commenters acknowledged that these are important areas to assess; however, they believe that their placement within the standard appeared to place more value on these two elements than on the other elements of the standard.

Response: We agree that neither bereavement nor drug therapy should appear to take precedence over the other comprehensive assessment elements. The drug therapy requirements, now referred to as drug profile requirements, are now codified at §418.54(c)(6) and the bereavement requirements are now codified at §418.54(c)(7), on par with the other elements of the standard.

Comment: Many commenters suggested that we should

rephrase the requirement that hospices identify “ineffective drug therapy” as a requirement that hospices assess the “effectiveness of drug therapy.” A single commenter suggested that this requirement should be removed because it is not within the nurse’s scope of practice.

Response: We agree that the phrase “effectiveness of drug therapy” is more inclusive and will help to capture the range of effectiveness of different drugs and therapies. For example, rather than noting that drug B is ineffective and remaining silent on the effectiveness of drugs A and C, this new requirement will require hospices to note for example, that drug A is fully effective, but only for a few hours, drug B is completely ineffective, and drug C is consistently minimally effective. The additional level of detail required by this new provision will help hospices develop a more complete overall assessment from which to make more accurate care planning decisions. This new provision is located at §418.54(c)(6)(i). If a nurse is unable to complete this part of the assessment, then it is appropriate for a hospice to use another discipline to complete the drug profile assessment.

Comment: Some commenters suggested that we require hospices to identify all drug side effects, rather than only those side effects that are not wanted. In addition, the

commenters suggested that we delete the term “toxic” because the phrase “drug side effects” would include issues of toxicity.

Response: Our original intent was to ensure that bothersome side effects were noted in the drug assessment so that they could be addressed in the care planning process. However, as the commenters noted, all side effects should be noted, even if they are desirable. Identifying desirable, as well as undesirable, side effects will help ensure that the desired side effects are not negatively impacted by other drugs and their side effects. Additionally, as the commenters noted, the term “toxic” is unnecessary. Any toxic effects would already be recorded as side effects, rendering the term “toxic” duplicative. Therefore, we are deleting the terms “unwanted” and “toxic” from §418.54(c)(6)(ii), and are simply requiring that the hospice review the patient’s drug profile for side effects.

Comment: Several commenters suggested that we require hospices to evaluate potential as well as actual drug interactions.

Response: We agree that more specificity is needed to clarify our intent. We agree that hospices must identify drug interactions that have occurred in the past or are occurring at the time of the assessment if at all possible,

and must identify drug interactions that have the potential to occur if the patient continues using the same drugs. The lack of a drug interaction to date does not mean that an interaction will never occur as long as the patient continues to use the potentially interacting drugs. The individual completing the drug profile must document the existence of the potential interaction so that the entire IDG is made aware of the potential problem and can then make an informed decision about the patient's drug regimen. For these reasons, we are revising the drug profile requirement at §418.54(c)(6)(iii), to require the hospice to evaluate both actual and potential drug interactions.

Comment: A commenter suggested that we require hospices to determine whether the patient is using duplicate medications or medications that require laboratory monitoring.

Response: We agree that adding these provisions will help hospices gather more detailed information from which to make accurate care decisions. Patients often come to hospice with a long list of medications prescribed by several different doctors. It is very possible that some of these medications have overlapping effects, in which case one or more medications may be safely and appropriately discontinued. Identifying unnecessary/duplicate drugs and

subsequently eliminating them will make it easier for patients to follow their drug regimens. Identifying drugs that currently require laboratory monitoring during the assessment will also help patients and hospices. Some patients come to hospice with the explicit desire to forgo more laboratory tests. It is imperative that hospices identify any drugs that the patient is currently taking that may require these tests so that patients know about the situation and the options available to them to help achieve their goals. Identifying drugs that require laboratory testing will enable patients to make informed decisions and may lead patients to forgo the use of certain drugs. For these reasons, we have incorporated these two suggestions at §418.54(c)(6)(iv) and §418.54(c)(6)(v).

Comment: A commenter suggested that, as part of the drug review, hospices should be required to identify:

Medications that are unnecessary or are not consistent with patient therapy goals;

Medications requiring dosage optimization;

Medications that are inappropriate according to evidence based guidelines; and

Missing medications that are necessary to prevent or address symptoms experienced by the patient.

Response: The purpose of the drug profile assessment is to gather the information necessary to enable the hospice to make appropriate care decisions, and it is the role of the individual completing this portion of the assessment to collect this information. Several of the commenter's suggestions (1, 3 and 4) require the individual completing the drug profile portion of the assessment to draw conclusions. We believe that these conclusions should be made by the IDG during care planning, rather than by a single member of the IDG who is completing this portion of the assessment. Suggestion 2 is already captured by the requirement that hospices review the effectiveness of drug therapy at §418.54(c)(6)(i). If a drug dosage needs adjustment, then that need will be reflected in its level of effectiveness. For these reasons, we are not incorporating these suggestions.

Comment: Numerous commenters expressed concern about the role of the initial bereavement assessment in the comprehensive assessment and in the bereavement plan of care. In particular, commenters noted that the information gathered in the initial bereavement assessment may not remain accurate when the patient dies and may unintentionally result in poor decision making in the final bereavement plan of care. For this reason, some commenters

requested clarification of the role that the initial bereavement assessment plays in the final bereavement plan of care. Other commenters suggested that we substitute the hospice plan of care for the bereavement plan of care. This would require hospices to use the information gathered in the initial bereavement assessment when developing the plan of care, but not when developing the bereavement plan of care. Still other commenters suggested that the initial bereavement assessment be completely removed from the comprehensive assessment.

Response: We appreciate the valuable insight that the commenters provided about the role of the initial bereavement assessment in hospice. The comments validated our understanding that hospices already assess patients and families for actual and potential bereavement issues before the patient's death rather than waiting until after death to begin this process.

We also appreciate the suggestions to help clarify the role of the bereavement assessment within the comprehensive assessment. We agree that the information gained in the initial bereavement assessment should be incorporated into the hospice plan of care. Issues identified in the initial bereavement assessment such as anticipatory grief and previous experiences with loss should inform care planning

decisions long before the patient dies. By requiring hospices to incorporate bereavement assessment information into the plan of care, hospices will be able to develop a more complete picture of the patient and family.

Likewise, we agree that feelings can change over time, rendering the information gathered in the initial bereavement assessment moot at the time of the patient's death. For this reason, we are no longer requiring that information gathered from the initial bereavement assessment be incorporated into the bereavement plan of care. Rather, we are requiring that the information from the initial bereavement assessment be considered in the bereavement plan of care. This change still requires hospices to begin the bereavement assessment process early in the patient's stay. However, the change reflects that fact that the bereavement assessment will change as it is updated. Furthermore, the change allows hospices to use the most accurate bereavement assessment information, regardless of when it was obtained, in developing the bereavement plan of care.

Comment: A single commenter suggested that we require, as part of the comprehensive assessment, that hospices assess the family's needs along with the patient's needs.

Response: One of the most unique aspects of hospice, and one of the most valued, is that it treats the patient

and family as a single unit of care. Hospices recognize that patients do not live in a vacuum. Rather, patients are continually affected by the well-being, or lack thereof, of the people who surround and care for them. We in no way want to discourage this holistic practice. However, comprehensively assessing all of the needs of the patient's family, as we require for the patient, is beyond the scope of the Medicare and Medicaid hospice benefits. Therefore, we are not incorporating this suggestion.

Comment: A few commenters suggested that we should add the phrase "consistent with patient self-determination" to the description of the elements that must be included in the comprehensive assessment. The commenters expressed that adding this phrase would convey to hospices that the comprehensive assessment is patient-driven.

Response: We agree that, within the broad outline provided in this rule, the comprehensive assessment is a patient-driven process. Hospice has a long history of tailoring patient care, including assessments, to the needs and desires of the patient. We do not believe that the new comprehensive assessment requirement will alter this existing practice because it provides broad outlines that allow hospices to continue tailoring their care. Therefore, we do not believe that adding the phrase "consistent with

patient self-determination" is necessary.

Comment: A single commenter suggested that we should add a new element to Standard (c), which would address the issue of the need for hospices to assess pain and symptom management as well as emotional and spiritual support.

Response: We agree that these are important areas to be assessed; however, we do not agree that they need to be separated out as new elements. Standard (c) already requires hospices to "identify the physical, psychosocial, emotional, and spiritual needs" of the patient. The specific issues of pain and symptom management and emotional and spiritual support are addressed by these broader categories, and therefore do not require separate elements in the assessment. To do so would be duplicative.

Comment: A few commenters asked us to specify which disciplines and providers within those disciplines must complete the comprehensive assessment. For example, one commenter asked us to specify the type of personnel who are qualified to provide a spiritual assessment. Many other commenters wanted us to specify that only certified chaplains should perform this function. Another commenter questioned whether MSWs should be required to complete social work assessments and whether, based on those assessments, patients could then be assigned to a

baccalaureate degree prepared social worker.

Response: A comprehensive assessment, in the context of this rule, is not a single document that all hospice providers are required to use. Instead, it is a flexible evaluative process that could be different for each hospice based on the hospice's own needs. If a hospice chooses to implement a policy that an MSW must assess the status and needs of all patients, then we would expect the hospice to follow its own policy. Likewise, if a hospice chooses to implement a policy that certified chaplains must be used to assess all patients who do not have existing spiritual support systems while community religious leaders must be used to assess all patients who have existing spiritual support systems, then we would expect the hospice to follow its own policy. These examples illustrate the flexible nature of the assessment requirement. To prescribe who may or may not complete different elements of the comprehensive assessment, or even what areas of care must be assessed, would remove this flexibility. We do not believe that removing flexibility is in the best interest of patients or hospices; therefore we are not adopting these suggestions.

Comment: A single commenter observed that the plan of care could not be completed until the comprehensive assessment was completed.

Response: The commenter is correct; however, the initial assessment would already have gathered the most critical clinical and psychosocial information, which would enable the hospice to begin completing the plan of care. Once the comprehensive assessment is complete, the hospice must then finish the plan of care based on the needs identified in the comprehensive assessment. Hospices may not wait until the comprehensive assessment is complete to begin to formulate the plan of care and provide services, as the commenter seemed to imply. Such waiting, when the hospice has assumed responsibility for caring for the patient and the patient has forgone all other services related to the terminal illness, would be a disservice to the patient and would likely lead to negative patient outcomes, patient and family complaints, and numerous other undesirable effects.

Comment: Several commenters expressed confusion about who would be responsible for completing the comprehensive assessment, how it would have to be completed, and who would review its content. Specifically, commenters suggested that the hospice registered nurse be required to complete the comprehensive assessment and that the IDG be required to review its content. Other commenters questioned whether all disciplines were required to make in-person visits or

whether phone contacts could be used to complete the assessment.

Response: The comprehensive assessment is not a single static document, a symptom and severity checklist, or a set of generic questions that all patients are asked. It is a dynamic process that needs to be documented in an accurate and consistent manner for all patients. While the comprehensive assessment often begins with a nursing assessment that is focused on the patient's physical status and conducted by a registered nurse, it does not end there. The comprehensive assessment must also focus on the patient's psychosocial and emotional status and needs, and this piece is often assessed by a social worker. In addition, the comprehensive assessment must address the patient's spiritual status and needs, which is often the domain of the pastoral or other counselor who is a member of the patient's IDG. Furthermore, the comprehensive assessment must focus on identifying any other needs that fall into the scope of the physical therapist, speech language pathologist, occupational therapist, dietitian, or any number of other disciplines that a hospice may provide. A nurse is not qualified to provide detailed assessments in all of these areas; therefore we cannot place the burden of completing the comprehensive assessment on the nurse alone.

The broad nature of the comprehensive assessment requires the active involvement of all of the members of the IDG in order to ensure that a complete and accurate picture of the patient and family is obtained.

The active involvement can occur in any number of ways depending on the patient's needs and preferences. Some families may need a face-to-face visit from a social worker to help them sort through myriad insurance papers or simply provide a supportive presence, while other families may find it easier to discuss difficult issues by phone. If families need or prefer in person visits, then those needs should be met. If they prefer the limited anonymity afforded by the telephone, then their preference should be accommodated. We cannot provide the clear cut answer that commenters are seeking because each patient, family, and situation is different. Decisions about who assesses and how they assess need to be based on the needs of the patient and family and the hospice's own policies and procedures.

Comment: A single commenter suggested that we should create a separate standard for assessing patients with short lengths of stay. The commenter stated that a separate standard would avoid overwhelming patients and families.

Response: We agree that patients and families should not be overwhelmed in the last days of life. However, we do

not agree that a separate short stay assessment standard is necessary. We are finalizing a requirement that hospices complete an initial, abbreviated patient assessment within 48 hours of the patient or representative electing the hospice benefit. This assessment, conducted by the hospice nurse in conjunction with other appropriate hospice staff, will provide hospices with the essential information to formulate a plan of care to address the patient's immediate care and support needs without overwhelming the patient and family. We believe that patients who stay for a short time in hospice will be well served by this initial assessment. Length of stay should not be the determinant of the quality of care that is to be furnished. For those patients who stay for a longer period of time, we are requiring hospices to complete a comprehensive assessment within five days of the patient or representative electing the hospice benefit. We are not prescribing what areas of hospice care must be assessed (that is, nursing, social work, therapies, etc.) or who must complete those assessments. Allowing hospices to make these choices allows them to strike a balance between the need for assessment information and the desire to not overwhelm patients and families. We believe that this built-in flexibility accomplishes the commenter's goal

without adding a separate short stay assessment standard. Therefore, we are not adopting the comments as suggested.

Comment: A commenter suggested that standard (d), “Update of the comprehensive assessment” should be renamed “Ongoing assessment” to clarify that the entire assessment does not need to be redone every 15 days.

Response: We do not believe that renaming the standard will accomplish the stated goal. Renaming the standard as “Ongoing assessment” would imply that every single change, regardless of how minute it was, would need to be documented on the comprehensive assessment, as these minute changes would be identified in the day-to-day clinical assessments of the patient. We believe this would add an unnecessary burden to hospice staff and would not advance patient care.

Comment: Many commenters supported the goal of requiring hospices to regularly update the comprehensive assessment. Most of these commenters suggested changes to proposed 14 day time frame for updating the comprehensive assessment. Some commenters suggested that we delete the time frame completely, while other commenters suggested that the time frame be every two weeks or at the beginning of each new benefit period.

Response: We appreciate the support for regularly updating the comprehensive assessment, as this support

generally reflects our understanding that most hospices already update patient assessments in accordance with some sort of self-imposed time frame. We believe that establishing a standard comprehensive assessment time frame in this rule will help those hospices ensure that their update time frame is consistent with patient needs and standards of practice. Deleting or greatly extending the time frame, as a few commenters suggested, would be out of step with current standards of practice and would likely lead to negative patient outcomes. Updating the comprehensive assessment at reasonable regular intervals ensures that hospices have the most recent information about the patient from which to make accurate care planning decisions. Without the timely updated assessment information, care planning decisions are likely to be inaccurate, inappropriate, and possibly harmful to the patient. This is not an acceptable outcome.

We also appreciate the many time frame suggestions that we received. We agree that the proposed 14 day time frame, while within reason and in the realm of acceptable standards of practice, may not be the best match between patient and hospice needs. Numerous commenters suggested that updating the comprehensive assessment at least every 15 days was the proper match, as the 15 day time frame would correspond with

the 60- and 90-day Medicare Hospice Benefit election periods described in §418.21. Corresponding the update time frame length to the benefit period length would help hospices avoid completing separate assessments for the routine comprehensive assessment update and the update to re-certify that the patient is terminally ill. Two separate assessments within a few days of each other would be overwhelming for the patient and burdensome for the hospice. Thus, we agree that requiring hospices to update the comprehensive assessment at least every 15 days is preferable to the proposed 14 day time frame. We believe that the new 15 day time frame accomplishes the flexibility goals of those commenters who suggested twice monthly, bi-weekly, and every 14-16 day updates as well. We note that hospices are still required to complete the comprehensive assessment update more frequently than every 15 days as the patient's status changes. We also note that hospices are permitted to update the assessment more frequently than every 15 days if the 15th day falls on a holiday or if day-to-day hospice operations are scheduled to be suspended for any reason on the 15th day.

Comment: Several commenters suggested that we should either delete the requirement that hospices must update the comprehensive assessment at the time of each

recertification, or allow a grace period at the time of each recertification to ensure that the assessment is not unnecessarily updated twice within a few days to meet the every 14-day and recertification time frames.

Response: As discussed above, we replaced the 14-day timeframe with a 15-day time frame. The 15-day time frame would coincide with the length of the benefit periods and the recertification time frames. Since the assessment and recertification time frames are now coordinated, we agree that it is appropriate to delete the recertification assessment requirement.

Comment: Several commenters expressed confusion about the nature of the comprehensive assessment update. A few commenters wanted to know if we expected hospices to complete an entire new set of comprehensive assessment forms each time an update is due. Other commenters wanted to know if the update of the comprehensive assessment referred to the regularly scheduled IDG meetings. Another commenter noted that the medical director should not be required to update the assessment.

Response: We understand that some hospices are confused by the proposed requirement that patient-specific comprehensive assessments should be updated at regular intervals. To clarify, we are requiring hospices to update

those sections of the comprehensive assessment that require updating. As a patient’s condition changes the comprehensive assessment must be updated to reflect these changes. For example, if a patient had a normal blood pressure reading at the time of the initial assessment and at a nursing visit nine days later the patient’s blood pressure becomes elevated for a period of time, this new elevated blood pressure must be documented. This becomes an update to the comprehensive assessment. A significant change in the patient’s condition must be documented and the assessment must then be updated to reflect the patient’s revised status. As in the case of the comprehensive assessment, hospices are not required to use specific forms or formats. However, there have to be dedicated documents that contain assessment information and that are easily identified. Hospices are free to choose the method that best suits their needs when documenting the comprehensive assessment and the updates to that assessment. The purpose of updating the assessment is to ensure that the hospice IDG has the most recent accurate information about the patient in order to make accurate care planning decisions. We are not requiring hospices to complete, in full, those documents which they identified as comprising their comprehensive assessment every 15 days, although hospices are free to do

so if they choose. Likewise, we are not requiring hospice medical directors to assume total responsibility for updating the comprehensive assessment, although we do expect to see the physician member of the IDG actively involved in all aspects of furnishing care, including updating the comprehensive assessment.

Comment: Many commenters expressed confusion about the role of patient outcome measures in the comprehensive assessment. Some commenters stated that data elements should be in the plan of care rather than in the assessments. Others stated that including data measures in the assessments may limit the amount of useful data available for a hospice's quality assessment and performance improvement (QAPI) program.

Response: In the QAPI CoP hospices are required to identify patient outcome measures that they will apply to all patients. These measures should help the hospice identify areas of strength and weakness in patient and family care delivery. Once the measures are identified, hospices must choose which data elements they will collect in order to measure their performance. For example, a hospice may choose to focus on pain control as one of its QAPI domains. Within the pain control domain, that hospice may choose an outcome measure that identifies the percentage

of patients whose pain was controlled within 48 hours of admission to hospice. In order to measure this outcome, that hospice may choose to incorporate a data element in its initial assessment that identifies those patients who are experiencing uncontrolled pain upon admission as well as a data element in its comprehensive assessment to identify patients who experienced uncontrolled pain upon admission and had that pain controlled within 48 hours of admission. The information gathered by these data elements during the comprehensive assessment can then be collected, aggregated, and used to identify areas of strength and weakness within the hospice's care delivery system. Without these individual pieces of information gathered during the assessments, the hospice does not have the information it needs to make effective judgments of its quality and to make appropriate performance improvement project decisions. Therefore, QAPI-related data elements must be included in the patient assessments completed by the hospice.

At the same time, we do not expect hospices to limit their QAPI-related data collection efforts to the data collected in the patient assessments. Data collection must look beyond patient assessment data to examine all facets of a hospices operation, from contract services to volunteer retention rates to adverse events. Rather than limiting the

amount of useful data available to hospices, this requirement simply ensures that patient level data are included as part of the broader data collection program.

For additional discussion of public comments regarding patient outcome measures and the proposed QAPI CoP, please refer to the quality assessment and performance improvement section in the preamble of this rule.

Comment: A commenter requested that we change the timing of the medical director's certification of the terminal illness to coincide with the completion of the comprehensive assessment.

Response: The commenter did not provide any particular rationale for this request. The timing of the certification of the terminal illness for Medicare beneficiaries is based on specific Medicare payment requirements. Since payment requirements are not within the scope of this rule, we are not accepting this suggestion.

Comment: Numerous commenters expressed varying levels of confusion regarding the exact sequence and timing of the initial assessment, comprehensive assessment, updated assessments, plan of care, and updated plans of care. Commenters believed that some of these elements would occur simultaneously while other elements, such as orienting

patients to hospices and evaluating patients for hospice appropriateness do not appear in the regulation at all.

Response: We appreciate the opportunity to explain how the finalized requirements will function in the hospice environment. First, hospices will obtain a signed election statement in accordance with §418.24. Next, the hospice registered nurse must complete an initial assessment of the patient's physical, psychosocial and emotional status related to the terminal illness and related conditions in order to evaluate the patient's immediate care and support needs within 48 hours of completing the election form. This assessment need not go into great detail in each of these areas. Rather, it needs to gather key information, as identified in the hospices policies and procedures, about the patient that will enable the hospice IDG accurately to determine what the patient immediately needs to begin or continue feeling comfortable. The purpose of the initial assessment is not to determine the patient's eligibility for the hospice benefit, which is addressed in 418.22 and 418.24, or to orient the patient to the hospice benefit and obtain the election statement. Additional information regarding physician certification of the terminal illness is available in the FY 2008 Hospice Wage Index, 72 FR 50214, 50223, August 31, 2007. These tasks, which are often part

of following-up on referrals from other providers, must already have been completed before the initial assessment is completed. This does not mean, however, that we expect hospices to conduct multiple visits to complete the patient admission and assessment. Once the initial assessment is complete, the hospice develops and implements a plan of care to address the immediate needs identified in the initial assessment.

Next, the hospice must complete a comprehensive assessment within five days of completion of the election statement. The comprehensive assessment is defined as a thorough evaluation of the patient’s physical, psychosocial, emotional and spiritual status related to the terminal illness and related conditions. This includes a thorough evaluation of the caregiver’s and family’s willingness and ability to care for the patient. This comprehensive assessment is based on the hospice’s policies and procedures as well as the information gathered in the initial assessment. For example, a hospice may have a policy that all patients will receive a psychosocial assessment conducted by an MSW. Therefore, we would expect that a patient’s comprehensive assessment in his or her clinical record would include the information gathered by and the conclusions made by an MSW. The comprehensive assessment

requirement is flexible to adapt to the needs of individual hospices and patients, and will help hospices gather the information needed to develop accurate and appropriate plans of care.

Then, based on the information gathered in the comprehensive assessment, the hospice IDG, in collaboration with the patient’s attending physician (if any), the patient or representative, and the primary caregiver, must develop an individualized plan of care for each patient. The plan of care must reflect patient and family goals, and include all interventions needed to address the problems identified in the initial and comprehensive assessments. The plan of care is where information turns into actions that will result in patient comfort and dignity, self-determined life closure, and any other goals that the hospice, patient, and family establish for the patient’s hospice care.

Once the plan of care is established and all disciplines are aware of their respective roles in caring for the patient, the hospice must implement the plan of care. If the patient’s status in one or more areas changes, hospice staff must update the comprehensive assessment to reflect the change(s). We do not expect hospices to complete an entire comprehensive assessment each time a patient’s status changes. Rather, we expect that the updated

assessment reflects status changes so that other disciplines furnishing services are aware of them. Updating the comprehensive assessment will ensure that all disciplines are providing care based on the most recent information about the patient. We require that these updates occur as frequently as that patient’s condition requires, but no less frequently than every 15 days. If a change in the patient’s status will affect the kind of care that needs to be furnished, then the plan of care needs to be modified. For example, information from a comprehensive assessment could indicate that a patient has a stage three pressure ulcer and the patient’s plan of care indicates that the hospice registered nurse will make three visits a week, in part, for wound care. The wound care provided by the registered nurse results in the pressure ulcer healing. This change in status would be recorded as an update to the comprehensive assessment. Based on this new information in the updated comprehensive assessment, the hospice IDG may decide to reduce registered nursing visits to two times per week because the patient’s status and needs no longer indicated that RN visits three times per week were necessary. The hospice IDG would then update the patient’s plan of care to reflect that RN visits will be two times per week and that wound care was no longer part of the treatment that the RN

would provide. In this way, the patient's assessment and plan of care are both updated to provide accurate and timely information to all disciplines providing services to the patient, and the hospice complies with our requirements to update both the comprehensive assessment and the plan of care.

We believe that the timeline described above will help illuminate the timeframe requirements for both the assessment and plan of care requirements, as well as how these two requirements are related.

Comment: A few commenters explicitly thanked us for not requiring hospices to use a standardized assessment form. Other commenters expressed concern that the proposed assessment requirement would result in CMS requiring hospices to use a specific assessment form. Several of these commenters specifically stated that we should not require hospices to use the OASIS data collection tool that is currently used by home health agencies.

Response: We appreciate the support from commenters who recognized that we are not requiring any type of assessment form, standardized or otherwise. As we stated in the preamble to the proposed rule, and restate here, we are not requiring hospices to use any particular form or tool to document the completion of the initial assessment,

comprehensive assessment, or updated assessments at this time. Hospices are permitted to use the written or electronic form or tool that best suits their needs and their patients' needs, provided that the information gathered in the assessments is complete and available in each patient's clinical record. Hospices need to choose a form or tool that gathers thorough information about the patient's physical, psychosocial, emotional and spiritual status related to the terminal illness and related conditions. This form or tool must allow hospices to document information in a systematic and retrievable way for each patient. Within the framework of these broad guidelines, it is within each hospice's discretion to choose its own patient assessment documentation form or tool.

Hospices may find it beneficial to examine the CARE (Continuity Assessment Record and Evaluation)tool developed by CMS in choosing their assessment forms/tools. Under the Deficit Reduction Act of 2005, Section 5008, CMS was directed to develop a uniform patient assessment instrument for use in a three year, post acute care-payment reform demonstration, to begin in January 2008. This uniform assessment instrument is now referred to as CARE. The purpose of the CARE tool is to collect standardized data on Medicare beneficiaries' medical conditions, functional and

cognitive impairments, and social support factors, affecting treatment and discharge, regardless of site of care. During the demonstration CARE will be administered to Medicare beneficiaries at time of hospital discharge, upon admission and discharge from post acute care (PAC) providers, as well as at interim points, if significant changes occur. CARE is comprised of a set of common assessment items administered to all patients across all settings, and a set of supplemental items only administered for specific conditions or at particular times(i.e., PAC discharge only). A master version of the CARE instrument and item matrix identifying common assessment items and supplemental items is available for viewing at http://www.cms.hhs.gov/PaperworkReductionActof1995/PRALSep2007/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS1205047&intNumPerPage=10

If, at some time in the future, we determine that it is necessary to require hospices to use a standardized patient assessment tool, we will follow the provisions of the Administrative Procedure Act, which generally requires us to publish a notice of proposed rule making and solicit public comment on the proposal.

4. Condition of participation: Interdisciplinary group care planning and coordination of services (Proposed §418.56)

This proposed CoP elaborated on the existing Interdisciplinary group CoP at §418.68 and combined it with elements of the Plan of care CoP at §418.58. It contained five standards: “(a) Approach to service delivery,” “(b) Plan of care,” “(c) Content of the plan of care,” “(d) Review of the plan of care,” and “(e) Coordination of services.” Together, these standards would have required a hospice, through its IDG, to develop, implement, and update a comprehensive plan of care for each patient and family that addresses their needs as identified in the patient assessment.

Standard (a), “Approach to service delivery,” would require each hospice to have an IDG that included at least the following: a doctor of medicine or osteopathy who is not the patient’s attending physician; a registered nurse; a social worker; and a pastoral, clergy, or other spiritual counselor. This IDG would be required to work together to meet the physical, medical, social, emotional, and spiritual needs of the patient and family. The IDG would also be required to designate a qualified individual to coordinate implementation of the plan of care and assessment of the patient. Paragraph 418.68(d) of the existing rule required

the IDG to designate a registered nurse to fulfill this role. In the proposed rule, the IDG would be required to establish policies governing the day-to-day provision of care and services. If a hospice has more than one IDG, one would be designated in advance to fulfill the policy role.

The next proposed standard, “(b) Plan of care,” would require hospices to provide care to patients and families in accordance with a written plan of care established by the IDG and the patient’s attending physician. This standard would also require hospices to ensure that patients and families received appropriate education and training that would enhance the implementation of the plan of care. Unlike the existing requirement, this proposed standard would incorporate families into the plan of care, recognizing that hospice care must reach beyond the patient to support those who surround and care for the patient.

In proposed standard (c), “Content of the plan of care,” we would require hospices to develop a plan of care based on the problems identified in the patient’s assessments. We proposed to require that the plan of care include: pain and symptom management interventions; a detailed statement of the scope and frequency of services; patient outcomes; any necessary drugs and treatments; any necessary medical supplies and equipment; and documentation

of the patient’s and family’s understanding, involvement, and agreement with the plan of care. The existing plan of care requirement at §418.58(c) mandated that the hospice describe the scope and frequency of services. The remainder of the elements were new in the proposed rule.

The fourth proposed standard, “(d) Review of the plan of care,” would require the hospice medical director or physician designee, along with the IDG and the patient’s attending physician, to review, revise, and document the plan of care at intervals specified in the plan of care. The review of the plan of care would be required to occur no less frequently than every 14 calendar days. The revised plan of care would be required to include information from the patient’s updated assessment, and the hospice would have to document any progress toward the outcomes specified in the plan of care. This proposed requirement directly linked the results of the updated assessment, including the data elements, to the changes that would be made in the plan of care. This would empower hospices to make care decisions based on evidence of the successes and failures of past care decisions in achieving the desired outcomes.

The final proposed standard, “(e) Coordination of services,” was a new addition to the hospice CoPs. Hospice has always been based on an interdisciplinary care model, which

requires frequent communication between care disciplines and settings, as well as between the hospice, the patient and the family. This proposed standard would require the hospice to maintain a system of communication and integration to enable the IDG to ensure that care and services are provided in accordance with the plan of care. This system would also be required to ensure the ongoing liaison of all disciplines providing care and services in the home, outpatient, and inpatient settings, notwithstanding the manner in which the care and services are furnished (that is, directly or under arrangement).

Comment: A commenter asked us to clarify the meaning of the following sentence at §418.56, "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." The commenter believed that this statement was confusing.

Response: The intent of the sentence is to ensure that there is a direct link between the needs identified in the patient assessment and the plan of care developed by the hospice. The intent is also that hospices are responsible for including those services and treatments in the plan of care that are related to the terminal illness and related

conditions, even if the hospice identified other needs in the patient assessment that are not related to the terminal illness and related conditions. We agree that minor grammatical changes to the statement are warranted to clarify our intent. Specifically, we are replacing the singular term “it” with the plural phrase “such needs” to correspond with the plural “specific needs” identified earlier in the sentence. This grammatical change provides a direct link between the needs identified in the comprehensive assessment and those specific needs related to the terminal illness and related conditions that must be addressed in the plan of care. The revised sentence at §418.56 now states, “The plan of care must specify the hospice care and services necessary to meet the patient and family-specific needs identified in the comprehensive assessment as such needs relate to the terminal illness and related conditions.” We have not attempted to enumerate the conditions in which care outside the hospice would be covered under Medicare because we recognize that there are many illnesses which may occur when an individual is terminally ill which are brought on by the underlying condition of the patient. For example, it is not unusual for a terminally ill patient to develop pneumonia or some other illness as a result of his or her weakend condition.

Treatment of such illnesses is considered a hospice service and payment under other Medicare benefits would be waived by the hospice election. We expect that the hospice interdisciplinary group will reasonably determine the services that the individual requires for palliation and management of his or her symptoms.

Comment: A commenter suggested that, when hospices are caring for residents of long term care facilities, the long term care facility medical director should be the individual responsible for designating the members of the IDG to care for the patient.

Response: It is the hospice's responsibility to furnish hospice care. While we agree that designated long term care facility staff should actively participate in a patient's hospice IDG, it is the hospice's responsibility to decide what care is provided, based on the information gathered during the patient assessments. Hospices are not permitted, and certainly should not be compelled, to delegate their responsibilities to the long term care facility medical director and staff.

Comment: Numerous commenters suggested that we include the term "psychosocial", rather than "social", in §418.56(a) when detailing the types of patient and family needs that IDGs are required to address during care planning. The

commenters stated that the term “psychosocial” is more consistent with the terminology used throughout the remainder of the rule.

Response: We agree that the word “psychosocial” is more consistent with the terminology in the rest of the rule and we have made this change.

Comment: Numerous commenters made suggestions to refine our proposal at §418.56(a) that “The hospice must designate a qualified health care professional that is a member of the IDG 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.” A few commenters supported our proposal to permit any qualified health care professional that is a member of the IDG to fulfill the coordinator role, while many other commenters suggested that only nurses and/or social workers should be considered qualified for this role. One commenter suggested that the coordinator should only be responsible for ensuring the assessment of each patient’s and family’s specific hospice care, rather than being personally responsible for assessing their needs. Another commenter suggested that the individual responsible for coordinating the plan of care be named the “interdisciplinary group coordinator.”

Response: We appreciate the many comments that were

submitted. We do not believe that the coordinator needs to be given a specific title in this rule. Hospices are free to refer to the coordinator in a manner that meets their needs, as long as there is an individual identified as being responsible for coordinating and implementing each patient's plan of care.

The majority of commenters noted the unique demands of the case coordinator role and the many skills that are necessary to successfully fulfill the role. Commenters described the need for the case coordinator to have solid knowledge of the biological, psychological and spiritual issues of terminally ill patients and their families. They also described the need for the case coordinator to act as an advocate, negotiator, and leader when dealing with the varied members of the IDG, the patient, and the patient's family. We agree that the specific demands of the case coordinator role, as described by the commenters, warrant a more specific requirement regarding who is qualified to fulfill this role. Therefore, we are requiring the coordinator to be a registered nurse. A registered nurse has the necessary medical and interpersonal background to meet the demands of the coordinator position in a way that no other discipline does. Social workers are not educated or trained to identify physical issues, just as physical or

occupational therapists are not educated or trained to identify psychosocial issues. The unique skills of registered nurses, who are educated to assess and manage the overall aspects of a patient's physical and psychosocial care, can be used to oversee the coordination and implementation of the care identified by the IDG.

Comment: The majority of commenters asked us to reconsider the specification in proposed §418.56(a)(1)(i) that the physician member of the IDG may not be the patient's attending physician. The commenters stated that hospice physicians often have their own private practice and may, at times, be in the position of caring for a private practice patient who has chosen to receive hospice care from the hospice the physician works with. Furthermore, the commenters stated that this prohibition could create a barrier to accessing hospice for those patients whose attending physicians also work with hospices. One commenter suggested we should replace the general requirement that a doctor of medicine or osteopathy be a member of the IDG with a requirement that the hospice medical director or physician designee be a member of the IDG.

Response: While it was not our intent, we agree that this prohibition could negatively impact hospice access and treatment. Therefore, we have removed the statement that the

physician member of the IDG may not be the patient's attending physician. In its place, we have added a statement that the physician member of the IDG must be an employee of or under contract with the hospice. While the physician member could be the hospice medical director or physician designee, this revised requirement does not mandate this. This new requirement accomplishes our original intent of ensuring that hospice physicians are actively involved in patient care through the IDG without the unintended effect of limiting access that accompanied the original proposal.

Comment: Numerous commenters suggested that we amend the language discussing spiritual counselors in §418.56(a)(1)(iv). Some commenters noted that the terms "pastoral" and "clergy" are Judeo-Christian terms that do not encompass other faiths. These commenters suggested that we require hospices to have a board certified chaplain as a member of the IDG because board certified chaplains are routinely educated and trained to work with individuals from various, non-Judeo-Christian faiths. On the other hand, some commenters specifically disagreed with the suggestion that a board certified chaplain be a required member of the IDG. Still other commenters suggested that we should use the language that appears in section 1861(dd)(2)(B)(i) of the Act, which reads that a hospice must have "at least one

pastoral or other counselor" as a member of the IDG.

Response: Spiritual advisors play an important role in helping many patients and families achieve their end-of-life goals. In the proposed rule we sought to further assure the role of spiritual advisors in hospice care by specifying that the counselor must be capable of addressing a patient's spiritual needs. As some commenters stated, not all patients need or desire the involvement of spiritual counselors in their care. These patients, the commenters contended, should not be compelled to accept the involvement, even if that involvement is only through the spiritual counselor's participation in the IDG meetings. We agree that spiritual counselors, whether they are certified chaplains, clergy, pastoral counselors, or any other discipline, should not be forced upon unwilling patients. Therefore, we have replaced the proposed "pastoral, clergy, or other spiritual counselor" requirement with the statutory requirement of "pastoral or other counselor." This revised requirement gives hospices the flexibility to use the counselor that best meets the patient's needs.

Nothing in this requirement prohibits hospices from using certified chaplains as the IDG member to fulfill this role. Indeed, some hospice patients who receive the services of certified chaplains may have better outcomes because

certified chaplains are trained to work with individuals from various faiths and backgrounds.

Comment: A few commenters suggested that we should require a bereavement counselor as a member of the IDG. The commenters stated that including the bereavement counselor in the IDG would help ensure that the information gathered in the bereavement assessment, required in final §418.54(c)(7), is included in the plan of care.

Response: We expect that all disciplines involved in caring for a patient and family will have a voice in the IDG. This voice may be reflected through reports given by the members of the patient's care team who are not part of the official IDG to the individual who is coordinating care plan implementation or through IDG members attending IDG meetings in some manner. Including a bereavement counselor, whether as an individual position or as a function of the counselor or social worker, in the IDG would satisfy our expectations that all disciplines communicate with each other and have a voice in IDG meetings and decisions, and may result in better patient and family satisfaction and outcomes. Nothing in this rule prevents hospices from involving a bereavement counselor in the IDG. The core members of the IDG are identified in section 1861(dd)(2)(B) of the Act. This section permits the use of another type of

counselor instead of, or in addition to, the pastoral counselor. Hospices are free to use a bereavement counselor when they believe the needs of the patient and family require it.

Comment: Many commenters took issue with the proposed requirement in §418.56(a)(2) that, if a hospice has more than one IDG, it must designate one IDG to establish policies governing the day-to-day provision of hospice care and services. Some commenters sought minor changes to the proposed requirement to allow hospices to create a special IDG, culled from all of its IDGs, for the job of establishing policies. Other commenters suggested that the hospice's administrator, clinical leaders, or governing body should be responsible for developing these policies.

Response: Section 1861(dd)(2)(B)(iii) of the Act requires a hospice IDG to establish policies governing the provision of hospice care and services. Therefore, we believe that it is appropriate to maintain the IDG's responsibility for developing a hospice's policies. At the same time, we agree that the IDG that is responsible for developing those policies does not need to be the same group that works together to care for patients. For example, a hospice may choose to have a policy IDG comprised of the physician from IDG 1, the nurse from IDG 2, and the social

worker and pastoral counselor from IDG 3. In order to clarify that an arrangement is acceptable, we have modified the requirement at §418.56(a)(2) to read, "[i]f the hospice has more than one interdisciplinary group, it must identify a specifically designated interdisciplinary group to establish policies governing the day-to-day provision of hospice care and services."

Comment: A commenter sought clarification of the phrase "policies governing day-to-day provision of hospice care and services" as it was used in proposed §418.56(a)(2).

Response: This phrase, which is also located in the previously existing CoPs at §418.68(b)(4), refers to the hospice's responsibility to establish its own policies and procedures to govern its practices within the framework of the CoPs. We are not prescribing the exact patient care, documentation, orientation and training, and administration policies and procedures that each hospice will use in its daily operations. Each hospice, through its designated IDG, will establish these policies and procedures. The policies and procedures established by the IDG must be in compliance with the CoPs and other applicable Federal, State, and local laws and regulations.

Comment: In proposed §418.56(b), many commenters sought clarification on the role of the patient's attending

physician in the IDG. Some commenters suggested that all mention of the attending physician's involvement in the IDG should be deleted because not all patients would have attending physicians. Other commenters suggested that the involvement of the attending physician in the IDG should be qualified by statements such as "at his/her discretion", or "only to the extent possible." Still other commenters suggested that the patient's attending physician should actively develop the patient's plan of care or even lead the IDG.

Response: The role of the patient's attending physician in the patient's hospice care will vary from hospice to hospice, and from patient to patient. This variability is reflected in the diverse comments that we received on this subject. Some commenters suggested that attending physicians should assume a leadership role in the IDG, while other commenters suggested that the role of the attending physician should be excluded all together. To accept either of the suggested extremes, that is, attending physician leadership or exclusion, would most certainly not meet the needs of all hospices. To meet these needs, we have chosen to qualify the role of the attending physician in the IDG by adding the phrase "if any" to §418.56(b). This phrase recognizes that not all patients have attending physicians.

We expect hospices to document their efforts to involve the attending physician in developing the hospice plan of care, as well as the results of those efforts. Hospices may determine the best method for this documentation in accordance with their own policies and procedures.

Comment: A commenter suggested that hospices be required to make efforts to include the patient and primary caregiver when establishing the plan of care.

Response: We agree that involving the patient and primary caregiver in developing the plan of care is an important step to ensuring that the plan of care reflects the patient's goals. We have achieved this goal by adding a provision to §418.56(b) that a patient or representative, and primary caregiver should be included in developing the plan of care if they so desire in accordance with the patient's needs. If a patient, his or her representative, and/or primary caregiver decline to participate in actively developing the plan of care, then hospices would need to document this. We also added a provision in the patient rights CoP at §418.52(c)(2) that patients have the right to be involved in developing their plan of care. In addition, we have added a requirement in §418.56(c) that the plan of care must reflect the patient's and family's goals. These provisions will, we believe, ensure that the patient's and

family's goals are reflected in the plan of care and that patients will have full and open access to the care planning process if they so desire.

Comment: A commenter observed that the proposed rule did not include a requirement that at least two members of the IDG establish the initial plan of care. The commenter appreciated that this requirement was not included in the proposed rule.

Response: The requirement that the commenter referred to is part of the interpretive guidelines that were issued for the current hospice regulations. While we did not include this requirement in the proposed rule, we do not recommend that a single member of the IDG independently develop the initial plan of care without input from other IDG members. This would violate the intent of the hospice interdisciplinary care model. Development of the plan of care is a collaborative effort involving all members of the IDG. We will continue to include this information in the new Interpretive Guidelines.

Comment: A commenter suggested that we should include timeframes for completing the initial plan of care and the comprehensive plan of care.

Response: We do not differentiate between the stages of the plan of care. We expect the first stage of the plan

of care to be completed after the initial patient assessment has been completed. This preliminary plan of care must address the immediate care needs identified during the initial assessment. Once the comprehensive assessment is complete, the hospice must then update the plan of care to address the other care needs identified through the comprehensive assessment. We believe that beginning and completing the first iteration of the plan of care should be based on the needs of the patient and family rather than specific timeframes. If a patient is in crisis or is actively dying, then it stands to reason that the plan of care must be developed by the IDG members rather quickly.

Comment: A commenter requested that, in §418.56(b), hospices only be required to provide education and training to the patient and primary caregiver. In addition, the commenter requested that hospices be permitted to tailor the training and education provided to patients and caregivers based on their responsibilities for care.

Response: We agree that requiring hospices to educate and train the family, as we proposed, is unnecessary because not all family members may participate in furnishing care to the patient. We also agree that hospices should be permitted to tailor the education and training provided to patients and caregivers based on the exact services that patients and

caregivers will be providing. For example, if a caregiver is assessed as being competent and willing to care for a patient's catheter, then we would expect the caregiver to be educated and trained on proper catheter care procedures. The relevant portion of section 418.56(b) now reads, "The hospice must ensure that each patient and the primary caregiver(s) receive education and training provided by the hospice as appropriate to their responsibilities for the care and services identified in the plan of care."

Comment: A commenter suggested that §418.56(b) should explicitly state that only one plan of care is required and that a separate plan of care is not necessary for the family's needs.

Response: One of the most unique and valuable aspects of hospice care is its treatment of the patient and his/her family as a single unit of care. It is current hospice practice to address the needs of the patient's family as part of the patient's plan of care. This standard practice will not change based on the requirements of this rule. We expect that this rule will reinforce this practice by requiring that all services provided to both patients and their families be included in the written plan of care. We note that the term "plan of care" is singular and in no way implies that there should be more than one plan.

Comment: A few commenters suggested that we should clarify the scope of the plan of care by stating that the plan of care must address all of a patient's needs, rather than only those services that the hospice is capable of providing. Another commenter suggested that we should specify that the plan of care must be individualized for each patient and that it must reflect the patient's hospice care goals. Still other commenters suggested that the plan of care, including drugs, durable medical equipment and supplies, should be limited to addressing those needs related to the terminal illness and related conditions. The commenters suggested that deleting the phrase "but is not limited to" in proposed §418.56(c) would accomplish this goal.

Response: The plan of care is one of the most important documents in hospice care. It is the essential link between the needs of the patient and the actions of the hospice. Therefore, we agree with the commenters that the plan of care must be individualized to meet all of the needs of the patient and family related to the terminal illness and related conditions. In order to achieve this goal, we have clarified the rule in several places. First, we have added the term "individualized" to both §418.56(b) and §418.56(c), to require hospices to develop and follow an "individualized

written plan of care." Second, we have revised the final sentence of the stem statement in §418.56(c) from "The plan of care must include but not be limited to-" to "The plan of care must include all services necessary for the palliation and management of the terminal illness and related conditions, including… ." This revised statement more explicitly links the patient's needs, as identified in the assessments, to the services furnished by the hospice. In addition, this revised statement clarifies that hospices are only responsible for furnishing services based on those needs identified in the assessments related to the terminal and related conditions. Needs that are not related to the terminal illness and related conditions are not the responsibility of the hospice, although the hospice may choose to furnish services for those needs regardless of responsibility.

If a hospice does not choose to furnish services for those needs unrelated to the terminal illness and related conditions, we would expect the hospice to communicate and coordinate with those health care providers who are caring for the unrelated needs, as described in §418.56(e). In such situations where a hospice coordinates its care and services for the terminal illness and related conditions with care and services provided by other health care

providers for unrelated conditions, we believe that it is essential for the hospice to be aware of their role within the larger comprehensive plan of care for that patient. Furthermore, we believe that it is essential for the hospice to be aware of any gaps in the overall comprehensive plan of care, and the parties responsible for filling those gaps.

Comment: A commenter questioned what was meant by the phrase “initial comprehensive and updated assessment” as it was used in proposed §418.56(c).

Response: Our intent was to require hospices to base the interventions described in the plan of care on information gathered in all of the assessments, that is, the initial, comprehensive, and updated assessments. We have modified the language in §418.56(c) to reflect this.

Comment: A commenter suggested that we should remove or define the terms “facilitate”, “targeted”, and “anticipated” in §418.56(c). Another commenter suggested that we should replace the term “measurable targeted outcomes” with “agreed-upon goals.”

Response: Section 418.56(c) describes the general areas that must be included in each patient’s individualized plan of care. We agree that when describing the interventions necessary to manage a patient’s pain and symptoms in §418.56(c)(1), the language should be

simplified. We deleted the term “facilitate” in this statement and further refined it to require that the plan of care include “Interventions to manage pain and symptoms.” We also agree that in §418.56(c)(3) the language should be simplified. We removed the term “targeted” from the statement, which now reads “Measurable outcomes anticipated from implementing and coordinating the plan of care.” We did not remove the term “anticipated” from this requirement, because the term “anticipated” explicitly recognizes that the measurable outcomes are goals and they may or may not be achieved. For example, a hospice may not be able to control pain within 48 hours of admission. The hospice may have anticipated meeting that goal and took all necessary steps. However, 100 percent success is not always guaranteed. The term “anticipated” recognizes that fact.

We did not, as the other commenter suggested, replace “measurable outcomes” with “agreed-upon goals.” Instead, we have added a statement to §418.56(c) to state that, “[t]he plan of care must reflect patient and family goals and interventions based on the problems identified….” We believe that this is an appropriate way to include patient and family goals in the plan of care without excluding measurable outcomes, which are part of the individual patient care planning process and the hospice’s overall QAPI

program. We expect the hospice plan of care to address all patient goals in some way. If a patient has a goal that is not related to the terminal illness and related conditions, and if the hospice does not intend to address this goal, then the hospice plan of care should identify the party that is responsible for meeting the unrelated goal. Furthermore, final §418.56(e) requires the hospice to actively communicate with the outside party to ensure that the goal is addressed.

Comment: Some commenters questioned the term "prescribed" as it is used in proposed §418.56(c). The commenters stated that the term "prescribed" implied that we were requiring a specific physician's order for each intervention included in the plan of care.

Response: We agree that the term "prescribed" implies that all interventions require physician's orders. Requiring physician orders for everything was not our intent. Therefore, we removed the term "prescribed" from this standard.

Comment: Some commenters suggested that we should delete the terms "detailed", "scope", and "specific" as related to the services provided (§418.56(c)(2)).

Response: We did not delete these terms in this final rule. In §418.58(c) of the existing hospice regulations,

hospices are required to “state in detail the scope and frequency of services needed to meet the patient’s and family’s needs.” We note that the proposed requirement that the plan of care include, ”[a] detailed statement of the scope and frequency of services necessary to meet the specific patient and family needs” is very similar to the requirement that has existed for the last two decades. We believe that hospices have already determined, and will continue to determine, through their own policies and procedures, how to meet this requirement. The level of detail established by the hospice in the plan of care should be clear enough to provide a complete picture of which disciplines will be furnishing which services, how frequently that care will be furnished, and what needs are being addressed by such care. The plan of care serves as a primary means of communication between all hospice disciplines, the patient, the primary care giver, and the family. It must contain enough information so that all of these individuals know exactly what is supposed to be done, by whom, at what time, and for what purpose.

Comment: A commenter suggested that non-pharmacological interventions should be included, in addition to drugs, in §418.56(c)(4).

Response: We agree that non-pharmacological

interventions should be included in the individualized hospice plan of care; however, we are not specifically referencing them in §418.56(c)(4). We believe that the provision of required non-pharmacological interventions are already strongly implied in the stem statement of §418.56, and also in §418.56(c)(1), which states that the plan of care must include “interventions to manage pain and symptoms,” as well as in §418.56(c)(5), which requires the plan of care to indicate the medical supplies and appliances necessary to meet the needs of the patient.

Comment: Numerous commenters expressed concern regarding our proposal at §418.56(c)(6) that the hospice document the patient’s and family’s understanding, involvement, and agreement with the content of the plan of care. The commenters stated that there are times when the patient may agree with the plan of care while members of his or her family do not. Commenters suggested either removing the term “agreement” or replacing the term “family” with “representative” or “primary caregiver” to narrow the number of individuals who must agree, and to ensure that the patient’s needs and goals take primacy. Commenters also suggested that, rather than requiring hospices to document complete understanding, involvement and agreement on the part of patients and families, which may not be attainable,

we should require hospices to document the level of understanding, involvement and agreement attained by the patient and family.

Response: We understand that patients and families may sometimes be in conflict regarding the content of the plan of care, and we agree that it is the patient's understanding, involvement and agreement with the plan of care that takes precedence. Therefore, we have removed the term "family" from this requirement and replaced it with the term "representative." As defined in §418.3, a representative is the individual who makes decisions for a patient when a patient is unable to do so. We believe that limiting this requirement to patients and representatives will help ensure that the patient's needs and goals are primary in the content of the plan of care. We continue to expect a hospice to also address, to the extent possible, the goals of the patient's family in the plan of care. We do not require the entire family to agree to the patient's plan of care.

Furthermore, we agree that, rather than requiring hospices to document complete understanding, involvement and agreement with the plan of care, it is more appropriate to require hospices to document the level of understanding, involvement and agreement attained by the patient or

representative. The terminal illness and numerous other factors may affect a patient's or representative's ability to participate in care planning or understand the content of the plan of care. Requiring hospices to document a level of understanding, involvement and agreement with the plan of care recognizes this fact. Hospices will now be required to note whether impediments to understanding are present and the degree to which those impediments impact the patient's or representative's participation in care planning. Documenting this information will help hospices tailor the content of the plan of care and their patient communication process to the needs of the patient, resulting in improved patient outcomes.

Comment: A few commenters questioned the type of documentation that would be necessary in terms of a patient's or representative's understanding, involvement and agreement with the plan of care.

Response: The documentation in the clinical record must be correct and complete, as required by §418.104, and should provide sufficient detail to fully describe the level of understanding, involvement and agreement with the plan of care. Hospices may choose to include a specific form for this documentation in each patient's medical record, include the documentation in the clinical notes or use any number of

other documentation methods as those methods meet the needs and circumstances of individual hospices.

Comment: A commenter suggested that we delete proposed §418.56(c)(6) because the plan of care is a process, not just a single document.

Response: While we agree that the plan of care is an on-going process with many updates along the way, we are retaining this regulatory element. As the plan of care evolves through updates by the IDG, patients and representatives should continue to be involved, and hospices should continue to seek their understanding of and agreement with the changes. This requirement will help to ensure that patients and representatives are involved in the care planning process and that hospices actively address the needs and goals of patients.

Comment: Some commenters sought clarification on the obligations of the hospice when the family disagrees with the plan of care, even though the patient agrees.

Response: As discussed previously, we have deleted the requirement that hospices must obtain family agreement with the plan of care. Although hospices are no longer required to obtain the family’s agreement, the plan of care must still address the family’s goals and will still require assistance from the family in its implementation. For these

reasons, it remains essential for hospices to actively educate and involve family members to the extent possible.

Comment: A commenter agreed with our proposal in §418.56(d) that the patient's attending physician should be involved, to the extent possible, in updating the plan of care.

Response: Involving the attending physician to the extent possible in the patient's care, including updating the plan of care, is an important step to help ensure continuity of care. We are setting forth this requirement at §418.56(d).

Comment: Many commenters requested that the specific reference to the medical director or physician designee's role in updating the plan of care be deleted or rearranged. Commenters stated that the medical director or physician designee is often a member of the IDG and does not need to be mentioned separately.

Response: We agree that it is not necessary to specifically require the involvement of the medical director or physician designee in updating the plan of care because each IDG must have a physician member and that physician member provides adequate medical input in the updates. Therefore, we deleted this proposed requirement.

Comment: We received numerous comments about the

proposed time frames for updating the plan of care (§418.56(d)). Some commenters requested that we delete the proposed requirement that the plan of care be updated at least every 14 days. Others suggested that the 14 day requirement be changed to every 14-16 days, every 15 days, every 30 days, or twice per month.

Response: The plan of care is the map that the hospice will follow when delivering care to a patient and family. It is essential that the plan of care accurately reflect the services that must be delivered in order to meet the needs of the patient and family. As the patient's condition changes, the plan of care changes as well. In order to ensure that these updates occur, we proposed timeframes for both updating the comprehensive assessment and the plan of care. As previously discussed, we changed the timeframe for updating the comprehensive assessment from 14 to 15 days. We also believe that it is necessary for the time frames for updating the plan of care and updating the comprehensive assessment to coincide. This will help to ensure that there is a direct correlation between the two. Therefore, we have also changed the update time frame for the plan of care from every 14 days to every 15 days.

Comment: Some commenters suggested that we should delete the requirement in proposed §418.56(d) that hospices

must update the plan of care at intervals specified in the plan of care. Commenters stated that the plan of care cannot project future changes in the patient's needs. Commenters suggested that the plan of care should be updated based on the updates to the comprehensive assessment instead.

Response: Our intent in the proposed rule was to tie the updates to the plan of care directly to changes in the patient's condition. Predicting changes in patient status and the related plan of care is too difficult; therefore, we agree that this requirement should be deleted. We have deleted this requirement that hospices must "review, revise and document the plan as necessary at intervals specified in the plan", and, in its place, require that hospices must "review, revise and document the individualized plan as frequently as the patient's condition requires… ."

Comment: A commenter suggested that IDGs should be required to meet once every 28 days with all team members and the patient and family. The commenter also suggested that two or three members of the IDG should meet once a week.

Response: We do not believe that mandating an IDG meeting schedule would meet the needs of patients and families or would enhance overall care planning. A large

number of patients in hospices die before the 28th day (NHPCO Facts and Figures 2005). In addition, the proposed smaller weekly meetings would lack the essential input of all disciplines involved in the patient's care, potentially resulting in patient and family needs being overlooked or inadequately addressed. Section 418.56(e), Coordination of services, already requires an IDG system of communication that enables frequent information sharing among disciplines and across service locations.

Comment: Several commenters sought clarification regarding the requirement in proposed §418.56(e) that hospices must have a system of communication and integration. Commenters requested clarification on how the system might be documented, how the system would interact with contract providers, and how the system might be implemented. Other commenters expressed support for the new requirement and stated that the communication system outlined in the requirement is already standard practice in hospice agencies.

Response: We appreciate the support for this standard, as it validates our understanding that hospices have already established robust communication systems. As an interdisciplinary care model, hospice relies on communication between and integration of providers to

effectively plan and furnish care to patients and families. Through the years, hospices have developed methods to ensure that all members of a patient's care team receive timely information about patients. This standard expands on the communication and integration systems that hospices have developed for their own uses. This standard requires hospices to communicate, not only with their employees, but also with their contractors. It also requires hospices to integrate those same contractors into the hospice team. Communication and integration with service providers outside of the hospice's direct purview will help hospices ensure that each patient receives appropriate, high quality care in accordance with his or her plan of care, regardless of whether that care is furnished by hospice employees or contractors. As always, the hospice is ultimately responsible for the care furnished on its behalf and must actively ensure that contractors are fulfilling their patient care and communication contractual obligations.

The exact structure of the system of communication and integration will vary depending on the unique needs of each hospice. Telephone, e-mail, instant messaging, the postal service, and any other form of communication may be used in accordance with a hospice's own policies and procedures. Likewise, clinical notes, IDG meeting minutes, and any other

form of documentation associated with the patient's plan of care may be used to demonstrate compliance with this requirement, in accordance with a hospice's own policies and procedures. We believe that allowing hospices to determine the structure of the system and the documentation necessary to ensure that the system is used in the best and most flexible method for ensuring that hospices are able to comply with this provision.

Comment: A commenter suggested that we should delete the phrase "through its designated professionals" from §418.56(e)(1) because the members of the IDG are already defined in §418.56(a)(1).

Response: We agree with the commenter that the above-referenced phrase is not necessary, and we have deleted it.

Comment: A commenter suggested that the language in proposed §418.56(e)(4) be simplified by substituting the phrase "all facilities" for the list of the various settings where hospice care may be provided.

Response: We agree that adopting an all-inclusive term will make it easier for hospices to understand their crosscutting communication responsibilities. Since "settings" is a broader term than "facilities", as the commenter suggested, we are modifying the text in §418.56(e)(4) to require that the system of communication

provides for and ensures the ongoing sharing of information between all disciplines in all settings..

Comment: A commenter suggested that, in §418.56(e), hospices should be required to share information with non-hospice providers who are also caring for a patient.

Response: We agree with this suggestion. We believe that it will enhance patient care in the unusual circumstances where patients with multiple illnesses and conditions receive care from multiple providers. This will ensure that hospices actively coordinate the care that they are providing with the care being furnished by other providers. The coordination will help hospices avoid a duplication of services as well as potentially dangerous drug prescribing and dosage problems. This new requirement is located at §418.56(e)(5). As stated previously, when coordinating care with other providers, it is essential that hospices are aware of their role within the larger comprehensive plan of care, as well as any gaps in the comprehensive plan of care and the parties responsible for filling those gaps.

5. Condition of Participation: Quality Assessment and Performance Improvement (Proposed §418.58)

The existing §418.66, “Condition of participation—Quality assurance,” relies on a problem-oriented approach to

identify and resolve patient care issues. Failure to meet the quality assurance condition is consistently one of the top 10 deficiencies cited by Medicare surveyors nationwide. During the last decade the health care industry, including the hospice industry, has moved beyond the problem-oriented, after-the-fact corrective approach of quality assurance to an approach that focuses on a preemptive plan that continuously addresses QAPI. Hospice industry associations have indicated that the upgraded QAPI approach used by many hospice providers is incompatible with the existing quality assurance condition. On the other end of the spectrum some providers do not have any quality program.

The proposed QAPI requirement would raise the performance expectations for hospices seeking entrance into the Medicare and Medicaid programs, as well the expectations of those currently participating in Medicare and Medicaid. We proposed that each hospice would develop, implement, and maintain an effective, continuous quality assessment and performance improvement program that stimulates the hospice to constantly monitor and improve its own performance, and to be responsive to the needs, desires, and satisfaction levels of the patients and families it serves.
The desired overall outcome of this proposed CoP would be that the hospice would drive its own quality improvement

activities and improve its provision of services. With an effective quality assessment and performance improvement program in place and operating properly, a hospice can better identify and reinforce the activities it is doing well, identify its activities that are leading to poor patient outcomes, and take actions to improve performance. A hospice would be free to develop a program that meets its needs. As proposed, a provider's QAPI program would not be judged against a specific model.

The proposed QAPI CoP was divided into five standards. Under standard §418.58(a), "Program scope," a hospice's quality assessment and performance improvement program would include, but not be limited to, an ongoing program that would be able to show measurable improvement in indicators that were linked to improving palliative outcomes and end-of-life support services. We expect that a hospice would use standards of care and the findings made available in current literature to select indicators to monitor its program. The hospice would measure, analyze, and track these quality indicators, including areas such as adverse patient events and other aspects of performance that assess processes of care, hospice services, and operations. ("Adverse patient events," as used in the field, generally refer to occurrences that are harmful or contrary to the targeted

patient outcomes.)

The second proposed standard at §418.58(b), “Program data,” would require the hospice program to incorporate quality indicator data, including patient care, administrative, and other relevant data, into its QAPI program. This would include data that were received from or submitted to hospice professional organizations. We did not propose to require that hospices use any particular process or outcome measures. However, a hospice that would choose to use the available quality measures would be able to expect an enhanced degree of insight into the quality of its services and patient satisfaction, compared to beginning the outcome-measure development process anew because currently existing measures have already been tested to some degree for reliability and validity.

Proposed standard (b) also would require that data collected by the hospice, regardless of the source of the data elements, would be collected in accordance with the detail and frequency specifications established by the hospice’s governing body. Once collected, hospices would use the data to monitor the effectiveness and safety of services, and to identify opportunities for improvement.

The third standard under the quality assessment and performance improvement program at proposed §418.58(c),

“Program activities,” stated that the hospice would set priorities for its performance improvement activities that focused on high risk, high volume and problem-prone areas, considered the prevalence and severity of identified problems’ and gave priority to improvement activities that affected palliative care, patient safety, and quality of care outcomes. In §418.58(c) we also proposed to require the hospice to track adverse patient events, analyze their causes, and implement preventive actions that would include feedback and learning throughout the hospice.

We proposed at §418.58(d), “Performance improvement projects,” that the number and scope of improvement projects conducted annually would reflect the scope, complexity, and past performance of the hospice’s services and operations. The hospice would document what improvement projects were being conducted, the reasons for conducting them, and the measurable progress achieved on them.

In the final proposed standard at §418.58(e), “Executive responsibilities,” a hospice’s governing body would be responsible and accountable for ensuring that the ongoing quality improvement program was defined, implemented, and maintained. The governing body would ensure that the program addressed priorities for improved quality of care and patient safety. The governing body would also specify

the frequency and detail of the data collection and ensure that all quality improvement actions were evaluated for effectiveness. The governing body's most important role would be to ensure that staff were furnishing, and patients were receiving, safe, effective, quality care. Therefore, it would be incumbent on the governing body to lend its full support to agency quality assessment and performance improvement efforts.

Comment: A few commenters stated that the phrases "measurable improvement," "palliative outcomes," "end of life support systems," and "quality indicators" as they were used in the QAPI CoP, were vague.

Response: We agree that the phrase "end of life support systems" is vague, and we have removed it in the opening paragraph and standard (a) because it is duplicative of the requirement that a hospice's QAPI program must involve all hospice services, including those services furnished under contract or arrangement. In §418.58(a)(1) we have replaced the term "end of life support systems" with "hospice services" to correspond with the "hospice services" described in the opening paragraph. We do not agree that the phrase "palliative outcomes" is vague. Outcomes are the results of care provided; therefore palliative outcomes are the results of palliative care provided. Since hospices

primarily furnish palliative care to patients and respond to the results of the care furnished, we believe that it is reasonable to expect hospices to include palliative outcomes, gathered as part of the comprehensive and updated comprehensive assessments in accordance with final §418.54(e), as part of their QAPI programs. We replaced the phrase “indicators for which there is evidence that improvement in those indicators will improve palliative outcomes” in §418.58(a)(1) with the phrase “indicators related to palliative outcomes.” We believe that this revised language is clearer and more precise. Therefore, revised §418.58(a)(1) now reads, “[t]he program must at least be capable of showing measurable improvement in indicators related to improved palliative outcomes and hospice services.” We do not agree that the phrase “measurable improvement” is vague. Hospices are required to have data-driven QAPI programs. Through these data, hospices measure their current performance, implement performance improvement projects, and measure their changes in performance after implementing the performance improvement project. Based on an analysis of the data, we believe that hospices will be able to measure the amount of improvement, stagnation, or decline in their performance and adjust their activities accordingly.

Comment: Numerous commenters asked for more clarification of the term “adverse event” as it is used in §418.58(a) and §418.58(c) of this Condition of Participation. Other commenters asked for a delay in the proposed requirement that hospices must collect and analyze adverse event data.

Response: We do not define the term “adverse event” because we believe that, as part of their QAPI programs, hospices should be free to define and implement the term in the manner that fits their needs. Hospices may choose to develop their own definition or use a definition developed by an accrediting body or industry organization. Once a hospice has identified the definition of an adverse event, it is responsible for adhering to the definition when tracking and analyzing these events and when implementing preventive actions. In general, an adverse event would be any action or inaction by a hospice that caused harm to a hospice patient. However, hospices are not bound to use this generic description.

We believe that it is essential to a hospice’s QAPI program to begin tracking and analyzing adverse events at the same time that it begins collecting patient level outcome measure data elements and hospice-wide measures. Since adverse events generally result in harm to a patient,

they serve as important indicators of areas for potential improvement. If hospices do not collect adverse event information, they may be missing important data from which to assess their performance. Therefore, we are not delaying the adverse event requirements in this final rule.

Comment: Many commenters submitted suggestions for what hospices may want to consider when selecting the elements of their QAPI program. Commenters suggested that hospices may want to examine such issues as pharmacy services, bar coding, electronic prescribing, clinical decision support programs, adverse event reporting systems, provider education efforts, patient and family education efforts, pain, nausea, shortness of breath, skin integrity, constipation, the appropriateness of emotional and spiritual interventions, and the timeliness of meeting patient needs at the start of care.

Response: We appreciate all of the suggested areas that hospices may choose to examine when developing their QAPI programs. In addition to these suggested domains, hospices may also want to consider issues surrounding patient transitions. Transitions from one care setting/provider to a hospice, or from a hospice to another care setting/provider, are an opportunity for hospices to improve their relationships with their referral sources

while improving patient care and safety. Hospices may want to consider the use of shared protocols, agreements to honor advance directives, medication reconciliation processes, caregiver training and support systems, communication arrangements, and feedback systems, all related to patient transitions, as areas to examine in their QAPI programs. We are not requiring hospices to use any of the suggested domains identified above at this time because there is no currently available set of standardized measures.

Comment: A few commenters requested clarification about when and where patient care measures will be documented.

Response: Different patient care measures require different data collection time frames. While some measures may require data collection only once, other measures may require data collection every few days or weeks. The nature of the patient care measure will determine the time frame for collecting and updating. We expect hospices to establish their data collection time frames within the specific context of the measures used, the available literature, any nationwide data collection projects they may participate in, their own data collection needs and goals, as well as the needs of their patients.

We require in §418.104(a)(4) that the patient care outcome measure data be included in the patient’s clinical

record because hospices must use such data for individual care planning and coordination of services (§418.54(e)(2)). Hospices are free to document the patient care measure data in other locations as well in order to meet their needs. All documentation must be in accordance with the data collection policies and procedures established by the hospice to ensure consistency and retrievability.

Comment: Many commenters requested clarification on the role of national standardized patient outcome measures and their relationship to standardized benchmarks. Specifically, commenters noted that, while some national measures are currently available, there is still work to be done in this area. A commenter suggested that any measures developed should relate to providing physical and emotional support, promoting shared decision-making, individualizing care, and attending to the needs of families. In addition, commenters expressed uncertainty about how national benchmarks may be used to measure patient outcomes. Some commenters suggested that we should work with the hospice industry and quality improvement organizations (QIOs) to establish such benchmarks while other commenters stated that benchmarking is not necessary because the variances between hospices put the validity of the benchmarks into question.

Response: We agree that more work is needed to establish a wide variety of valid patient outcome measures that hospices may choose from. We commissioned a special study, the PEACE project, conducted by the North and South Carolina QIO. This study created a quality-focused self-audit tool for hospices to use, and identified quality measures that focus on the quality of clinical care furnished to hospice patients. Results of the study are available at http://medqic.org/dcs/ContentServer?pagename=Medqic/MQPage/Homepage.

In addition, the National Hospice and Palliative Care Organization launched a National Quality Initiative and Quality Collaborative to improve hospice and palliative care outcomes. This initiative is helping hospices develop functional QAPI programs, including patient outcome measures.

Furthermore, the National Quality Forum has issued voluntary consensus standards for end-of-life care of cancer patients, who comprise approximately 50 percent of the hospice patient population (*National Voluntary Consensus Standards for Symptom Management and End-of-Life Care in Cancer Patients,* December 2006, www.qualityforum.org/publications/reports/palliative.asp).

The National Quality Forum also issued the “National Framework and Preferred Practices for Palliative and Hospice Care Quality” (2006, www.qualityforum.org). This report identified eight domains of quality care as follows: structures and processes of care; physical aspects of care; psychological and psychiatric aspects of care; social aspects of care; spiritual, religious, and existential aspects of care; cultural aspects of care; care of the imminently dying patient; and ethical and legal aspects of care. Using the structure of these domains, the report identifies 38 preferred practices that have been endorsed as suitable for implementation in hospice programs.

Furthermore, the agency for Healthcare Quality and Research (AHRQ) issued an evidence-based review of end-of-life care and outcomes (www.ahrq.gov/clinic/epcsums/eolsums.htm) that may also assist hospices.

We believe that these efforts, combined with the measures already identified by the NHPCO and Brown University (Time Toolkit, www.chcr.brown.edu/pcoc/toolkit.htm), are sufficient to provide hospices with patient outcome measure options that suit their needs. Some of the measures that already have been or are being developed relate to comfortable dying,

self-determined life closure, and family satisfaction with care.

We do not believe that these efforts are sufficient to establish nationwide benchmarks that are appropriate for inclusion in this rule. More time is needed to test, refine, and collect further data related to any specific measure before we could establish a nationwide benchmark that all hospices should be required to meet. The necessary information is simply not available at this time to establish mandatory benchmarks, although hospices are free to use existing benchmarks to measure their own performance against that of other similar hospices who use the same measures.

In order to further the process of establishing widely-accepted, valid, benchmarked quality measures, CMS is actively pursuing additional research on selected quality measures. This research will help identify and refine measures that are valid, meaningful, and reliable for hospices. It will also help establish benchmarks for hospices to attain.

Following publication of this final rule, CMS will issue further sub-regulatory guidance on QAPI.

Comment: A few commenters questioned the ability or appropriateness of using the same outcome measures for each

patient within a hospice. Some commenters noted that not all measures may apply to all patients. Likewise, the commenters noted that certain patients may need individualized measures unique to the patient's needs and goals. Other commenters noted that measures may be different based on the location in which care is provided (that is, in the patient's home or in an in-patient facility). Still other commenters noted that outcome measure data may not be statistically significant when the data are collected from extremely small samples due to a low patient census.

Response: A variety of hospice-specific patient outcome measures are currently available. Many of these measures capture data about universal issues such as patient pain or discomfort. We believe that these universal measures can be successfully applied to all of a hospice's patients, regardless of their diagnosis or care location. At the same time, we agree that hospices may need to add specific outcome measures for specific patients in order to gather data related to the individual's needs and goals. Hospices may add patient-specific measures to the core set of standard measures that they choose to collect data on for all patients. As with the core set of standardized patient data, patient-specific data must be gathered and documented in a consistent, systematic and retrievable manner.

When analyzing data on a patient level, sample size does not matter. To use the patient outcome measure of pain controlled within 48 hours of admission discussed above in the patient assessment section, a hospice would need to document for a patient the presence or absence of uncontrolled pain upon the patient’s admission to hospice. If a patient has uncontrolled pain, the hospice would then reassess his or her pain 48 hours after the patient’s admission to hospice and document the presence or absence of uncontrolled pain at that time. This does not mean that the hospice does not assess the patient’s pain between the initial pain assessment and the 48 hour pain assessment. Indeed, the hospice may need to assess the patient’s pain far more frequently in order to adjust the treatments being provided to control the patient’s pain. In completing a patient-level analysis of the patient’s data, the hospice would be able to judge the effectiveness of the initial care furnished in controlling the patient’s pain.

In completing the hospice-wide analysis, this patient’s pain control data would be aggregated with the pain control data of the other patients that the hospice cared for. This aggregated data would allow the hospice to look for patterns such as a high level of pain control success for patients with cancer diagnoses and lesser levels of success for

congestive heart failure patients. Identifying patterns, areas of strength, and areas of weakness allows the hospice to reaffirm promising practices that lead to positive patient outcomes and re-examine practices that lead to inadequate or negative patient outcomes.

Aggregation of data must be done in accordance with the policies and procedures established by the hospice. If a hospice has an extremely small average monthly census, then it may make sense for that hospice to aggregate several months of data. Likewise, if a hospice has an extremely large average monthly census, then it may make sense for them to aggregate the data more frequently to ensure that the amount of data does not become overwhelming to those analyzing it. The flexible nature of the patient outcome measure standard and the quality assessment and performance improvement CoP allow hospices to adapt data collection and analysis to their needs and goals.

Comment: A few commenters expressed enthusiastic support for the requirement that hospices collect patient outcome measure data, noting that other health care providers have been collecting this data for several years. Other commenters, while expressing support for the overall goals of data collection and QAPI, expressed concern about the potential costs. Commenters cited the potential cost and

availability of software to aid in data collection as the single largest concern.

Response: We appreciate the overall support for data collection and QAPI. At the same time, we understand the concerns that some hospices have about implementing these new requirements. We note that the new regulation does not require hospices to use electronic health records or any specific software for data collection. Hospices are free to choose the data collection methods and tools that best suit their needs. We do not believe that this rule is imposing a burden on hospices by requiring them to obtain sophisticated data collection and analysis computer programs. Analysis of patient outcome measures, as well as administrative data, will allow hospices to determine objectively what care results in the best outcomes for a particular patient or subset of patients. This will help hospices identify best practices and avoid ineffective practices, which may reduce hospice expenditures in the future. We believe these benefits will outweigh any costs associated with the process.

Comment: A commenter suggested that, in §418.58(b)(2)(ii), hospices should be required to use quality indicator data that they collected to identify priorities, as well as opportunities, for improvement.

Response: We agree that hospices should use data to prioritize their areas for improvement, and we have incorporated this suggestion into the final rule. Section 418.58(b)(2)(ii) now reads, “[i]dentify opportunities and priorities for improvement.”

Comment: In proposed §418.58(b)(3), a commenter suggested that the governing body should approve, rather than specify, the frequency and detail of data collection.

Response: We agree that the governing body’s general QAPI oversight responsibility would be more appropriately described by the term “approved” than the proposed term “specified,” and we have made this change.

Comment: Some commenters suggested that the requirement for hospices to conduct performance improvement projects should be phased in.

Response: In accordance with this rule, hospices are required to identify opportunities and priorities for improvement based on the data that they have collected. We agree that it would be appropriate to delay implementation of the performance improvement projects requirement to allow hospices time to develop and implement a data collection program, and actually amass several months of data. For this reason, we have added a 240 day phase-in period. This phase-in period will allow hospices to gather several months of

data before being required to develop and implement their data-driven performance improvement projects. Once the 240 day phase-in period is complete, we expect hospices to begin developing and implementing their data-driven performance improvement projects, with evaluation of those performance improvement projects to follow thereafter.

Comment: A commenter asked us to specify, in §418.58(d)(1), that the number and scope of performance improvement projects that a hospice undertakes should be based on the needs of the hospice's population and its own internal organizational needs. Another commenter asked us to clarify our proposed requirement that performance improvement projects must reflect a hospice's past performance.

Response: While we understand that some hospices may want additional guidance on the number and scope of projects that must be undertaken, we believe that a hospice's performance improvement projects should be required to reflect the needs of its patient population as well as its own needs, and this requirement is included in the final rule. We also believe that hospices must examine their past performance when developing performance improvement projects. If a hospice is aware that it had issues in a particular area in the past, then we believe that it is

appropriate to re-examine that issue to assure that it has been remedied. Hospices should conduct these performance improvement projects that focus on previously existing concerns in concert with performance improvement projects that focus on more recently occurring issues, to ensure that they are consistently furnishing quality services to patients. Revised §418.58(d)(1) reads, “The number and scope of distinct performance improvement projects conducted annually, based on the needs of the hospice’s population and internal organizational needs, must reflect the scope, complexity, and past performance of the hospice's services and operations.”

Comment: A commenter suggested that, in §418.58(d)(2), hospices should be specifically required to document any national quality improvement projects they are participating in. Other commenters questioned whether or not participation in national quality improvement projects would satisfy the QAPI requirement.

Response: Section 418.58(d)(2) requires hospices to document all performance improvement projects they are conducting, including national performance improvement projects. There is no need to single out national performance improvement projects as needing to be documented separately because they are one part of a hospice’s larger

performance improvement project plan, which must be documented. Hospices are free to participate in such national projects. We would caution however, that participation in such projects does not guarantee that hospices are in compliance with this requirement. As required by §418.58(b)(2)(ii), hospices must use the quality indicator data that they have gathered to identify and prioritize opportunities for improvement. In addition, §418.58(a)(1) requires a hospice's QAPI program to be able to show measurable improvement in areas related to improved palliative outcomes and hospice services. Furthermore, §418.58(d)(1) requires that the scope and number of a hospice's performance improvement projects are to be based on the needs of the hospice and its patient population. Read together, these requirements require hospices to develop, implement, and assess performance improvement projects that reflect their areas of weakness, as identified through the data that they have collected, and the needs of their organizations. If a hospice participates in a national performance improvement project that does not address one or more of its areas of weakness, or if that performance improvement project will not enable the hospices to demonstrate measurable improvement in areas identified as needing to be addressed, then participation in the national

performance improvement project would not meet the QAPI requirements of this rule.

Comment: Numerous commenters stated that the proposed QAPI requirement at §418.58(e) assigned a hospice's governing body too much responsibility for the hospice's QAPI program. Commenters believed that the hospice IDG or a professional advisory committee would better fulfill the executive responsibilities described in this paragraph. One commenter suggested that the role of the governing body should be augmented by requiring it to monitor the QAPI program rather than simply ensuring that is it functioning. Another commenter suggested that the role of the governing body should be further clarified by adapting leadership standards for home care agencies established by the Joint Commission.

Response: Section 418.100(b) of this rule requires the hospice's governing body to assume full legal authority and responsibility for the management of the hospice, including its QAPI program. Section 418.58(e) of the proposed rule specified the QAPI responsibilities of the governing body. It would require the hospice's governing body to ensure that a QAPI program is defined, implemented, and maintained. In addition, the rule proposed that the governing body must ensure that the QAPI program addresses the hospice's quality

priorities and that its effectiveness is evaluated. As the entity that is legally responsible for the hospice, we believe that it is essential that the hospice governing body ensures that the hospice's QAPI program is meeting the requirements of this rule.

We believe that our governing body requirements meet the intent of the Joint Commission leadership standards. Therefore we are setting forth this requirement as final. The governing body may assume hands-on control of the QAPI program to ensure that the program is in compliance with this rule, or it may choose to appoint one or more individuals to handle the structure and administration of the QAPI program while the governing body retains ultimate responsibility for the actions of the designated individual(s).

As many commenters noted, the individuals who compose the governing body may not have significant experience in a hospice QAPI program and would therefore not be the best candidates to actively supervise or direct its activities. For this reason, it may not be appropriate to require the governing body to actively monitor the QAPI program if this function can be managed by others more knowledgeable in clinical and/or related fields of endeavor. A new provision has been added at §418.58(e)(3) explicitly requiring the

governing body to appoint QAPI leaders.

Comment: A commenter asked us to delete the proposed §418.58(e)(3) which required the governing body to ensure that clear expectations for patient safety are established. The commenter stated that patient safety is already addressed throughout the regulations, and that it is redundant to include this requirement in the QAPI CoP.

Response: We agree that patient safety is already addressed throughout the rule and does not need to be separately included in the QAPI section.

Comment: The majority of commenters that submitted comments on the proposed quality assessment and performance improvement CoP supported its overall goals. The commenters appreciated our recognition of the role that QAPI now plays in the hospice industry as well as its current limitations. The commenters requested assistance from CMS in implementing some aspects of the proposed QAPI requirement. Commenters sought additional CMS involvement in developing measures that hospices may choose to use. Commenters also sought assistance from the QIOs that CMS contracts with to provide quality assistance for other provider types.

Response: In August 2006 CMS contracted with the North and South Carolina QIO to conduct a special study on hospice quality measures. This study created a quality-focused self-

audit tool for hospices to use and identified quality measures that focus on the quality of clinical care furnished to hospice patients. Results of the study are available at http://medqic.org/dcs/ContentServer?pagename=Medqic/MQPage/Homepage.

In addition to this completed project, CMS plans to sponsor additional research that will examine the validity, reliability, appropriateness, and usefulness of select quality measures. Furthermore, CMS plans to sponsor work that will develop a method for QIOs to actively assist interested hospices in developing and implementing QAPI programs.

Comment: Many commenters made general statements in support of the broad framework adopted by the proposed QAPI requirement. These commenters liked the fact that we did not propose that hospices use any specific quality measures, data elements or benchmarks. Commenters voiced approval that they would be permitted to identify their own quality goals, measures and elements, and that they would be permitted to identify how many performance improvement projects they undertook and what those projects would focus upon. Conversely, other commenters specifically asked for the regulation to detail the quality measures and data elements

that must be collected, the number and topics of performance improvement projects that must be undertaken, and the exact benchmarks or results that must be achieved.

Response: The two diametrically opposed viewpoints expressed by commenters are difficult to reconcile. Our intent in developing the QAPI CoP was to ensure that hospices would develop a data-driven program for continuous quality improvement that reflects the needs of patients and hospices alike. We believe that prescribing specific data measures and improvement projects is not appropriate at this time because there is no currently available, valid, reliable, widely applied set of clinical and/or administrative quality measures. As hospice quality measurement and best practices continue to evolve, we believe that a set of measures and practices may be identified, and that such measures and practices may be appropriate for inclusion in the hospice rules.

At the same time, we are sensitive to the concerns of hospice providers who are wary of the new and unknown. As described above, we conducted a special study through the Carolina QIO to identify hospice measures focusing on the quality of clinical care furnished to hospice patients. These measures are publicly available at no cost to hospice providers. In addition, the largest hospice industry group,

the National Hospice and Palliative Care Organization, has launched a major quality initiative to provide hospices with the tools they need to begin collecting and analyzing QAPI data and to develop, implement, and analyze performance improvement projects. Furthermore, Brown University has made available the TIME Toolkit, which contains quality measures and related data elements that hospices may use in their QAPI programs. We are confident that these efforts, and others that may arise in the future, will help hospices transition from the quality assurance approach to the QAPI approach. For additional discussion of the former quality assurance requirements and the new QAPI requirements, see pages 30847-30849 of the May 27, 2005 hospice proposed rule (70 FR 30840).

Comment: Many commenters expressed general concern about the cost of implementing a QAPI program. Several of these commenters suggested that implementing a QAPI program will require more staff hours and money than estimated in the impact analysis section of the proposed rule.

Response: We recognize that moving from the basic QA approach to a QAPI approach will require some hospices to reallocate funds to expand and evolve their existing quality programs. However, an effective QAPI program will allow hospices to identify areas for improvement. The analysis of

patient care and administrative data for the QAPI program may help hospices identify ineffective therapies, opportunities for staff improvement, low performing contracts for services, etc., and allow hospices the chance to improve services and efficiency. A vigorous QAPI program will benefit hospices and patients, and will help ensure that hospice resources are being used in the most effective and efficient manner possible. While we have adjusted the cost estimate for this CoP in the impact analysis section, we have not factored in the cost savings that hospices may achieve.

Comment: Several commenters stressed the importance of ensuring that all hospice employees are involved in the QAPI program. Of these commenters, a few highlighted the need for board certified chaplain involvement in QAPI.

Response: We agree that it is important to involve employees, both paid and volunteer, as well as individuals furnishing services under contract, in the hospice's QAPI program. In order to ensure such involvement, we require in §418.62, that all licensed professionals furnishing services on behalf of the hospice must actively participate in the hospice's QAPI program. Hospices have the flexibility, within the licensed professional requirement, to determine which individuals will lead QAPI efforts based on their own

needs and goals. Hospices may choose to use the services of board certified chaplains in developing and implementing their QAPI program.

Comment: A few commenters suggested that we should require hospices to publicly report the results of their data collection, while other commenters expressed concern that we may require hospices to use a data collection tool such as OASIS, which would enable public reporting of hospice data. Similarly, commenters expressed concern that we would expect hospices to use computerized systems in implementing the QAPI requirement.

Response: Quality assessment and performance improvement is a fast growing approach to quality improvement in the hospice industry. However, there is no nationally standardized and accepted set of measures that could be used at this time to develop an OASIS-like tool that would enable public reporting. The intent of this rule is to establish the framework of QAPI in hospice, not to prescribe specific measures or tools. As such, we are not requiring hospices to use specific outcome or process measures, data elements, forms, or computer systems. These decisions are at the discretion of each hospice based on its own needs and goals. We caution that we cannot, at this time, predict with any certainty the future of hospice data

collection and its relationship to the public reporting of data.

Comment: Many commenters asked for more information about how State surveyors will survey hospices for compliance with the QAPI requirements. Commenters sought more information about how hospice surveyors will use hospice data and how they will determine a QAPI program's scope, complexity and adequacy of improvement projects.

Response: Hospices are required to collect and analyze patient care and administrative quality data and to use that data to identify, prioritize, implement, and evaluate performance improvement projects to improve the quality of services furnished to hospice patients. In order to assess compliance with the QAPI requirements, hospice surveyors will need to access, upon request, a hospice's aggregated data and its analysis of that data. Surveyors will also need access to the hospice's QAPI plan, any meeting minutes or notes for meetings concerning the development and implementation of the hospice's QAPI program, those individuals responsible for the QAPI program, and any other necessary resources needed to assess a hospice's compliance. This information will allow surveyors to match the data provided by the hospice with the actual experiences of hospice employees and patients to ensure that the QAPI

program is prevalent throughout the hospice's operations and services, and that it is positively influencing patient care. Furthermore, this information will enable surveyors to assess the adequacy and appropriateness of a hospice's QAPI program. Surveyors will focus on areas such as how and why a hospice chose its quality measures, how it ensures consistent data collection, how it uses data in patient care planning, how it aggregates and analyzes data, how it uses the data analysis to select performance improvement projects, how it implements such projects, and its use of data to evaluate the effectiveness of those projects. We will include more detailed information about the QAPI survey process and goals in future sub-regulatory guidance such as the State Operations Manual and Interpretive Guidelines.

We note that hospitals are currently required to comply with a very similar performance improvement project regulation and have successfully determined their performance improvement project needs and goals without prescribed minimums. Likewise, hospital surveyors have successfully assessed hospital compliance with the performance improvement project regulation without such minimums. We will use the knowledge gained through the hospital survey process to guide our understanding and

implementation of surveys for hospices complying with this performance improvement project regulation.

6. Condition of Participation: Infection control (§418.60)

There are no current requirements for infection control other than the requirements at §418.100(a) that read in part, “each patient is to be kept comfortable, clean, well groomed, and protected from accident, injury, and infection,” and the requirement at §418.100(e) regarding isolation areas. We proposed a new CoP to help manage the seriousness and hazards of infectious and communicable diseases.

We recognize that a hospice cannot be directly responsible for the maintenance of an infection-free environment in every setting. We proposed in §418.60(a), “Prevention,” that hospices follow accepted infection control standards of practice and ensure that all staff that provide hospice services know and use these current best prevention practices to curb the spread of infection. Periodic training is one way to assure that staff take all appropriate infection prevention and control precautions. Hospices may also consider immunizing their patient care staff for influenza as part of their infection control programs. Hospice staff may transmit influenza to patients, compromising their quality of life at this important time,

and to caregivers, compromising their ability to effectively care for the patient. Furthermore, infected staff may create a staffing shortage, compromising the entire hospice's ability to safely and effectively deliver care to all hospice patients and their families.

In §418.60(b), "Control," we proposed that the hospice be required to engage in an ongoing system-wide program that focuses on the surveillance, identification, prevention, control, and investigation of infections and communicable disease. Where infection and/or communicable disease are identified, we expect that this information would be made part of the hospice's quality assessment and performance improvement program.

As proposed in §418.60(c), "Education," each hospice would be expected to educate its staff, as well as patients, families, and other caregivers in the "current best practices" for controlling the spread of infections within the home during the course of the family/care giver's interactions. We did not propose any specific approaches that a hospice would be required to adhere to. A hospice would be expected to aggressively seek to minimize the spread of disease and infection through its efforts to help families and caregivers understand what can and should be done to minimize infection.

Comment: Several commenters thanked us and supported the incorporation of this new requirement.

Response: We appreciate the support from the commenters on this proposal. We believe that this requirement is necessary to ensure that patients receive quality care from hospices, regardless of the patient's setting. Due to the potential negative effects on health and safety that are posed by infection and communicable diseases, we believe hospices need to address infection standards of practice and ensure all staff that provide hospice services know and use the current best prevention practices to curb the spread of infection.

Comment: One commenter requested that we add the word "visitor" to the list of those protected by the infection control program.

Response: We agree, and the word "visitor" has been added to the opening paragraph. The final language at §418.60 reads, "[t]he hospice must maintain and document an effective infection control program that protects, patients, families, visitors and hospice personnel by preventing and controlling infections and communicable diseases."

Comment: One commenter recommended that the disease prevention plan in §418.60(b)(2)(ii), should ensure the comfort of the patient.

Response: We strongly agree. The comfort, safety and well-being of the patient must always be the main objective when providing care and services. Section 418.100(a), “Serving the hospice patient and family,” already requires hospices to furnish all care, including care related to infection control, in a manner that optimizes patient comfort.

Comment: A few commenters expressed concern about our proposed requirement at §418.60(c) that hospices must provide infection control education to staff, patients, family and other caregivers. One commenter expressed concern that the tracking of infection in hospice patients, especially in the home setting, is difficult and that in many cases infection is a natural progression of the disease and is not unexpected.

Response: We acknowledge the limitations hospices may encounter regarding infections in patients, and in determining the outcomes for patients that are terminally ill, immune-suppressed and that may have other co-morbidities. However, we believe that this should not affect the need to apprise family and caregivers about infection control. The education standard in §418.60(c) allows the hospice flexibility in meeting infection control, prevention and education objectives. While we would expect the hospice

to adhere to best practices, we are not requiring any specific approaches. Due to the negative effects of infections on the health and safety of patients and staff and the potential financial burden on the hospice, we believe that it is in the best interest of hospices and the patients they serve to focus on controlling the spread of infections in the home.

Comment: A few commenters asked how hospices should handle extremely short lengths of stays, where there may not be an opportunity to educate the caregivers on infection control procedures.

Response: We certainly appreciate that hospices may encounter patients that elect the benefit in the last 24-72 hours of life. We agree that, due to the short time frame, there may not be time to educate the patient, family and caregiver on myriad infection control procedures, nor given the circumstances, may it be appropriate. Nonetheless, we believe that the demonstration of best practices by the hospice staff while caring for the patient and the ability of the staff to talk to the patient and family regarding basic precautions such as hand washing while providing care would be sufficient. This information will be included in future sub-regulatory guidance.

7. Condition of Participation: Licensed professional services (§418.62)

Sections of current regulations at §418.82, “Nursing services;” §418.84, “Medical social services;” and §418.92, “Physical therapy, occupational therapy and speech-language pathology,” identify detailed tasks that must be performed by agency staff. We proposed to remove §418.82, §418.84, and §418.92, and replace them with a more simplified condition, “Licensed professional services.” Instead of identifying detailed tasks, we broadly described the expected contributions of the licensed professionals who are furnishing hospice services. Licensed professional services, for purposes of this section, would include, but not be limited to, skilled nursing care, physical therapy, speech language pathology, occupational therapy, and medical social services. We proposed that licensed professionals who provide services to hospice patients either directly or under arrangement would participate in coordinating all aspects of care, including updating the interdisciplinary comprehensive assessments, developing and evaluating plans of care, participating in patient and family counseling, participating in the quality assessment and performance improvement plan, and participating in in-service training.

Comment: Several commenters suggested that we amend the

language in proposed §418.62(b) to apply to the coordination of the patient's hospice care. One commenter stated that we should limit the hospice's responsibility to coordination of hospice care, since the hospice cannot control other aspects of patient care that are unrelated to the terminal illness and related conditions.

Response: We appreciate the comments and are accepting the suggested changes. Although we expect that the hospice will actively participate in the coordination of hospice care, it is unrealistic and beyond the scope of the hospice regulations to require hospices to coordinate all aspects of a patient's care. Therefore, we have amended this provision and the final language at §418.62(b) now reads, "[l]icensed professionals must actively participate in the coordination of all aspects of the patient's hospice care…." As previously noted, if a hospice does not coordinate all aspects of a patient's care, it is incumbent upon the hospice to know who is performing this function, and to actively communicate and coordinate with other providers to ensure that the patient's needs and goals are met.

Comment: One commenter asked that we not require contracted staff to participate in the hospice's QAPI program. The commenter suggested that we amend this language so that contracted licensed professionals are encouraged to

participate whenever possible.

Response: For QAPI to work effectively for the hospice, all professionals must be involved in the quality process. This would include contracted licensed professionals. We expect all hospices to provide high quality care for all of the patients they serve, and believe that the care should be "seamless," meaning that, whether the individual providing services is an employee or contracted licensed professional, the care provided to patients and their families must be provided at the same high level of quality.

8. Condition of Participation: Core services (§418.64)

The conditions of participation containing the current core services requirements are in §418.80, "Furnishing of core services;" §418.82, "Nursing services;" §418.84, "Medical social services;" §418.86, "Physician services;" and §418.88, "Counseling services." We proposed to combine these into a single condition. We also proposed to incorporate the requirement at existing §418.50(b)(3) which required that core services would be provided in a manner consistent with accepted standards of practice.

This section was revised to reflect changes to the Act made by section 946 of the MMA. In accordance with section 946 of the MMA, we proposed to allow a hospice (the primary hospice) to enter into arrangements with another Medicare-

certified hospice to obtain core hospice services. The Act provided that this could be done under extraordinary or other nonroutine circumstances. Pursuant to section 1861(dd)(5)(D) of the Act (as amended by section 946(a) of the MMA) those circumstances are: unanticipated periods of high patient loads; staffing shortages due to illness or other short-term temporary situations that interrupt patient care such as natural disasters; and temporary travel of a patient outside the hospice's service area.

In the first proposed standard, "(a) Physician services," we incorporated the existing requirements of §418.86. The existing and proposed requirement states that hospice physicians, 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. As a result of changes made to the Act by the BBA, we also proposed to add a provision to the CoPs permitting hospices to contract for physician services. This proposed provision would align the CoPs with current CMS policy permitting hospices to contract for physician services.

The second proposed standard, "(b) Nursing services," incorporated the requirements of §418.82 of the existing CoPs. We also proposed to add specific language to address

the role of nurse practitioners in providing hospice care. The services provided by nurse practitioners continue to be guided by Medicare statutory requirements. Within these statutory requirements, we propose to allow nurse practitioners to perform hospice functions that are within the scope of their practice and license, as well as within the laws of the State in which they practice.

We also proposed in §418.64(b) to allow hospices to provide certain types of nursing services under contract. This proposed change also resulted from section 946 of the MMA, which amended the Act by adding section 1861(dd)(5)(E). As amended, the Act provides that these nursing services must be highly specialized and provided non-routinely and so infrequently that their provision by hospice employees would be impracticable and prohibitively expensive. We recognize that it may be cost-prohibitive for a hospice to employ a nurse that possesses very highly specialized skills when he or she may only care for a few patients a year. By allowing hospices to contract with specialized nursing providers or others to provide these highly specialized nursing services to the few patients who require them, hospices would be able to better implement an efficient staffing plan and ensure proficiency in the skilled services being provided.

In standard “(c) Medical social services,” we proposed

to maintain the requirements of the current medical social services requirement at §418.84. This standard would continue to require that medical social services be provided by a qualified social worker under the direction of a physician. This standard would also require that medical social services, when accepted by a patient and family, be based on an assessment of that patient's psychosocial needs.

In proposed standard §418.64(d), we addressed the counseling services that would be available to hospice patients and their families. Those services would be bereavement, nutritional, and spiritual counseling. In the bereavement counseling section, we proposed that a hospice would be required to have an organized program of bereavement services furnished under the supervision of a qualified professional with experience in grief/loss counseling. These services would be required to be made available to individuals identified in the bereavement plan of care up to one year following the death of the patient, and would reflect the needs of those individuals. When appropriate, residents and staff of a SNF/NF, ICF/MR, or other facility would be offered bereavement services.

In the nutritional counseling section, we proposed to allow qualified individuals, such as dietitians and nurses to furnish this service, provided that it was within their

scope of practice and expertise according to State law. We believed that allowing other qualified individuals to participate in nutritional counseling would give hospices greater flexibility and would help ensure that all hospice patients had access to this service when needed. This proposal conformed to a recommendation made by the Secretary's Advisory Committee on Regulatory Reform.
In the spiritual counseling section, we proposed that a hospice would be required to assess the patient's and family's spiritual needs and provide spiritual counseling to meet those needs, in accordance with the patient's and family's beliefs and desires. If a patient and family did not desire spiritual counseling, then they would not have to be provided this service. If a patient and family did desire spiritual counseling, then a hospice would be expected to facilitate visits by local clergy, pastoral counselors, or others to the best of its ability.

Comment: Numerous commenters requested that the regulations permit hospices to contract for core services with various entities and for various reasons. Some of these commenters believed that hospices should be permitted to contract with hospice and non-hospice agencies on a routine basis for the provision of core services to hospice patients. Other commenters believed that, in extraordinary

circumstances, hospices should be allowed to contract with non-hospice agencies in addition to contracting with other Medicare-certified hospice agencies, as we proposed. Still other commenters stated that hospices should be permitted to use contracted staff when they are providing continuous care to one or more patients, either because continuous care increases the amount of hours of patient care, which results in a period of peak patient loads, or because providing continuous care requires highly specialized nursing skills.

Response: Section 1861(dd) of the Act requires hospices to provide substantially all core services directly (see section 1861(dd)(2)(A)(ii)(I) of the Act). Thus, in accordance with the Act, hospices are prohibited from contracting with other hospices and non-hospice agencies on a routine basis for the provision of core services to hospice patients. The Act specifically states “substantially all” in recognition of the fact that there are times when hospices must contract for core services. The Act identifies the circumstances in which hospices are permitted to contract for core services as those that are “extraordinary” or otherwise “non-routine” such as unanticipated periods of high patient loads, temporary staffing shortages, and travel of a patient outside of the hospice’s service area. We agree that hospices should be permitted to contract with non-

hospice providers as well as other Medicare certified hospices in order to meet patient needs in extraordinary circumstances, and we have amended the final rule as such.

We also agree that simultaneously providing continuous home care to multiple patients may result in an unanticipated period of high patient load that would warrant contracting for core services through the extraordinary circumstance exception. If a hospice chooses to contract with another Medicare-certified hospice or a non-hospice entity, the contracting hospice must maintain professional management responsibility for the services provided, in accordance with this final rule at §418.100(e). In addition, all licensed professionals who provide services to hospice patients under contract must actively participate in the coordination of all aspects of the patient's hospice care, including patient assessments; care planning development, delivery, and evaluation; patient and family counseling and education; in-service training; and the hospice's quality assessment and performance improvement program, to the extent applicable, in accordance with §418.62.

Comment: A commenter suggested that, in order to ensure the quality of nurses providing care under contract, CMS should survey nurse staffing agencies.

Response: Medicare does not currently have the authority to survey nurse staffing agencies because they are not themselves providers under Medicare. We expect hospices that use the services of a nurse staffing agency to ensure that the nurses provided by such agency are qualified to furnish nursing care to hospice patients. In addition, we expect hospices to exercise full professional management responsibility for the services provided by contractors to ensure that those services are appropriate and are of high quality.

Comment: Many commenters submitted suggestions to refine the proposed “Physician services” standard at §418.64(a). One of these commenters suggested that this standard should be removed, because having a standard for physician services separates physician services from the rest of the IDG. Another commenter suggested that this standard should explicitly state that the hospice medical director would not be required personally to provide direct physician services to every patient. Still another commenter suggested that the role of physician assistants should be included in this standard. Several other commenters suggested that we remove the proposed requirement that hospice physicians be responsible for the general medical needs of the patient, because this responsibility would

create a conflict with the role of the attending physician and/or the physicians of a SNF/NF.

Response: We believe that including a standard for physician services under the umbrella of the core services CoP, highlights the fact that physician services are one piece in the larger interdisciplinary services model of hospice care. Physician services are, in this rule, treated as equal to nursing services, medical social services, and counseling services. These four disciplines are required to work together as the core members of the IDG, and we believe that it is appropriate to group them together under a single CoP.

We do not believe that it is appropriate or necessary to state that medical directors are not required to furnish hands-on services to each patient. Elements of the proposed rule, such as the proposed requirement that the hospice medical director communicate with the medical director of a SNF/NF in proposed §418.112(d), may have incorrectly implied that the hospice medical director would be expected to furnish direct care to every patient. We have removed or revised these elements to reflect the fact that the hospice IDG, including its physician member, is required to fulfill the role originally designated for the hospice medical director. Now that these implications have been removed, it

is not necessary to explicitly state that the hospice medical director is not required to furnish care to each patient.

We proposed the provisions governing the role of nurse practitioners in hospice because the use of nurse practitioner services is prevalent in the hospice industry, and we have received numerous requests for this guidance for several years. Conversely, we are not aware of any need to address the role of physician assistants in hospice because, to our knowledge, physician assistant services are rarely used in hospices and are not recognized under the Medicare hospice benefit. We believe that there is no need to regulate services that are not used.

We agree that we need to revise the proposed rule requiring hospice physicians to assume responsibility for the general medical needs of the patient. This responsibility could well be beyond the scope of hospice physician services and could conflict with the responsibilities of other physicians furnishing services for needs unrelated to the patient’s terminal illness and related conditions. Therefore, this proposed requirement has been removed. We have retained the requirement that, when the patient’s attending physician is not available, a hospice physician is responsible for meeting the patient’s

medical needs. We do not believe that this requirement creates a conflict because it only applies when the attending physician is not available to perform his or her duties.

Comment: Several commenters suggested that requirements for nurse practitioner services should be included in the same standard as those for physician services. Some of these commenters also suggested that the “Physician services” standard should be renamed “Medical services.” In addition, some of these commenters suggested that the requirements for nurse practitioner services, as included under the physician services heading, should be expanded to govern the role of all advanced practice nurses.

Response: Section 1861(dd) of the Act clearly delineates those services provided by physicians from those provided by nurses. We believe that the services of nurse practitioners fall squarely into the nursing services category, because they are services provided by nurses. We also believe that, as such, it is not appropriate to relocate the regulation governing the services of nurse practitioners from the nursing services standard to the physician services standard. Since we are not placing nurse practitioner services into the same standard as physician services, it is not necessary to rename the standard. We

agree that it is appropriate to replace the term “nurse practitioner” as used in proposed §418.64(b), “Nursing services,” and we have replaced it with the broader term “registered nurse.” If a registered nurse, including a nurse practitioner, advanced practice nurse, etc., is permitted by State law and regulation to see, treat, and write orders, then they may perform this function while providing nursing services for hospice patients. Hospices are free to use the services of all types of advanced practice nurses within their respective scopes of practice to enhance the nursing care furnished to patients. The Medicare Hospice per diem payment includes nursing costs. Nurse practitioners cannot bill separately for care provided to Medicare hospice patients, except under very limited circumstances. Please refer to the Hospice chapter of the Medicare Benefit Policy Manual for additional instructions regarding coverage and payment policy.

Comment: A commenter suggested that we remove the proposed requirement that the patient’s plan of care describe the role and scope of services provided by nurse practitioners.

Response: We agree that it is not necessary to describe the role and scope of services provided by nurse practitioners separately from the role and scope of general

nursing services in the patient's plan of care. Therefore, we have removed this proposed requirement. We continue to expect that the role and scope of nursing services, including those provided by nurse practitioners and other advanced practice nurses, will be specified in each patient's plan of care in accordance with final §418.56(c)(2).

Comment: A few commenters suggested that we should revise the requirements of proposed §418.64(b)(3). Some of these commenters suggested that we should delete the requirement that, in order to contract for highly specialized nursing services, those services must be provided infrequently. The commenters believed that the term "infrequently" was not specific. Other commenters suggested that we should clarify that the contract for highly specialized nursing services is not required to be with another Medicare-certified hospice in order to differentiate this contracting requirement from the general core services contracting requirement.

Response: Section 946(a)of the MMA amended 1861(dd)(5) of the Act by adding a new subparagraph (E). That subparagraph states, "A hospice program may provide services described in paragraph (1)(A) other than directly by the program if services are highly specialized services of a

registered professional nurse and are provided non-routinely and so infrequently so that the provision of such services directly would be impracticable and prohibitively expensive." We believe that this criterion, established by the MMA, is sufficient for hospices to assess whether or not they may contract for a highly specialized nursing service. If providing the nursing service through direct hospice employees is impossible and cost-prohibitive because the service is provided infrequently, and if the service requires highly specialized nursing skills, then the hospice may contract for the service.

We do not believe that it is necessary to state that the contract for highly specialized nursing services need not be with another Medicare-certified hospice because we have revised the requirements for the general core services contract to permit hospices to contract with Medicare-certified hospices and non-hospice providers for core services under certain circumstances. Since hospices may contract with hospice and non-hospice providers for the general core services contract and for the highly specialized nursing skills contract, there is no need to differentiate between the two contracts.

Comment: Several commenters suggested that we should revise proposed §418.64(c), "Medical social services." Many

of these commenters suggested that we should remove the requirement that medical social services be provided under the supervision of a physician. Others suggested that medical social services should be provided under the direction of the hospice medical director or the IDG. Another commenter suggested that this standard should require social workers to have an MSW from an institution of higher learning that is accredited by the Council on Social Work Education. Still another commenter suggested that the scope of medical social services should be broadened.

Response: Effective supervision of medical social services is essential for ensuring high quality care. Section 1861(dd)(1)(C) of the Act requires hospices to provide “medical social services under the direction of a physician.” Since the Act specifically requires a physician to supervise medical social services, it is not appropriate to assign supervisory responsibility for medical social services to the IDG. It is also not appropriate to assign supervisory responsibility to the medical director because he or she may not necessarily be the physician member of the IDG assigned to the patient. The medical director, if he or she is not the physician member of the patient’s IDG, may not have sufficient knowledge about the patient’s care to effectively supervise the medical social services provided

to that patient.

In addition to effective supervision, it is essential that the individuals providing medical social services to hospice patients be qualified to provide these services. Section 418.114 addresses the personnel qualifications that social workers must meet in order to provide services to hospice patients. We have addressed the commenter's suggestion of requiring an MSW for social workers in the section addressing §418.114 in the preamble of this final rule.

Supervision and qualifications both affect the scope of medical social services that are provided to patients. These services are required to be based on the needs of patients and families as those needs are identified through a thorough psychosocial assessment. Since the scope of services provided is directly tied to the needs of the patient and family, it is not possible to generically broaden their scope. Some patients and families may have limited social work needs, and should not be compelled to accept broader social work services that do not meet their needs.

Comment: A commenter suggested that medical social services should be included in the counseling services

standard because social workers perform counseling functions in hospices.

Response: While social workers do perform counseling functions in hospices, their duties and responsibilities go beyond counseling. Therefore, it is not appropriate to place the requirements for social workers under the counseling services heading.

Comment: Many commenters requested that we broaden the definition of “counseling services” to address the purpose of counseling services rather than naming precisely which types of counseling services are included in hospice.

Response: “Counseling services” is a broad category of services that has undergone a change from the traditional physical and psychological interventions and now includes the use of alternative therapies (for example, art therapy, yoga therapy, massage therapy, and light therapy). These therapies are now frequently used to benefit hospice patients and their families. We encourage hospices to continue to explore and employ alternative counseling services. We have adopted the suggestion and have incorporated a broader description into the requirements for counseling services at §418.64(d). In the proposed rule we stated, “Counseling services for adjustment to death and dying must be available to both the patient and the family.”

This final rule now states, “Counseling services must be available to the patient and family to assist the patient and family in minimizing the stress and problems that arise from the terminal illness, related conditions, and the dying process.” We believe that this revised language reflects the broad nature of counseling services described by the commenters.

Comment: Many commenters suggested that hospices should be permitted to provide certain specialized counseling services under contract, either by inserting a provision to allow such contracting or by relocating the counseling requirements to §418.70, “Furnishing of non-core services.” Commenters suggested that the contract services include dietary counseling provided by dietitians, art therapy and music therapy, to name a few.

Response: Section 1861(dd)(2)(A)(ii)(I) of the Act requires hospices to routinely provide substantially all core services, including counseling services to care for the terminally ill patient and to assist the patient in adjusting to his or her condition. The Act permits hospices to contract for counseling services as well as other core services, only under extraordinary or otherwise non-routine circumstances such as short-term staffing shortages, periods of peak patient loads, and travel of a patient outside of a

hospice's service area. Therefore, it is not appropriate to permit hospices to routinely contract for counseling services.

Comment: Numerous commenters suggested changes to the proposed bereavement counseling requirement at §418.64(d)(1). One of these commenters suggested that hospices should be required to incorporate bereavement services into their daily patient care services. Another commenter suggested that either education or experience in grief/loss counseling should be an appropriate qualification for the individual supervising the bereavement services program. Other commenters pointed out a distinction between offering and providing bereavement services. They suggested that hospices should only be required to offer bereavement services because they cannot provide such services to individuals who are unwilling to receive them.

Response: We appreciate the general support received for the bereavement services requirement. We agree that bereavement counseling must be a daily hospice activity for each patient and family. To that end, we have revised the definition of the term "bereavement counseling" at final §418.3 to require the services to be provided before and after the death of the patient. We also require hospices to complete an initial bereavement assessment as part of the

comprehensive assessment, which must be completed within five days of the completion of the hospice election statement and certification form. Furthermore, as part of the comprehensive assessment, the bereavement assessment must be updated in accordance with §418.56(d). We believe that these requirements will ensure that bereavement counseling is incorporated into patient care throughout the patient’s hospice stay.

We also believe that it is necessary to ensure that the individual supervising this thorough bereavement program is appropriately qualified. We agree that, in addition to experience, education in grief/loss counseling is an appropriate qualification for the program supervisor. We have made this change in §418.64(d)(1)(i).

We also appreciate the support that we received regarding bereavement services furnished within a SNF/NF or ICF/MR. As we stated in the proposed rule preamble, there are times when facility staff and residents fulfill the role of a patient’s family, providing caregiver services, being companions, and generally supporting the patient. We believe it is appropriate for a hospice to consider the bereavement needs of these individuals. However, we agree with commenters that requiring a hospice to offer bereavement services to facility staff may create a conflict between the

hospice and the facility, which bears ultimate responsibility for its staff. Therefore, we have separated this requirement into two parts. A hospice may offer bereavement services to facility residents as identified in the patient's plan of care. Additionally, a hospice must include a provision in its contract with a facility that addresses the offering of bereavement counseling to facility staff. Through this contractual provision, hospices and facilities can mutually agree upon a plan that meets the needs of the hospice, the facility, and the staff (see §418.112(c)(9)).

Additionally, we believe that the offer of bereavement services, as opposed to providing them, is the appropriate requirement for hospices to meet. Hospices cannot force bereavement services upon unwilling recipients; therefore, the bereavement plan of care is only able to state what services will be offered because it cannot predict what services will actually be accepted and provided. As such, we have revised §418.64(d)(1)(iv) to state that the hospice is to, "[d]evelop a bereavement plan of care that notes the kind of bereavement services to be offered and the frequency of service delivery…."

Comment: One commenter stated that the reference to "dietary counseling" in proposed §418.74 is confusing

because we use the term “nutritional counseling” in the proposed “Core services” requirement at §418.64.

Response: We agree with the commenter. Therefore to be consistent, we have amended the language at §418.64(d)(2) to require hospices to furnish “dietary counseling.”

Comment: The majority of commenters that submitted comments concerning our proposed requirements for nutritional counseling supported the provision allowing nurses to furnish such counseling if appropriate. However, a small number of commenters suggested that hospices should be required to employ a registered dietitian to furnish this counseling.

Response: In §418.64(d)(2) hospices are required to assure that the dietary needs of the patient are met. If a nurse is capable of meeting the patient’s needs, then we believe that it is appropriate to permit the nurse to fulfill this task. However, if the needs of the patient exceed the knowledge and expertise of a nurse, we expect the hospice to have available an appropriately educated and trained individual, such as a registered dietitian or nutritionist, to meet the needs of the patient. We believe that this needs-based requirement, rather than a prescriptive requirement dictating the individuals that a hospice must employ for this service, will assure that

patient needs are met and that hospices have the flexibility to structure their staff in the manner that meets their needs.

Comment: While commenters generally supported the proposed requirement at §418.64(d)(3) that hospices must assess a patient's and family's spiritual needs, and provide care to meet those needs in accordance with the patient's and family's acceptance of the hospice's service, commenters expressed confusion regarding the statement that hospices are not required to go to extraordinary lengths to facilitate visits by individuals who can support the patient's needs. Some of these commenters noted that spiritual counseling is often extremely important to patients and families and that hospices should try very hard to facilitate outside spiritual support. Other commenters stated that the phrase "extraordinary lengths" is unclear and should be removed or replaced. Some of these commenters suggested that the requirement should read, "[t]he hospice must make all reasonable efforts to facilitate visits by local clergy, pastoral counselors…" or "[t]he hospice must facilitate visits by local clergy, pastoral counselors, or other individuals who can support the patient's spiritual needs consistent with the patient's and family's wishes and the willingness of the designated counselors to respond."

Response: We agree that spiritual counseling is an essential hospice service for many patients and families, and that hospices should strive to facilitate visits and contacts by those spiritual supporters that the patient and family need. However, we realize that there is a limit to what hospices should be expected to do in order to facilitate such visits, as reflected by the proposed requirement that hospices are not required to go to extraordinary lengths. We replaced the proposed "extraordinary lengths" requirement with a requirement that reasonable efforts must be made. This change continues to reflect the value of spiritual counseling without burdening hospices with unrealistic expectations.

9. Condition of participation: Nursing services waiver of requirement that substantially all nursing services be routinely provided directly by a hospice (§418.66)

The requirements for obtaining a nursing services waiver as provided by section 1861(dd)(5) of the Act is currently set forth in §418.83, and remained virtually unchanged in the proposed rule. This condition provides hospices the opportunity to obtain a waiver from the requirement that substantially all nursing services be routinely provided directly by the hospice. The Act specifies that to obtain a waiver a hospice must be located

in an area that is not an urbanized area, must have been in operation on or before January 1, 1983, and must demonstrate a good faith effort to hire a sufficient number of nurse employees. Section 1861(dd)(5)(B) of the Act also specifies that if a waiver is requested by an organization that meets the statutory requirements and other provisions required by the Secretary, then the waiver will be deemed granted unless the request is denied within 60 days after the request is received by the Secretary. We proposed to maintain the existing requirement, as well as the regulatory time frame that provides that waivers are effective for 1 year at a time, and that CMS may approve a maximum of two 1-year extensions for each initial waiver.

Comment: A few commenters asked us to define “urban area.”

Response: The statute at section 8161(dd)(5)(a)(i) of the Act specifically references urbanized areas as defined by the Bureau of the Census. We refer the commenters to the website at HYPERLINK "http://www.census.gov" www.census.gov. In addition, hospices may contact their fiscal intermediary or check the hospice wage index, which is updated and published yearly.

Comment: Several commenters requested that the waiver language requiring a hospice to be in operation on or before

1983 be amended by requiring that hospices to be in operation a specific number of years in order to qualify. Commenters also asked that urban as well as rural hospices be eligible for the nursing waiver.

Response: The nursing waiver language at §418.66 tracks the statutory language and cannot be significantly changed absent a change in the statute. Therefore, we are unable to promulgate a regulation that would modify the requirements of this statutory provision.

Comment: A few commenters stated that the waiver process described in proposed §418.66 is complex, cumbersome and time-consuming. Other commenters urged CMS to streamline and simplify the process. One commenter asked that the waiver be deemed granted unless the request is denied within 30 days after it is received. Other commenters asked if it is CMS' intent to limit the waiver for individual hospice programs to only 3 years.

Response: While we understand the waiver process may be at times a lengthy process, CMS is unable to change most of these statutorily based requirements. Changing the current 60-day time frame to a 30-day time frame would not allow the CMS Regional Office time to sufficiently review the waiver request. In the proposed rule, we specifically requested information on how frequently this waiver was being used.

We heard back from very few hospices or other entities. All of those responding stated that they were not using this waiver. At the request of those commenters that requested clarification on the restriction of only two 1-year extensions, CMS has removed the first sentence in the requirement at §418.66(d). We are not restricting the number of extensions a hospice can receive on its original waiver request. We believe that this will reduce the burden of requesting a waiver because hospices will no longer be required to submit a new waiver request every three years (original request + two 1-year extensions). Instead, a hospice can submit a single waiver request and an unlimited number of extensions as long as it continues to meet the waiver requirements.

Comment: One commenter requested the waiver not impede a hospice from contracting with non-Medicare-certified hospices. Other commenters requested that CMS allow hospices to contract for continuous nursing care.

Response: The proposed language at §418.66 does not specify with whom a hospice can contract, nor does it specify the level of nursing care for which contracts be written. The purpose of the waiver was to allow hospices in rural areas, which were having difficulty hiring nurses, to have the ability to contract for overall nursing services.

For a discussion of contracting for continuous nursing care, see the preamble language relating to core services at §418.64 and existing regulations at 418.204 and 418.302.

Comment: Some commenters confused the proposed §418.66 with the nursing shortage exemption, which was implemented on October 14, 2004 and renewed on September 14, 2006 by CMS (S&C-05-02, www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter06-28.pdf). Other commenters stated that the proposed rule fails to recognize the national nursing shortage.

Response: We understand that there may be some confusion about this nursing waiver at §418.66, which is currently in regulations at §418.83, and the nursing shortage exemption that has been in effect the past several years. The nursing waiver at §418.66 is statutory and allows rural hospices in operation before 1983 the opportunity to obtain a waiver from the statutory requirement that substantially all nursing services be routinely provided directly by the hospice, thereby permitting such hospices to contract for nursing services if they meet the statutory requirements. The nursing shortage exemption implemented in 2004, and renewed in 2006, permits all hospices that are having difficulty hiring nurses to apply for an exemption that allows the hospice to contract for nursing services.

These two waivers are completely separate from one another. As noted, the nursing waiver is statutory and applicable only to hospices located in a nonurbanized area and in operation since 1983. By contrast, the nursing shortage exemption provides short-term relief to all hospices who qualify during this nursing shortage.

Comment: One commenter requested that this waiver not be available to for-profit hospices, stating that "for-profit hospices are the fastest growing sector in the hospice industry, and there is no evidence that they need this waiver."

Response: The statute does not differentiate between for-profit or not-for-profit hospices. Therefore, this waiver applies to any hospice meeting the waiver requirements. We note that hospices must clearly demonstrate that they have made a good-faith effort to hire nurse employees before seeking a waiver.

10. Condition of Participation: Furnishing of noncore services (§418.70)

The current CoP governing non-core services is contained in §418.90. We proposed to re-number the CoP and maintain its requirements, with slight language modifications. We also proposed to amend this CoP by adding language contained in §418.50(b)(3) of the current rule,

which states that non-core services must be provided in a manner consistent with current standards of practice.

There were no comments received on this condition of participation. Therefore, we are finalizing it as proposed.

11. Condition of Participation: Physical Therapy, Occupational Therapy, and Speech-Language Pathology (§418.72)

Currently, the CoP concerning physical therapy, occupational therapy, and speech language pathology is found at §418.92(a). We proposed to recodify this CoP at §418.72 without changes. This CoP requires hospices to make physical therapy, occupational therapy, and speech-language pathology services available to patients, and to ensure that these services are provided in a manner consistent with current standards of practice.

Comment: Several commenters requested that we add dietary counseling provided by dietitians to the list of non-core services (that is, physical therapy, occupational therapy, and speech-language pathology) included in proposed §418.72.

Response: Dietary counseling is seen as a core service, and therefore falls under the regulatory requirements proposed at §418.64. Within §418.64 we have proposed that qualified individuals, including dietitians

and nurses, may furnish dietary counseling, provided that it is within their scope of practice and expertise according to State law. Also within §418.64, we allow hospices to contract with other Medicare-certified hospices and contracting agencies for core services under specific circumstances, such as extraordinary or other non-routine circumstances, unanticipated periods of high loads, and staffing shortages due to illness or other short-term temporary situations that interrupt patient care. Additionally, in §418.74, we allow hospices located in non-urbanized areas to receive a waiver of the requirement that dietary counseling be provided directly pursuant to statutory authorization at 1861(dd)(5)(C). We believe that the staffing flexibility and waivers give hospices the flexibility to provide dietary counseling to all patients who require the service.

12. Condition of Participation: Waiver of requirement-Physical therapy, occupational therapy, speech-language pathology and dietary counseling (§418.74)

We proposed a new CoP that would provide for a waiver of certain requirements. This CoP would establish authority to waive the requirement that eligible hospices must provide physical therapy (PT), occupational therapy (OT), and/or speech-language pathology (SLP) services as needed on a 24-

hour basis as otherwise required by section 1861(dd)(2)(A)(i). This CoP would also establish authority to waive the requirement that eligible hospices must provide dietary counseling services on a 24-hour basis and/or that eligible hospices must routinely provide dietary counseling services directly through hospice employees.

As in the case for a waiver of nursing services (proposed §418.66), eligibility for a waiver is based on the primary location of a hospice. For a hospice that operates in multiple locations, its primary location is considered to be the location of its central office. This central office must be located in a non-urbanized area as determined by the Bureau of the Census. The hospice must provide evidence that it made a good faith effort (for example, copies of advertisements in local newspapers, documentation of competitive salaries and benefits, and evidence of recruiting activities) to hire a sufficient number of PTs, SLPs, OTs, and dietary counselors to provide services directly through hospice employees or under arrangement on a 24-hour as needed basis.

Comment: Several commenters supported the optional waiver for PT, OT, SLP and dietary services, but one commenter stated that these services are so critical that it seemed inappropriate to provide a waiver.

Response: We agree that these can be very valuable services for the care of the hospice patient. However, we do not believe that these services need to be offered as needed on a 24-hour basis if the 24-hour requirement places an undue burden on rural hospices. Because of the scarcity of those professionals in non-urbanized areas, we believe the option for a waiver is appropriate. We also note that the waiver conditions are statutory.

Comment: A few commenters requested that we consider allowing hospices located in urban areas the waiver option as well.

Response: As noted above, this waiver language, like the nursing waiver option at proposed §418.66, is statutory. We are unable to promulgate a regulation that would contravene the statutory provision.

Comment: One commenter asked if it is our intent to limit the waiver for individual hospice programs to only three years.

Response: As proposed, a hospice would have been required to submit an original waiver request. The hospice could then request up to two extensions on the original request. Once those two extensions expired, the hospice would have been required to submit another original waiver request. Thus, while the proposed requirement did not limit

a hospice to receiving a waiver for three years in total, it did require a hospice to submit substantially more paperwork once every three years in the form of an original waiver request. We believe that it is not necessary to require an original waiver request every three years. Therefore, we have removed the first sentence in the proposed requirement at §418.74(d). We are not restricting the amount of extensions a hospice may receive to the original waiver request.

Comment: One commenter requested that this waiver not be available to for-profit hospices, stating that "for-profit hospices are the fastest growing sector in the hospice industry, and there is no evidence that they need this waiver."

Response: The statute does not differentiate between for-profit or not-for-profit hospices. Therefore, this waiver applies to any hospice meeting the waiver requirements. We believe that the criteria set out at 1861(dd)(5)(C)(ii) of the Act will ensure that waivers are granted only on an as-needed basis.

13. Condition of Participation: Hospice aide and homemaker services (§418.76)

Section 1861(dd)(1)(D) of the Act requires Medicare covered home health aide services to be furnished by an

individual who has successfully completed training or a competency evaluation program that meets the requirements established by the Secretary. This section also provides for coverage of homemaker services. Currently, the condition of participation concerning home health aide and homemaker services is set forth at §418.94, which incorporates by reference the home health aide requirements of the home health agency CoPs at §484.36. We proposed in §418.76 to use most of the substance of the requirements of §484.36. The home health aide CoP establishes that a home health aide must complete a State-established or other training program, and in §418.76(b) we outline the requirements that this training must meet, which are similar, but not identical to, the provisions of §484.36. In §418.76(e) and §418.76(f) we outline requirements for the individuals and organizations eligible to provide the aide training.

We proposed that three standards be particularly adapted for the hospice conditions of participation. First, §418.76(h), “Supervision of home health aides,” would be revised from the current §484.36(d), to require that a registered nurse or appropriate qualified therapist conduct an on-site supervisory visit no less frequently than every 28 days while the home health aide is providing care. This

in-person supervisory visit would need to be conducted with at least one patient to whom the aide is providing services at the time. Thorough supervision of home health aides is crucial to ensuring that the patient's and family's needs are being met, and conducting supervisory visits when the aide is performing his or her duties is a key way to provide thorough supervision. Onsite supervisory visits will still be required every 14 days, as in the current rule at §484.36(d)(2), but the aide would not be required to be present for these visits. This supervision schedule would allow hospices to maintain control over the quality and continuity of care being provided, and would help ensure that all patients receiving home health aide services were having their needs met by these services.

Second, proposed §418.76(j), "Homemaker qualifications," was adapted from the existing §418.94. The proposed standard would define a qualified homemaker as a home health aide, as described in §418.76, or an individual who met the standards in §418.202(g) and has successfully completed hospice orientation addressing the needs and concerns of patients and families coping with a terminal illness. Homemaker services, as noted in §418.202(g), may include assistance in maintenance of a safe and healthy environment to enable the patient to benefit from care that

is furnished.

Finally, §418.76(k) would require a member of the IDG to coordinate homemaker services, and supply instructions for the homemaker on duties to be performed. The homemaker would be required to report all concerns about the patient or family to the member of the IDG who was coordinating the homemaker services. We have proposed these changes to ensure proper training and supervision, and to protect the quality of the homemaker services provided.

Comment: Numerous commenters suggested that we should change the term that we use to refer to aides who furnish hospice care. Commenters suggested that the phrase “nursing aide”, “certified nursing assistant”, or “hospice aide” be used instead of the phrase “home health aide.”

Response: We agree that it is appropriate to re-name aides who furnish hospice care in order to differentiate them from aides who furnish care in other environments. Therefore we have adopted the term “hospice aide” as best describing that role.

Comment: A commenter suggested that all of the hospice aide requirements (that is, training, education, and supervision) should be replaced by those for nurse aides, as described in 42 CFR part 483, which sets out standards for long term care facilities.

Response: We agree that nurse aide training and education in accordance with §483.151 through §483.154 is an appropriate qualification for hospice aides, and we have incorporated these provisions at new §418.76(a)(1)(iii). However, we do not believe that the supervision requirements for nurse aides in long term care facilities meet the needs of hospices, whose hospice aides furnish care in the community rather than in a self-contained facility. Therefore, we are not adopting the supervision requirements from part 483.

Comment: Many commenters suggested that, in order to adapt the requirements of the home health aide regulations to the hospice regulations, we should replace all references to home health agencies with references to hospice agencies. Several commenters singled out the reference to home health agencies in proposed §418.76(f), “Eligible training organizations,” which prohibits certain home health agencies from training aides, as a place where a reference to hospice agencies should be substituted.

Response: We agree that, throughout most of this CoP, references to home health agencies should be replaced with references to hospice agencies, and we have made these changes. However, in §418.76(f), we are unable to substitute hospices for home health agencies. The

provisions of standard (f) come directly from Section 1891(a)(3) of the Act. Therefore, certain home health agencies must be prohibited from providing aide training. Hospices, however, are not prohibited from providing aide training, even if they meet the exclusion criteria established for home health agencies. Although hospices are not excluded from providing training, we caution all hospices to ensure that training furnished by other providers meets all of the requirements of this rule and is of the highest quality. It is essential that aides be well trained to perform their patient care duties.

Comment: A commenter suggested that hospice aides should be required to be certified in hospice and palliative nursing assistant care.

Response: Hospices are free to require their hospice aides to be certified in hospice and palliative care. However, this certification goes beyond the standards of aide education and training that are currently in place for other provider types and is uncommon within the hospice industry. Requiring such certification for all hospice aides nationwide would likely result in a shortage of qualified aides, which would negatively impact patient care and outcomes. For these reasons, we are not adding this suggested requirement.

Comment: A commenter suggested that, in the first sentence of §418.76(c), we should add the word “aide” to state that “an individual may furnish home health aide services on behalf of a hospice….”

Response: We agree that adding the term “aide” will clarify our intent, and we have made this change. In this section, the term “home health aide” has been replaced by the term “hospice aide”.

Comment: Many commenters suggested changes to our proposal at §418.76(e) that would require the registered nurse who provides or supervises hospice aide training to have at least two years of nursing experience, one of which must be in home health care. The commenters suggested that the term “home health” be replaced with the term “hospice”.

Response: We agree that experience in hospice care is an appropriate source of knowledge for a registered nurse to perform or supervise practical training for hospice aides. We replaced the term “home health” with the term “home care,” which is used broadly in this standard and encompasses both home health care and hospice care. We believe that this fulfills the commenters’ request without limiting the opportunity for the registered nurse to gain the necessary experience.

Comment: Numerous commenters made suggestions regarding

the proposed requirement at §418.76(g)(2) that aide services must be ordered by a physician or nurse practitioner and included in the plan of care. Specifically, some commenters suggested that the IDG as a whole, of which the physician is a member, should be allowed to order hospice aide services. Other commenters supported our proposal to allow both nurse practitioners and physicians to order hospice aide services. Still other commenters suggested that the frequency and scope of aide services should not need to be detailed, as is required of all other services contained in the plan of care. A single commenter suggested that the proposed provisions regarding hospice aide assignments and duties should only apply in the absence of State requirements.

Response: While we appreciate the support for our proposal that a nurse practitioner or physician must order hospice aide services, we agree that the IDG as a whole may order hospice aide services because physicians and nurse practitioners are already active members of the IDG. When ordering hospice aide services, we believe that it is necessary to detail the scope and frequency of such services. The purpose of the order, as included in the plan of care, is to provide a comprehensive map of which disciplines are providing which services at which time(s). Without such detailed information there is a lack of clarity

that may compromise patient and family care. Therefore, we are keeping the detailed scope and frequency requirements.

Comment: Many commenters requested clarification about what duties hospice aides are permitted to perform. The commenters were particularly interested in proposed §418.76(g)(3)(iv), which would permit hospice aides to provide assistance in administering medications that are ordinarily self-administered. Some commenters wanted to know how to determine which medications are ordinarily self-administered, while other commenters noted that the hospice aide training requirement at proposed §418.76(b) does not require aides to be trained in medication administration. Related to these comments on aide training are commenters who sought clarification on the proposed requirements of §418.76(g)(2)(iv), which stated that aides may only furnish services that are consistent with their aide training. Still other commenters suggested that medication administration requirements should defer to State laws.

Response: Section 418.106 of this rule requires hospices to evaluate a patient’s and family’s ability to safely administer medications. This requirement is present because various factors may interfere with a patient’s ability to safely adhere to a medication regimen. Allowing hospice aides to help administer those medications that

patients are typically allowed to administer to themselves, if they are competent to do so, allows hospices to meet the medication needs of patients and caregivers who are not capable of safely self-administering medications. Assistance in medication administration may consist of helping a patient with hand tremors apply or remove a medication patch or any number of other similar tasks. Allowing aides to fulfill this role may decrease the demand for nursing visits for the purpose of medication maintenance, thus allowing nurses to provided services where needed.

Determining those medications that are appropriate for aides to help administer is the decision of the IDG, based on the needs of the patient and family, the training of the aide, the policies of the hospice, and any applicable State and local laws and regulations. We do not require all hospice aides to be trained in medication administration because not all hospices will choose to have aides perform this task. Section 418.116 of this rule requires hospices to comply with all health and safety related State and local laws and regulations. State or local rules may very well prohibit hospice aides from administering medication. However, if medication administration is within the bounds of State and local rules, and if hospices do choose to have

aides perform this task, §418.76(b)(3)(xiii) requires those hospices to provide aide training for any other task that an aide is expected to perform, which would include medication administration. This, in conjunction with the requirement at §418.76(g)(2)(iv), that aide services furnished must be consistent with hospice aide training, effectively requires medication administration training for those aides who are charged with assisting patients in administering medications that are ordinarily self-administered.

Comment: Some commenters suggested that we should replace the proposed hospice aide supervision requirements with the supervisory requirements for home health aides found in the home health regulations at §484.36. Commenters also suggested that we should replace the every-14-day supervisory visit requirement, which was designed to ensure the adequacy and appropriateness of aide services for each hospice patient, with a requirement that the RN should review the patient's plan of care with the aide at least every 60 days, and as needed. These commenters stated that supervising the aide every 14 days, as is currently required in the existing hospice regulations, is overly burdensome. Other commenters explicitly supported the 14 day supervision requirement.

Response: We appreciate the support for this

requirement among some commenters. We believe that supervising the aide every 14 days to ensure that aide services are adequate and appropriate for each hospice patient is appropriate, given the length of time that most hospice patients receive hospice services. Many hospice patients die within a few weeks of beginning hospice services. If we were to extend the supervision time frame, the extension would likely result in no supervisory visits occurring between the time the patient begins receiving hospice care and the time the patient passes away (for example, a hospice patient begins receiving aide services on day three and passes away on day 24, without ever receiving an aide supervisory visit to assess the adequacy and appropriateness of the aide care provided). This lack of supervision would in no way benefit patients and families. In addition, this lack of supervision would likely not help hospices because they would remain completely unaware of the quality and adequacy of the aide services they were providing. This could lead to an over- or under-use of aide services, low quality aide services, patient and family dissatisfaction, and a wide variety of other negative outcomes that hospices wish to avoid. In short, we believe that adequate frequent supervision benefits patient and hospices alike, and the requirement remains in this final

rule.

Comment: A commenter suggested that all hospice aide supervision requirements should be removed in favor of outcome and patient satisfaction measures and performance improvement projects when measures indicate inadequate performance in aide services. Another commenter suggested that all hospice aide supervision requirements should be removed because hospices are already required by §418.76(b) and §418.76(c) to ensure that hospice aides are trained and that competency evaluations are completed.

Response: We are not deleting these requirements for two reasons. First, while hospice aide training and competency evaluations ensure that aide skills are adequate upon hiring or initial training, they do not ensure that those same skills remain adequate as time passes. We believe that aide skills should be continuously reexamined to ensure competency at all times. Second, hospice quality and outcome measures have not yet reached the point where there is consensus on a single set of measures that have been thoroughly tested and determined to be valid, reliable, and widely applicable. As quality and outcome measures continue to evolve we will consider this suggestion. Nonetheless, hospices may use an outcome measure that targets aide services as part of their QAPI program, however

the measure could not replace aide supervision. Outcome measures and supervision can and should work together, rather than replace each other, in order to enhance the quality of the service provided, patient outcomes, and patient satisfaction.

Comment: A few commenters requested clarification about the nursing personnel who may function as hospice aide supervisors. One commenter suggested that licensed vocational nurses (LVNs) and licensed practical nurses (LPNs) should be permitted to supervise hospice aides. Another commenter suggested that any nurse should be permitted to supervise a hospice aide, rather than having a designated nurse supervise a specific hospice aide's care of a patient.

Response: Registered nurses (RNs) have the education and training to adequately supervise hospice aide services. In addition to ensuring that hospice aides furnish the care identified in the plan of care, nurse supervisors must be able to assess the adequacy of the aide services in relationship to the needs of the patient and family. Registered nurses possess the assessment skills necessary to fulfill this function to a greater degree than LVNs and LPNs, which makes registered nurses uniquely qualified to fulfill the hospice aide supervisory position.

In addition to having the necessary assessment skills, it is important that registered nurses have a relationship both with the aide being supervised and the patient receiving the aide's services. Ideally, the RN responsible for supervising the aide is the RN chiefly responsible for the patient's nursing care. This allows the RN to develop a complete picture of the patient and family and of the aide's services. For this reason, we believe that it is necessary for hospices to identify a specific RN who will serve as the aide's supervisor during the care of a specific patient. We understand that, at times, it is necessary to use other RNs to fill-in and supervise aide services. If a substitute supervising RN is used, this should be noted.

Comment: A large number of commenters expressed concern about our proposal in §418.76(h) to allow therapists to supervise hospice aides. Some commenters sought clarification regarding the exact meaning of the term "qualified therapist." Other commenters suggested that therapists should only be allowed to supervise hospice aides when aides are furnishing delegated therapy services. Still others suggested that only nurses be allowed to supervise hospice aides.

Response: We proposed to allow hospices to use therapists to supervise home health aides in order to

provide more flexibility in meeting the every-28-day in-person supervisory visit requirement discussed later. We have changed the 28-day time frame, thereby alleviating many of the related supervisory demands. For this reason, we believe that it is no longer necessary to allow therapists, who are not routinely involved in the care of most hospice patients, to supervise hospice aides. Thus, the term "therapist" has been deleted from this standard, as well as this CoP.

Comment: A commenter suggested that the every-14-day supervisory visit could be conducted through a telephone contact with the patient or family, rather than through a visit to the patient's home.

Response: In-person visits by the supervising nurse to the patient's home allow the nurse directly to observe the patient and the results of the aide's care. Telephone contacts do not allow the nurse to see if the patient has been bathed, and patients may be hesitant to report these failures of duty to nurses for any number of reasons. In-person home visits simply provide nurse supervisors with more information than telephone contacts do.

Comment: A commenter suggested that we should clarify the purpose of the every-14-day supervisory visit required by §418.76(h), to state that the visit is designed "to

assess the quality of care and services provided" by the aide.

Response: We agree that clarifying the intent of the every-14-day supervisory visit will be helpful to hospices. We have added language at §418.76(h)(1)(i) to reflect the intent of the suggestion. In addition, we have added a statement that the every-14-day supervisory visit is also meant to ensure that the services ordered by the hospice are sufficient to meet the patient's needs.

Comment: Numerous commenters submitted suggestions on the proposed every-28-day time frame for in-person supervision of hospice aides at §418.76(h). Although some commenters expressed support for the 28-day supervision requirement, most suggested that the 28-day time frame be changed to every 60 days, every quarter, every 6 months, every 12 months, or even every 24 months. Some commenters also suggested that the in-person supervision requirement be deleted in its entirety.

Response: We believe that all hospice employees, including hospice aides, must be supervised. To ensure that aides are adequately supervised, we proposed that each aide would be supervised while he or she is furnishing care to a patient for the purpose of observing the aide's skills. In addition, we proposed that this in-person supervision would

occur at least every 28 days. After reviewing the comments that we received, we agree that assuring aide skill competency 12 times per year is not necessary. In keeping with our desire to maintain consistency with the aide requirements in the home health regulations, we have changed the in-person supervisory visit time frame from once every 28 days to once annually per aide.

At the same time, we have added a new requirement at §418.76(h)(1)(ii) that requires hospices to conduct in-person supervisory visits to observe and assess aide skills if a potential deficiency in care furnished by the aide is noted in the regular 14-day supervisory visit (during which the aide is not required to be present). We believe that linking more frequent in-person supervisory visits to the actual performance of the aides will ensure that aides furnish quality care and that hospices have the flexibility to supervise their staff in a manner that meets their needs.

Comment: A few commenters suggested that the aide in-person supervision visit (proposed as occurring every 28 days and finalized as occurring annually) should be documented in the aide's personnel record, rather than in the patient's clinical record.

Response: We agree that the aide's personnel record is

an appropriate place to document the annual in-person supervisory visit. Hospices may determine the appropriate location to document the annual aide evaluation in accordance with their own policies and procedures.

Comment: Many commenters expressed confusion about the in-person supervisory visit to observe the aide furnishing care. Commenters wanted to know whether the observation visit needed to be conducted with each patient that the aide is caring for, or whether the observation visit only needed to be conducted with a single patient that the aide is caring for. The commenters noted that conducting an observation visit with each patient that the aide is caring for would be difficult to schedule and cost-prohibitive.

Response: The intent of the proposed rule was to require an observation once every 28 days with a single patient that the aide was caring for at the time of the visit. In response to public comments, we changed the time frame for the observation visit from once every 28 days to once annually. In addition, we have changed the phrasing of this requirement to more clearly state our intent for only a visit to a single patient's home. The revised requirement at §418.76(h)(2) states, "A registered nurse must make an annual on-site visit to the location where a patient is receiving care in order to observe and assess each aide

while he or she is performing care." We believe that "a patient" is clearer than the language we originally proposed, "the patient." We are not requiring that the aide be supervised with each patient annually to evaluate the aide's proficiency.

Comment: Many commenters addressed the relationship between hospice aide services, hospice homemaker services, and Medicaid personal care benefits. Specifically, commenters suggested that we should state in the regulation text that hospice aide and homemaker services are not 24-hour-a-day primary caregiver services and are not meant to replace personal care aide services covered under Medicaid or other insurers. Commenters also suggested that we should clarify the relationship between the hospice and personal care aides by stating that hospices may use the personal aides in implementing the plan of care only to the extent that the hospices would routinely use the services of a patient's family in implementing the plan of care. Furthermore, commenters suggested that hospices should be required to coordinate their services with those furnished by personal care aides.

Response: We understand that there may be confusion relative the interaction between the Medicaid personal care aide benefit and the hospice benefit. The Medicaid personal

care benefit is designed to assist eligible Medicaid beneficiaries with daily personal care tasks such as household chores and personal hygiene. The hospice aide and homemaker services covered under the Medicare hospice benefit cover many of the same tasks. However, hospice aide and homemaker services are not necessarily meant to be daily services, and are certainly not meant to be 24-hour daily services. Hospices are neither expected to nor prohibited from fulfilling the caregiver role for a patient. Rather, hospice aide and homemaker services are provided to supplement the primary caregiver(s).

Since there may be occasions where a patient receives services through a personal care aide benefit while receiving hospice services, we agree with the commenters that this rule should address the responsibilities of the hospice for coordinating the care provided by hospice personnel and the Medicaid personal care aide. We have added new elements to address this, §418.76(i)(2) and §418.76(i)(3). Section 418.76(i)(2) provides that services furnished by the Medicaid personal care benefit may be used to the extent that the hospice would routinely use the services of a hospice patient’s family in implementing a patient’s plan of care. Section 418.76(i)(3) requires that a hospice coordinate hospice aide and homemaker services

with the services furnished by the Medicaid personal care aide benefit to ensure that patients receive all the services that they require.

Comment: Numerous commenters requested clarification of the requirements at proposed §418.76(j), Homemaker qualifications. The commenters interpreted the proposed standard to mean that only those individuals who have completed hospice aide training are considered qualified to function as homemakers. The commenters disagreed with this policy and stated that orientation to hospice care should be sufficient for homemakers.

Response: In §418.76(j) we proposed that a homemaker be either an individual who has completed aide training or an individual who has successfully completed hospice orientation addressing the needs and concerns of patients and families coping with a terminal illness. We believe that the commenters misinterpreted this requirement, and that the misinterpretation led to a great deal of confusion. We agree with the commenters that homemakers do not need to complete hospice aide training in order to be qualified, which is why we proposed that hospice orientation is sufficient. We do not agree that hospice aide training should be completely removed from this standard. If an individual has completed hospice aide training, he or she

should not be prevented from serving as a homemaker. Indeed, hospice aide training provides an extra level of education and training that would go above and beyond hospice orientation. In order to clarify our intent in this standard, we have reformatted it to place hospice orientation as the first option for homemaker qualifications and hospice aide training as the second option for homemaker qualifications. We believe that this reformatting will make it clearer that either qualification is acceptable.

Comment: A commenter asked whether or not hospices are permitted to contract for homemaker services.

Response: Section 1861(dd)(2)(A)(ii)(I) of the Act requires hospices to provide substantially all nursing, medical social, and counseling services through direct employees. Homemaker services do not fall into any of these categories; therefore hospices may contract for homemaker services. If hospices choose to contract for homemaker services, then the professional management responsibility requirements of §418.100(e) will apply. We believe that this question may have been prompted by a requirement in proposed §418.76(h)(4) regarding contracting for hospice aide services. The inclusion of specific requirements for aide contracting, and the omission of requirements for homemaker contracting, seemed to imply that homemaker

contracting would not be allowed. We have removed the aide contracting provision at §418.76(h)(4) in order to remove any implication that homemaker services may not be contracted.

Comment: A commenter suggested that we should explicitly state that homemakers can be volunteers.

Response: Volunteers are permitted to fulfill many roles in hospice care, including providing homemaker services, provided that the volunteers meet all qualifications and personnel requirements established by this rule. We do not believe that it is necessary to explicitly state in this standard that volunteers may function as homemakers. We believe that making this statement may unintentionally imply that volunteers may not function in other capacities within a hospice program. The implication would negatively impact the role of volunteers in hospice and may affect the level of volunteer services that hospices furnish.

Comment: A commenter sought clarification about who is responsible for supervising homemaker services.

Response: We agree that this rule should explicitly require such supervision. We have added a provision at §418.76(k)(1), stating that the member of the patient’s IDG group who is responsible for coordinating homemaker services

must also be responsible for supervising those services.

14. Condition of Participation: Volunteers (§418.78)

The current CoP for volunteers is located at §418.70. We proposed to recodify this CoP at §418.78 with minor changes. We proposed to remove the existing §418.70(f), regarding the availability of clergy, because the role of the pastoral, clergy, or other spiritual counselor would be described as part of the IDG at proposed §418.56(a)(1)(iv). This change would not preclude the hospice from continuing to use or starting to use clergy as volunteers. We did not propose any changes to the requirements to document cost savings and to maintain a sufficient level of volunteer activity.

Comment: A few commenters suggested that we should remove the term “day to day” from the proposed §418.78(b). The commenters stated that removing the phrase would permit hospices to use volunteers for special events that occur infrequently.

Response: The phrase “day-to-day,” as used, requires hospices to incorporate volunteer services into their daily patient care and operations routine in order to retain the volunteer-based essence of hospice as it originated in the United States. The phrase does not preclude hospices from using volunteer services for special events or non-routine

occurrences. Hospices must use volunteers for day-to-day services, and may use volunteers for other services as well.

Comment: Some commenters asked us to clarify that volunteer time spent in training, orientation, travel, direct patient care, and administrative services may be included when documenting the cost savings that the hospice achieves through the use of volunteers.

Response: Section 1861(dd)(2)(E)(ii) of the Act requires hospices to maintain records on the cost savings achieved through the use of volunteers. That is, hospices must document those hours that volunteers furnished care and services for which a hospice would otherwise have been required to pay its employees to furnish such care and services. If a hospice is training and orienting volunteers, it is most likely using its paid employees to do so. Therefore, no cost savings is achieved. However, if a hospice does pay an employee for time spent traveling for direct patient care and administrative purposes, and does not compensate a volunteer for the time, then it may include the volunteer’s travel time, direct patient care and administrative services in its documentation of the cost savings it achieves. Likewise, hospices may document the time that volunteers actually spend providing direct patient care and administrative services, because hospices would

compensate paid employees for the time spent performing these duties. We note that travel time is not the same as direct patient care. Following publication of this final rule, we will issue further sub-regulatory guidance addressing the manner in which the cost savings needs to be calculated and documented.

Comment: Several commenters requested clarification about what volunteer hours may be included in calculating the level of volunteer activity within a hospice, as required by proposed §418.78(e). Commenters specifically suggested that time spent traveling, providing care or services, documenting, and phoning patients should be included in the level of volunteer activity calculation.

Response: We understand that traveling, providing care or services, documenting information, and calling patients all consume volunteer time, and we agree that the time may be used in calculating the level of volunteer activity in a hospice. If a hospice chooses to include any of these areas that are directly related to providing direct patient care or administrative services in its percentage calculation of volunteer hours, it must ensure that the time spent by its paid employees and contractors for the same activity is also included in the calculation. That is, if a hospice chooses to count the hours spent by volunteers traveling to and from

patient homes in its calculation of the numerator, it must count the hours spent by its paid employees and contractors in traveling to and from patient homes in its calculation of the denominator. In this way, hospices will be able to accurately assess the proportion of volunteer hours to paid staff and contractor hours. Upon issuance of this final rule, we will issue sub-regulatory guidance to reflect the potential inclusion of certain volunteer hours in the overall calculation.

Comment: Some commenters suggested that hospices should only be required to provide volunteer hours equal to five percent of the routine home care level of care hours furnished to patients. Commenters stated that this would be easier for hospices to comply with because providing direct inpatient, respite, or continuous home care accounts for a substantial number of paid staff hours. Eliminating the hours spent providing direct inpatient, respite, or continuous home care would decrease the number of hours in the denominator, thereby altering the ratio of volunteer hours to paid hours. Other commenters suggested that the five percent goal should be completely eliminated.

Response: Section 1861(dd)(2)(E)(i) of the Act requires the Secretary to ensure a continuing level of effort to use volunteers in providing care and services to

hospice patients. In addition to serving as companions, homemakers and administrative staff, volunteers often serve as medical directors, nurses, alternative counselors, and spiritual advisors. All of these services, when provided by volunteers, count toward the five percent goal. Since we permit hospices the flexibility to use volunteers to function in such a wide variety of roles within hospices, we do not believe that it is necessary to artificially lower the standard for achieving continual volunteer use in hospice by eliminating the hours spent by hospices furnishing direct inpatient, respite, or continuous home care. Additionally, we note that hospices have not historically failed to meet the five percent requirement, as this is not a frequently cited deficiency during hospice surveys conducted by the State survey agencies.

Comment: A commenter asked us to define the role of a hospice volunteer.

Response: Hospice volunteers are permitted to fill any role within the hospice, provided that the volunteer filling the role meets the appropriate qualifications of this rule and any other applicable State and local requirements (for example, State licensure). Since volunteers may be used in any role, there is no one volunteer role that can be defined in this rule. Any definition may unintentionally limit a

hospice's use of volunteer services, thus compromising its ability to comply with the requirements of this rule.

Comment: Some commenters suggested that board certified chaplains should be required to train and supervise hospice volunteers.

Response: Hospices are responsible for ensuring that volunteers are trained, oriented, and supervised. While a designated employee must supervise volunteers, their training and orientation may be conducted by a person(s) of the hospice's choosing. We believe that it is inappropriate to prescribe the qualifications for the person(s) responsible for training and supervising volunteers because hospices need the flexibility to make the staffing decisions based on their individual needs. If hospices choose to use board certified chaplains to train and/or supervise volunteers, they are free to do so.

15. Condition of Participation: Organization and administration of services (§418.100).

We proposed to combine several conditions of the existing CoPs into a single new CoP. The proposed CoP included the requirements of current §418.50, "General provisions," §418.52, "Governing body," §418.56, "Professional management," §418.60, "Continuation of care," and §418.64, "In-service training." We believe that the

proposed CoP simplifies the structure of the requirements, making them easier to understand. We also proposed to condense the list of all services that hospices are required to furnish into a single standard. We believe that this single list will emphasize hospice's holistic approach to patient and family care.

We made minor changes to the "General provisions," "Governing body," "In-service training," and "Continuation of care" requirements. In §418.100(e), "Professional management responsibility," we proposed to revise some of the current requirements found at §418.56(b) and §418.56(c). This proposed standard would require written agreements for services furnished under arrangement, and would require that the hospice retain professional management, supervisory, and financial responsibility for all services that are provided to the patient and family. The hospice would be required to ensure that it authorizes all services that it provides, that they are furnished in a safe and effective manner by qualified personnel, and that items and/or services specified in the plan of care are provided.

We proposed to add a new standard to address the issue of multiple service locations. This provision was intended to codify long-standing Medicare survey and certification policy, which allows for the operation of multiple locations

by a single hospice provider with a single Medicare agreement. We expect that any hospice that requests to establish a satellite location (now referred to as a multiple location) will be able to demonstrate how it is able to manage and monitor all of the services provided in its entire service area, including services from a multiple location. Patients who receive care and services from a hospice multiple location must receive the full range of services that are documented in the plan of care.

Before operating a multiple location, also known as a practice location on CMS form 855, a hospice must enroll with the fiscal intermediary and notify the State agency and CMS of all currently approved multiple locations at the time it requests approval for any additional multiple locations. If a hospice provides care and services to Medicare beneficiaries from an unapproved or disapproved multiple location, these services may be determined to be non-covered. At the time of any multiple location closure the hospice is expected to notify the fiscal intermediary, State agency and CMS. Hospice multiple locations are also subject to survey by the State survey agency or CMS regional office. Deficiencies that are identified at any multiple location will apply to the entire hospice issued the provider agreement number. Multiple locations must comply with the

hospice conditions of participation at §418.52 through §418.116.

Comment: A few commenters suggested that we restate the requirements in proposed §418.100(a)(1) to clarify that hospices are responsible for providing care that meets the patient's needs for comfort and dignity, but are not responsible for ensuring that patient's actually experience such care because patient perceptions are outside of the hospice's control. A commenter suggested that this requirement should be further qualified by adding a statement that hospices should only be responsible for providing such care to the extent that it is possible within the context in which the patient is living.

Response: We agree that hospices are responsible for providing care rather than ensuring experiences. We also believe that the term "optimizes" already reflects the fact that hospices must work within the context of the patient's living situation to address the patient's unique needs and goals. Rather than holding hospices responsible for actually assuring comfort and dignity, we are requiring hospices to optimize, or take all appropriate steps, to provide care that promotes comfort and dignity. The revised requirement reads, "[t]he hospice must provide hospice care that [optimizes] comfort and dignity."

Comment: Many commenters suggested that we should reexamine the proposed requirement at §418.100(a)(2) which would require that the hospice must ensure "[t]hat each patient experiences hospice care that is consistent with patient and family needs and desires." The commenters stated that hospices are not necessarily able to ensure that patients experience care that is consistent with their needs and desires. Rather, hospices are able to, through their actions, promote care that is consistent with patient needs. Furthermore, commenters stated that the term "desires" was too broad to be successfully met by hospices. The commenters suggested that it be deleted; qualified by phrases such as "consistent with hospice practice" or "that are reasonable and necessary"; or replaced by "goals." In addition, the commenters expressed concern about the requirement to meet family desires when those desires are in conflict with each other or those of the patient.

Response: We agree with the commenters that hospices should be required to provide care consistent with patient and family needs rather than requiring hospices to ensure that patients and families experience care that is consistent with their needs and desires. Using the term "provide" holds hospices responsible for those things that are within their control in contrast to the term

“experience,” which is subjective and out of a hospice’s control. We also agree that the term “desires” is too broad and subjective, even when qualified by the suggested phrases. We believe that the term “goals” is more objective, and it corresponds with the requirement at §418.56(c) that the hospice plan of care must reflect patient and family goals. Therefore, we have replaced the term “desires” with “goals” in this requirement. Furthermore, we have added a statement in §418.100(a)(2) affirming that the patient’s needs and goals are the hospice’s primary consideration in care planning and delivery. While hospice treats the patient and family as a single unit of care, this new statement recognizes that not all members of a family may agree about the patient’s hospice care. In situations where agreement cannot be reached regarding the goals of hospice care, the patient’s needs and goals must take precedence.

Comment: A commenter suggested that the requirement for the governing body to assume full responsibility for management of the hospice may be in conflict with State laws regarding management of entities. The commenter stated that Boards of Directors generally do not perform hands-on management of the entity.

Response: We believe that the commenter may have

misunderstood our intent in this section. We are not requiring the governing body to actually perform day-to-day management functions. We clarified in proposed and final §418.100(b) that the administrator, who is appointed by the governing body, is responsible for the 24-hour operation of the hospice. If the administrator is not available to fulfill his or her assigned duties and responsibilities, the hospice must identify another individual to assume those assigned duties and responsibilities in accordance with the hospice's established policies and procedures. The governing body must assume responsibility for ensuring that the hospice is managed by the administrator and any managers that the administrator appoints.

Comment: A commenter requested that we provide a definition for the term "administrator" at §418.100(b).

Response: At §418.100(b) we are requiring hospices to have an administrator who reports to the governing body and who is responsible for the day-to-day operations of the hospice. We have added a new requirement that the administrator be appointed by the governing body, to further clarify the relationship between the two parties. We are requiring that the administrator be a hospice employee who possesses the education and experience determined to be necessary by the governing body. We intentionally are not

including specific personnel requirements or a job description for the administrator because this leadership position varies from hospice to hospice, based on the unique needs of each hospice. A hospice's governing body, with knowledge of its operations and needs, is far better suited for making administrator personnel and job description decisions.

Comment: A commenter suggested that we should add requirements related to advanced beneficiary notices and expedited determination notices to proposed §418.100(d), which states that hospices may not discontinue or reduce care provided to a Medicare or Medicaid beneficiary because of the beneficiary's inability to pay for that care.

Response: It is not appropriate to add information about advanced beneficiary notices and expedited determination notices to this rule because these notices are not within the scope of this rulemaking.

Comment: Many commenters expressed concern about our proposed requirement at §418.100(e) that hospices must retain supervisory responsibility for services furnished under arrangement. The commenters stated that the word "supervision" implies that hospices are responsible for providing personnel supervision for those individuals furnishing services. Personnel supervision, the commenters

further stated, is the role of the entity with which the hospice has an arrangement. The hospice should be responsible for ensuring that such supervision occurs. Commenters suggested that the word “supervision” be deleted and replaced with “oversight”, “supervisory responsibility”, or “continually monitor and manage.”

Response: It was not our intent to imply that hospices must provide personnel supervision for contracted staff. We agree that the term “supervision,” as used in the proposed regulatory standard, implies much more than was intended. Therefore, we are deleting the term “supervision” and replacing it with the term “oversight” to clarify that the hospice must be responsible for the services furnished rather than the individuals furnishing the services.

Comment: Numerous commenters suggested that the proposed requirement at §418.100(e)(2) regarding the qualifications of contracted personnel be clarified. The commenters suggested that the phrase “qualified personnel” replace the phrase “personnel having at least the same qualifications as hospice employees.” The commenters stated that for some contracted services, for example, durable medical equipment, there are no equivalent positions between the hospice and the contractor. Therefore, it would not be possible for the contractor’s employees to have at least the

same qualifications as hospice employees.

Response: Our intent was to ensure that hospice patients receive the same quality service regardless of whether that service is provided by hospice employees or contracted staff. We believe that the commenters suggestion is appropriate and we revised the requirement found at §418.100(e)(2). This revised element requires contracted staff to be “qualified,” meaning that they must meet the personnel qualifications of whatever profession or job description they are in, as well as any regulatory requirements particular to that profession or job description.

Comment: A large number of commenters expressed support for, or requested clarification regarding, our proposal at 418.100(f), “Hospice satellite locations.” Commenters appreciated our inclusion of regulations on this fast growing part of hospice care and our exclusion of mileage restrictions. Some commenters sought specific criteria that hospices must meet in order to open a multiple location, while other commenters requested more detailed information on the Medicare approval process, including what would constitute an “initial determination” under §498.3, regarding such locations. A few commenters suggested that

the entire proposed multiple location requirement be deleted.

Response: We appreciate the support from commenters on this proposal. We believe that this proposed requirement is necessary to ensure that patients receive quality care from hospices, regardless of whether those services are being provided by the hospice location originally issued the certification number or by a multiple location of the hospice. (As noted in the discussion of public comments in §418.3, the term “multiple location” is more current and appropriate than the term “satellite location.”) We also believe that the proposed requirement at §418.100(f), coupled with the definition of “multiple locations” at §418.3, will provide much-needed guidance for hospices considering operating one or more “multiple locations.”

As previously stated, we relocated the requirement that hospices must exercise supervision and management over multiple locations from the definition of the term “multiple location” at §418.3 to §418.100(f)(1)(ii). Furthermore, we reorganized §418.100(f) to group all requirements related to Medicare approval of multiple locations under a single regulatory element, §418.100(f)(1), “Medicare approval.” We believe that grouping these elements will clarify our expectations for hospices seeking to operate multiple

locations. Revised §418.100(f)(1)(iii) now requires that the lines of authority, and professional and administrative control be clearly delineated in the hospice's organizational structure and in practice. It also requires that the lines of authority be traceable between the hospice location issued the certification number and all multiple locations. This new requirement further clarifies how a hospice must demonstrate supervision and management of the multiple location by the hospice issued the provider number. Revised §418.100(f)(1)(iv) also includes a provision that a determination of whether or not a location qualifies as a multiple location in accordance with the considerations described above is an "initial determination" under §498.3. An "initial determination" is an administrative action made by CMS, and is subject to appeal. Section 498.5 sets out the procedures for appellate review of CMS administrative actions that qualify as initial determinations. Therefore, hospices may appeal an unfavorable multiple location determination in accordance with the procedures of §498.5.

In the preamble to the proposed rule, we described some of the factors that are currently examined when hospices apply to their CMS regional office for Medicare approval of a multiple location. The factors further explain what evidence must be presented by a hospice to CMS to

demonstrate that the requirements of §418.100(f)(1), such as supervision and management by the hospice issued the certification number, are met by the hospice. The factors, which will be updated in sub-regulatory guidance [(Pub. 100-7, Chapter 2, section 2081)] for this final rule, include, but are not limited to, the following:

The hospice’s ability to supervise the multiple location to assure the provision of quality care for the patients and families served by the multiple location;

The hospice’s past compliance history;

Relevant state issues and recommendations, such as a reciprocal agreement between states to assure that at least one of the state agencies assumes responsibility for any necessary surveys of multiple locations in situations in which a hospice provides services across State lines, certificate of need requirements, State licensure requirements, etc.; and

The ability of the hospice to ensure that each patient receives care from an assigned IDG that effectively works together to identify and meet the needs of the hospice patient and family.

Once a hospice has received approval from Medicare and the State (where applicable) to operate multiple locations, §418.100(f)(2) requires that supervision and management of

the multiple locations must continually ensure that services delivered through the multiple locations are delivered in a safe and effective manner, and that the care of each patient and family is provided in accordance with the plan of care. All care and services provided by multiple locations must be in accordance with all hospice conditions of participation at all times. Deficiencies identified at any multiple location will apply to all locations operating under the CMS-issued certification number.

Comment: A few commenters suggested that existing multiple locations should not be required to have individual Medicare approval. Other commenters suggested that multiple locations, whether existing or new, should not be required to have Medicare approval.

Response: Hospices have been required through a CMS policy memorandum from the Director of the Office of Chronic Care and Insurance Policy and the Deputy Director for Survey and Certification to all Regional Administrators on the subject of the Hospice Conditions of Participation (June 27, 1997) to obtain Medicare approval for multiple locations since 1997. Thus, there is no need to exclude existing multiple locations from obtaining Medicare approval because they should have already received such approval. Furthermore, we believe that Medicare approval is essential

for ensuring that hospice services furnished from multiple locations are in accordance with all Medicare conditions of participation and that hospice services meet the needs of the patients and families being served.

Comment: Some commenters suggested that we should require hospices to orient each hospice employee to specific job duties that the employee is expected to perform and to the fundamentals of hospice philosophy.

Response: We agree that employees and contracted staff furnishing patient care should be oriented in hospice philosophy, and this requirement has been added to 418.100(g)(1). We do not believe that it is necessary for employees and staff that do not have patient contact to be knowledgeable in hospice philosophy, and requiring them to be oriented as such would be an unwise use of hospice resources. We also agree that hospice employees should be oriented to their specific job duties, and this requirement has been added to §418.100(g)(2). If hospice employees provide hospice care to patients who reside in regulated facilities (for example, a nursing facility), we believe that it would be beneficial to educate hospice employees regarding the regulatory requirements that the facility and its staff are required to meet. Such education may help improve hospice-facility understanding and cooperation to

ensure consistent, high quality care for hospice patients residing in facilities.

Comment: A commenter requested that we add a provision to this standard stating that board-certified chaplains who furnish hospice care must maintain national standards of practice and serve as teachers to other disciplines on the topics of patient rights, advance directives, ethics, and cultural and spiritual needs.

Response: Hospices are permitted to use certified chaplains in the manner that best meets their needs. If a hospice chooses to use the services of certified chaplains, then we would expect the chaplains to maintain national standards of practice just as all other disciplines are expected to do.

16. Condition of Participation: Medical Director (§418.102)

We proposed to revise the existing medical director requirements at §418.54 in several ways. First, we proposed that the medical director could provide services under contract to the hospice. This proposal would have prohibited general contracts with agencies or organizations for medical director services, and reflected existing CMS policy, as permitted by section 4445 of the BBA 1997. Second, we proposed that another physician would be identified by the medical director to assume the role of the

medical director in the medical director's absence. We believe that having another physician prepared to assume the medical director role would ensure continuity of care for the hospice's patients, even when the regular medical director was unavailable.

Third, in standard (a) and (b), we proposed to add further guidance on the factors that would need to be considered when certifying and recertifying the terminal illness. We believe that these factors, such as related diagnoses, current medication and treatment orders, and the patient's desire to continue hospice care, are already routinely considered by most medical directors when certifying and recertifying the terminal illness.
Fourth, we proposed to further define the role of the medical director. We proposed that the medical director coordinate with other physicians and health care professionals to ensure that patients receive care that is consistent with hospice policy. Additionally, we proposed that the medical director, in tandem with the IDG, be responsible for patient medical care in its entirety.
Finally, we proposed that the medical director be responsible for directing the hospice's QAPI program. We believed that these medical director responsibilities would ensure that the medical director was an active leader and

participant in all aspects of the hospice's operations and services. We believe active participation would lead to better quality care and patient outcomes.

Comment: While several commenters expressed general support for our proposed medical director requirements, calling them "appropriate" and "much needed," many commenters expressed concern that the medical director's role appeared to supersede the role of the IDG. Specifically, commenters stated that the proposed requirement at §418.102 that, "[t]he 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" seemed to elevate the medical director above the other members of the IDG. In addition, the commenters stated that making the medical director and physician designee responsible for this coordination would be burdensome for volunteer medical directors. Some commenters also stated that a patient's hospice care should reflect the hospice philosophy rather than hospice policy.

Response: Our intent in this proposed standard was to ensure that medical directors are actively involved in patient care. However, after considering commenter concerns, we agree that this level of involvement is not

always necessary. Some larger hospices have several physicians who may serve on IDGs, and it is the physician member of the IDG, whether he or she is the medical director or not, who shares the responsibility with the rest of the IDG for communicating with other physicians and health care providers and for ensuring that the care furnished by the hospice reflects hospice policy. Since the medical director may not be the physician member of the IDG, we agree that this requirement should be removed. Hospices will still be required to have a communication system in place to ensure the ongoing sharing of information, both between all disciplines providing care and services in all settings, and with other non-hospice health care providers furnishing services to the patient in accordance with final §418.56(e). In addition, hospices will still be required to develop and implement an individualized plan of care for each patient that addresses the patient's and family's hospice care needs and goals in accordance with §418.56(c). The individualized plan of care and the services furnished to execute the plan should be in accordance with hospice policies, which should, in turn, reflect the individual hospice's philosophy of care.

Comment: A few commenters wanted to know if a medical director could be a volunteer.

Response: Medical directors may be volunteers, and we did not intend to imply otherwise. We believe that this question arose from the phrasing in the proposed rule that was used to describe the employment status of the medical director. In §418.102 of the proposed rule, we stated that the medical director could be “employed by, or [be] under contract with,” the hospice. Additionally, in §418.3 we define the term “employee” to include volunteers. Since the proposed phrasing did not explicitly use the term “employee”, we believe that commenters were confused about our intent. We have clarified in this final rule that the medical director may be an “employee” of the hospice, which includes volunteers.

Comment: Many commenters suggested that the hospice, rather than the medical director, should be responsible for identifying the physician designee who fulfills the role of the medical director in the medical director’s absence. A few commenters suggested that hospices should be allowed to contract with physician groups, without designating a specific physician, for medical director services, while still other commenters suggested that hospices should not be required to have physician designees at all.

Response: We agree that the hospice is better suited than the medical director exclusively to choose the

physician designee, and we have incorporated this suggestion in §418.102. We are requiring hospices to employ or contract with physician designees because, in many hospices, the medical director may be the only physician employee or contractor in the entire hospice. It is essential that another physician be available to assume the medical director's role when the medical director is absent to ensure continuous quality care for the hospice's patients. Likewise, it is essential that there be a specific individual identified to be the physician designee. Allowing numerous physicians to fulfill the medical director role would likely result in inconsistent care and decreased accountability.

Comment: Numerous commenters requested that hospices be allowed to contract with physicians employed by a professional entity or a physicians' group. The commenters explained that, for tax and paperwork purposes, it is often easier for the hospice and the physician to arrange the contract for a particular physician's medical director services through the physician's practice or professional organization. In such a case, a specific physician would fulfill the medical director position at the hospice, but the hospice's contract for that particular physician's services would be with the physicians' group or professional

organization.

Response: Our intent in this standard is to ensure that there is a specific physician who fulfills and is held accountable for the medical director's responsibilities. We agree that there may be times when it is beneficial for hospices and physicians to handle contracts through established entities, rather than through direct individual contracts. For this reason, we have added a new standard at §418.102(a), "Medical director contract," which permits hospices to contract with a self-employed physician or a physician employed by a professional entity or physicians' group. The new standard at §418.102(a) establishes that, when contracting for medical director services, the contract must specify the name of the physician who assumes the responsibilities and obligations of the medical director.

Comment: A commenter suggested that we should add attending physicians to proposed §418.102(a), which requires the medical director or physician designee to review clinical information for each patient and provide written certification of the patient's terminal illness.

Response: The attending physician is a participant in the certification process pursuant to §418.22(c)(1)(ii). Although regulating the actions of the attending physician is not within the scope to this rule, we agree that

attending physicians should consider the same clinical information as the medical director or physician designee to help ensure that all physicians make certification decisions based on the same information.

Comment: Many commenters sought clarification on our proposal at §418.102(a) that the medical director must consider certain factors when initially certifying that it is anticipated that a patient's life expectancy is 6 months or less if the illness runs its normal course.

Response: We proposed that the medical director must consider the primary terminal condition, related diagnoses, current subjective and objective medical findings, current medication and treatment orders, and information about unrelated conditions when considering the initial certification of the terminal illness. In the proposed rule, we called these areas "criteria", and we believe that this term may have been the source of commenter concern. Our intent was to ensure that medical directors carefully examine all relevant information that is gathered about the patient before making this determination in accordance with the requirements for establishing eligibility for the Medicare hospice benefit found at 418.22 and 418.25. The interdisciplinary group may consider the information gathered during the certification in and developing the

patient specific plan of care. We have removed the term "criteria" in order to remove any implication that there are specific CMS clinical benchmarks in this rule that must be met in order to certify terminal illness.

We believe the requirements in this final rule compliment and encompass the existing Medicare hospice certification requirements and may enhance the health and safety of patients by ensuring that hospices have all relevant information about a patient in the patient's record.

Comment: Several commenters suggested that the IDG as a whole, rather than the medical director or physician designee individually as we proposed, be responsible for reviewing the patient's clinical information in preparation for recertifying the terminal illness. One commenter wanted to know if a review of the patient's clinical information would include a review of the plan of care.

Response: Certifying and recertifying the terminal illness is the function of the medical director or physician member of the IDG, and the patient's attending physician, if any, (in accordance with §418.22(c)), not the entire IDG. The contributions of the other members of the IDG should be considered when making the recertification decision. Section 418.102(c) of the final rule requires that the

patient's clinical information be reviewed before recertification. During this review the physicians would consider all of the patient's clinical information from all disciplines providing services to the patient. The review would, by definition, include the patient's plan of care since we would deem the plan of care to be "clinical information." The plan of care is required to be updated at least every 15 days, and the 90- and 30-day benefit periods that require recertification would coincide with the plan of care updates. We believe that this review will allow the collection of the necessary information from which to make a determination.

Comment: Many commenters asked for clarification of the proposed requirement at §418.102(b)(2) that provides for review of the patient's and family's expectations and wishes for the continuation of hospice care. Some commenters suggested that the review should focus on the patient's or representative's expectations and wishes, rather than the family's. Others suggested that a review of the patient's goals would be more appropriate. Some of these commenters contended that, because hospice is an elected benefit and patients are free to revoke their election at any time, this requirement is unnecessary. In addition, commenters expressed concern that reviewing the patient's and family's

desire for hospice care may appear to patients and families as though they are being pressured to change their minds about hospice care.

Response: We agree that the proposed requirement is not necessary because patients may choose to leave hospice at any time. Therefore, we are not finalizing this requirement.

Comment: Numerous commenters expressed concern regarding the proposed requirement at §418.102(c) that the medical director or physician designee and the other members of the IDG have joint responsibility for coordinating the patient's medical care in its entirety. Some of the commenters believed that the proposed standard unnecessarily separated the medical director or physician designee from the rest of the IDG, thereby downplaying the interdisciplinary nature of hospice care. Other commenters believed that the hospice should only be responsible for coordinating the patient's hospice care, because other care being furnished to a hospice patient for unrelated conditions is not within the hospice's control. Still other commenters believe that the patient's attending physician (if any) or the physician of the long term care facility where the patient resides (if applicable) would be the appropriate provider to coordinate the patient's medical

care in its entirety.

Response: We agree that it is inappropriate to create an environment which separates the medical director or physician designee from the IDG. We expect that all members of the IDG, including the physician, will actively work together to ensure that a patient's care is coordinated. We believe that this IDG approach to care is already reflected in final §418.56. Section 418.56(e) of this final rule requires hospices to have a communication system that allows for the sharing of information with health care providers who are furnishing care to hospice patients for unrelated conditions. In addition, §418.56(a)(1) of this final rule requires hospices to designate a registered nurse who is a member of the IDG to coordinate implementation of the plan of care, which is required to address all of a patient's hospice needs. Since these provisions adequately ensure that each patient's hospice care is coordinated both within the hospice and with other health care providers, we have removed the language in question.

Comment: The majority of commenters expressed support for involving medical directors in a hospice's quality assessment and performance improvement program, but expressed concern about holding medical directors responsible for directing the QAPI program. Commenters

stated that medical directors may not be the individuals who are most qualified to direct QAPI programs. Commenters also stated that these medical director responsibilities would be burdensome, particularly for part-time and volunteer medical directors. Some commenters suggested that the IDG designated as being responsible for establishing a hospice's day-to-day policies should have the responsibility for directing the QAPI program, while others suggested that the governing body or a professional advisory committee should have this responsibility.

Response: We agree that the medical director may not be the individual who is most qualified to direct a hospice's QAPI program; therefore, we have removed this requirement. As licensed professionals, §418.62(c) requires medical directors to actively participate in a hospice's QAPI program. We believe that this requirement is sufficient to ensure that QAPI programs benefit from the expertise of medical directors. We considered commenter suggestions for reassigning responsibility for directing the QAPI program. The final rule at §418.58(e)(3) requires the governing body to designate individuals to be responsible for directing the hospice's QAPI program.

Comment: A commenter suggested maintaining the existing requirement at §418.54 that the medical director must be a

hospice employee who is a doctor of medicine or osteopathy who assumes overall responsibility for the medical component of the hospice's patient care program.

Response: We do not believe that the medical director requirement in the current regulation is sufficient, because it does not address the issues of contracting for medical director services, physician designees, or the role of the medical director in certifying and recertifying terminal illness status. These are important areas to address, as they impact a hospice's ability to obtain medical director services as well as patient care and patient eligibility. At the same time, we agree that it continues to be appropriate to require the hospice medical director to assume overall responsibility for the medical component of the hospice's patient care program. We have incorporated this requirement into the final rule at new §418.102(d).

Comment: A commenter suggested that we should incorporate the definition of the term "medical director" from the American Academy of Hospice and Palliative Care into the final rule.

Response: No publication or policy of the American Academy of Hospice and Palliative Care defines the term "medical director"; therefore, we cannot incorporate this suggestion into the final rule.

Comment: One commenter stated that the “Medical director” condition of participation should be deleted because the requirements can be incorporated into the physician services requirement at §418.64(a).

Response: The hospice medical director’s role is above and beyond that of general physician services because, in addition to furnishing physician services and being a member of the IDG, the medical director also is responsible for providing overall medical leadership in the hospice. We believe that this additional level of responsibility, coupled with the medical director’s supervisory role of other hospice physicians, warrants a separate condition of participation.

Comment: Some commenters suggested that we should require hospice medical directors to have additional education, experience, and/or training in palliative and end-of-life care.

Response: We agree that hospices should choose a medical director with an appropriate set of knowledge and skills to meet the needs of patients and the hospice. We do not believe that a single set of personnel requirements for medical directors would achieve this goal. Hospices need the flexibility to determine the qualifications of the medical director based on the role of the medical director in that

particular hospice. That is, a medical director who is the only physician in the hospice, and who is thus expected to provide direct patient care to each patient needs a very different set of skills and knowledge than the medical director of a large hospice whose job it is to manage numerous hospice physicians and perform various other administrative-type tasks.

17. Condition of participation: Clinical records (§418.104)

The proposed condition of participation, “Clinical records,” would incorporate several of the existing requirements in §418.74 of the current regulation, “Central clinical records” (for example, that clinical records contain past and current findings, be maintained for each patient who is admitted by the hospice, be protected from loss or unauthorized use, and be readily accessible). We proposed to add a new requirement that the clinical record contain accurate clinical information that would be available to the physician and hospice staff.

At §418.104(a), “Content,” we proposed to retain the requirement that the clinical record include all assessments (including the initial assessment and all updated assessments), plans of care, consent and election forms, and clinical and progress notes. We proposed the following additional requirements for the content of the clinical

record—

- Advance directive information as described in proposed §418.52(a)(3);
- Authorization forms;
- Responses to medications, symptom management, treatments and services;
- Patient process and outcome measures as they relate to the plan of care; and
- Physician certification of terminal illness as required in §418.22(c) and described in proposed § 418.102(a) and

(b) (now (b) and (c) in the final rule).

We proposed to add a new standard at §418.104(b), “Authentication,” to require authentication of clinical records. This proposed standard was similar to a requirement in the conditions of participation for hospitals. We proposed that all entries be legible, clear, complete, and appropriately authenticated and dated. Authentication would include verification of handwritten and/or electronic signatures by signature logs or a computer secure entry of a unique identifier for a primary author who has reviewed and approved the entry. This new standard would address technological changes in information management, such as the computerization of records and

electronic signatures.

Under §418.104(d), “Retention of records,” we proposed to ensure protection of patient information by adding a new requirement that patient records be retained for five years after the death or discharge of the patient, unless State law stipulated a longer period of time.

Under §418.104(e), “Discharge or transfer of care,” we proposed a new requirement that Medicare/Medicaid-approved hospice facilities forward a copy of the patient’s clinical record and hospice discharge summary to the facility or provider to which the patient was being transferred. We believe that this would help to ensure that the information flow between the hospice and the transfer facility/provider would be smooth, and that appropriate care would continue without being compromised. Furthermore, we proposed that the hospice discharge summary would include information that accurately described the patient’s stay; current plan of care; recent treatment, symptom, and pain management information; most recent physician orders; and any other documentation that would assist in post-discharge continuity of care.

Comment: One commenter requested that we clarify the term “accurate” as it pertained to the information contained in the clinical record.

Response: CMS expects that the hospice will ensure that information placed into the clinical record is correct and we have replaced the term “accurate” with the term “correct” to reflect this expectation. This would include providing correct information in appropriate sections of the clinical record in accordance with accepted hospice documentation policies.

Comment: One commenter suggested that updated plans of care as well as assessments should be included in the clinical record requirement because updated plans of care are better to use than progress notes.

Response: We agree with the commenter’s suggestion and have amended the language at §418.104(a)(1) to indicate that the patient’s clinical record must include, “the initial plan of care, updated plans of care, initial assessment, comprehensive assessment, updated comprehensive assessments, and clinical notes.”

Comment: Several commenters asked CMS to clarify what is meant by the term “authorization” in proposed 418.104(a)(2). Another commenter asked that we amend the language to read “election statement, which is required to include consent to start hospice services as well as patient rights.”

Response: We agree that the word “authorization” was

confusing in this context. We also agree that “election statement” should be added to this section. Therefore we have removed “authorization” and have added “election statement” to the regulatory text. The election statement must be completed in accordance with the requirements of §418.24, which is not a part of these conditions of participation. The new §418.104(a)(2) now requires the patient’s clinical record to include signed copies of the notice of patient rights and election statement.

Comment: The majority of commenters believed that proposed §418.104(b) was too broad and held hospices to a higher standard than home health agencies. They recommended that we consider using the language in the home health CoPs regarding authentication issues. Another commenter recommended that we mirror the home health requirements by not having a signature requirement. The commenter stated that making a home health agency and a hospice conform to the same requirements would offer entities that have both a hospice and a home health agency an administrative advantage. For example clinical record software could be utilized by both entities. One commenter believed that the proposed language looked too much like the hospital conditions of participation. The majority of commenters strongly recommended that this section be excluded from the

hospice conditions of participation.

Response: We do not believe it is the best interest of the hospice to exclude this requirement, nor do we believe the clinical record requirement of the home health agency conditions of participation meets the needs of hospices. We agree that the proposed language could be difficult for the hospice to comply with; therefore we have amended the language to allow greater flexibility. We believe that a hospice should have the authority to create its own policy on authentication of clinical records. We have modified the proposed rule to reflect this change. Hospices will follow State laws regarding authentication of clinical records, and, within this context, alter their policies as often as necessary to adapt to changing technologies and practices.

Comment: One commenter asked if a unique user name and password that would allow access to, and creation of, an electronic health record would constitute authentication. One commenter stated that electronic medical records already have multiple protections in place, such as frequently changed passwords, making the proposed signature requirement duplicative and unnecessary. Some commenters stated that hospices have no mechanism to authenticate a signature of a covering physician beyond the initial verbal order taken by the registered nurse. Another commenter suggested that we

require authentication of documents, not signatures. One commenter asked if authentication requirements apply to consulting physicians and covering physicians. Another asked whether they would be required to maintain a sample signature on file as proof of the legitimacy of an authentication. An additional commenter suggested that hospices should only be required to authenticate handwritten and electronic signatures made by hospice employees.

Response: It will be up to the individual hospice to decide how it will handle authentication of entries made by employees, contracted staff, attending physicians, and any other individuals who input information in a patient's clinical record. Hospices must first decide on who is permitted to enter information into a clinical record. If the hospice is using electronic medical records, electronic authentication must have a user ID and frequently changed passwords. Every entry, both written and electronic must be signed and dated. Hospices must continue to comply with any applicable State laws regarding record authentication.

Comment: Many commenters asked what we meant by "primary author" in proposed 418.104(b). Commenters asked whether faxed signatures would meet the authentication requirement, and who (if anyone) would be required to authenticate a faxed signature. Commenters also asked if we

were requiring hospices to be held accountable for signature logs for attending physicians not employed by the hospice, or whether we were requiring a signature log for everyone. Finally, they asked whether this standard would apply to contracted entities.

Response: "Primary author," a term that has been removed from this final rule, referred to the person who wrote the entry. For information that is transcribed, we would require both the physician's and transcriber's signatures. Faxed signatures supporting orders and documentation, or care and services delivered would be acceptable, and we will provide sub-regulatory guidance to that effect. The hospice would need to make its own decision as to how it wanted to approach authentication; it will be up to the hospice to make decisions regarding signature logs.

Comment: Several commenters noted that there were differences between the hospice proposed record retention standard and Health Insurance Portability and Accountability Act (HIPAA) requirements as set out at 45 CFR 164.530(j)(2).

Response: We thank the commenters for pointing out the different time frame requirements under HIPAA. It was an oversight by us. To ensure consistency between these two regulations, we have changed the language at §418.104 (d) to

read: "Patient clinical records must be retained for 6 years after the death or discharge of the patient, unless State law stipulates a longer period of time."

Comment: Several commenters requested that we amend the discharge summary language by stating that we prefer the use of electronic methods for sending discharge summaries and/or clinical records when a patient is discharged.

Response: We believe that when electronic clinical records are available, sharing of discharge summaries and/or clinical record information through an electronic format would be acceptable if agreed upon by both the sender and the receiver. Electronic sharing of information may include access to a record through a secure internet access portal. We understand that many hospices may not have this capability. We are not mandating this as a requirement. Paper copies of the discharge summary and clinical record are acceptable.

Comment: One commenter requested that we amend the language at §418.104(e) so that it does not apply to patients discharged as a result of their death.

Response: We have amended the regulatory text to indicate that a discharge summary is only necessary for patients discharged under §418.26. We agree with the commenter that a discharge summary need not be completed for

deceased patients; we do not deem a patient's death to be a discharge within the meaning of §418.26.

Comment: Several commenters requested language changes under §418.104(e); for example, commenters requested that "Medicare/Medicaid approved" be changed to "Medicare/Medicaid certified"; that we add the phrase "as requested" to the end of proposed §418.104(e)(3)(iv); and that we add the phrase "patient's written consent" to the same element. Others commented on the unnecessary requirement that both the clinical record and discharge summary be sent. Many commenters believed that the discharge summary contains enough information to maintain continuity of care, and believed that a copy of the clinical record should only be sent upon request of the receiving entity. One commenter questioned whether sending the discharge summary would violate the HIPAA "minimum necessary" standards.

Response: In response to these suggestions we have decided to amend the language under §418.104(e). We have changed "Medicare/Medicaid approved" to "Medicare/Medicaid certified," and have added the term "if requested" when forwarding the clinical record. Pursuant to the HHS privacy rule at 45 CFR 164.502(a)(1)(i), 164.502(b)(2), and 164.506 the "minimum necessary" standard does not apply to

disclosures to or requests by a health care provider for treatment. The transfer of patient information is permitted when the patient transfers from one provider to another.

In the reorganization of §418.104(e) we believe we captured the commenters' concerns in the area of discharge summary. We recognize that the discharge summary and clinical record are very important, and have amended the language to specify that the discharge summary will be sent automatically, but that a copy of the patient's entire clinical record will only be sent if requested. When patients transition from a hospice to another provider, it is important for hospices to establish communication channels with receiving providers. The communication channels give hospices to opportunity to receive feedback from receiving providers regarding the adequacy and appropriateness of the hospice's discharge process. This feedback, which can be incorporated into a hospice's QAPI program, gives hospices the opportunity to improve patient transitions to ensure that patients receive safe and effective care at all times during the transfer process.

Comment: A commenter asked us to elaborate on the proposed requirement at §418.104(f), "Retrieval of clinical records."

Response: Clinical records, either in electronic or

hard copy form, must be made available to the appropriate requestor, such as the State survey agency or and accrediting body, within a reasonable amount of time. Access needs to be granted to any and all patient related documentation that the hospice maintains. If the hospice maintains electronic clinical records, equipment must be available to allow access to the clinical record information.

Comment: Many commenters responded to our request for information and input on the use of electronic health records. The overwhelming consensus at this time was that electronic health records (EHR) would be burdensome and cost prohibitive, especially for smaller hospices. A few commenters stated that financial assistance may be necessary to achieve EHR standards, and one commenter suggested that at the very least, EHR standards would need to be phased in.

Response: Given the potential financial constraints, we are not amending the final rule to mandate EHRs. Hospices may use EHRs if they choose, and would need to ensure trouble-free record retrieval.

Comment: A few commenters requested that Federal regulations as a whole need to address the development of EHRs that can be accessed and used in multiple care sites, including the patient’s home. One commenter included the

specific pieces of information that should be in the EHR. Some commenters commented on the advantages of the EHR, such as: improved coordination of care, increased communication, increased accuracy, accessibility from any computer, easy portability and legibility, with documentation available to others much more rapidly.

Response: We acknowledge and appreciate the comments. The overall goal of the EHR is to achieve and improve collaborative practice among all care providers and to ensure continuity of care as patients move across the care continuum.

Promoting the use of health information technology (HIT) is a major health initiative of the President and the Secretary of the Department of Health and Human Services (HHS). The President has made implementation of interoperable HIT a national priority and has expressed a goal that most Americans have an electronic health record (EHR) by 2014. While this rule does not require hospice providers to use specific health information technology solutions, including EHRs, we encourage hospice providers to become knowledgeable about ongoing HHS activities and actively participate in efforts to develop and implement cost-effective HIT. For example, one activity recently undertaken by the Secretary has been the formation of the American Health Information

Community (AHIC), a public-private sector federal advisory body charged with providing advice on accelerating the adoption of interoperable EHRs. In another effort, the Health Information Technology Standards Panel (HITSP) has identified widely accepted, consensus-based HIT standards to enable and support the development and use of interoperable HIT products in several healthcare domains. While HITSP did not focus on the quality measures that are typically important to hospice providers, several of the identified standards could be used to support the development of interoperable quality measurement and reporting HIT products needed by hospice providers.

Comment: Some commenters noted the disadvantages of EHRs. For example, software requirements to meet regulatory requirements and quality initiatives have not been finalized, EHRs may be less flexible that paper records, EHRs can be time consuming to computer challenged staff, and EHR systems may be more prone to failures. Commenters believed that one of the biggest barriers to the EHR was the potential to allow personal health records to automatically be left available to the patient/caregiver. The commenters stated that clear safeguards need to be in place to ensure the security and appropriate use of personal health records in the home. A commenter believed that caregivers might be

less likely to record certain procedures or observations because of open access in the EHR.

Response: We acknowledge the disadvantages the commenters listed. Because of these and other issues, we are not abandoning the traditional clinical record keeping process in favor of the EHR at this time.

18. Condition of Participation: Drugs and biologicals, medical supplies, and durable medical equipment (§418.106)

This proposed condition of participation would revise the current general requirement, found at §418.96, that durable medical equipment, supplies, appliances, 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.

Section 418.106(a)(1), “Administration of drugs and biologicals,” would have required that all drugs and biologicals be administered in accordance with accepted hospice and palliative care standards of practice and according to the patient’s plan of care. In §418.106(a)(2) we proposed to add a new requirement that the IDG be responsible for reviewing the plan of care to determine whether the patient and/or family has and continues to have the ability to safely administer drugs and biologicals.

In §418.106(b), we proposed that the hospice would have a written policy for tracking, collecting and disposing of controlled drugs that are maintained in a patient's home. We proposed that this policy would be discussed with patients and their families during the initial assessment to ensure that patients and families were educated about the uses and potential dangers of controlled drugs. We believe that the hospice's policy, coupled with patient and family education, would result in shared responsibility for these beneficial, but potentially dangerous, drugs.

Standard 418.106(c) proposed that hospices assume responsibility for the use and maintenance of durable medical equipment and supplies. This standard proposed that hospices, either directly or under contract, would be responsible for ensuring the maintenance and repair of durable medical equipment in a manner that conformed to manufacturer recommendations. If no manufacturer recommendations existed for a piece of equipment, then repair and routine maintenance policies and procedures would have to be established. This standard also proposed that the hospice ensure that the patient, family, and all other caregivers receive instruction in the safe use of equipment and supplies. Likewise, the hospice would have to ensure that the patient, family, and other caregivers could

demonstrate the safe use of such equipment and supplies to the satisfaction of hospice staff. We believe that proper maintenance and education are essential to ensuring the patients benefit from fully functional equipment and supplies that they are able to use in a safe and effective manner.

Comment: A commenter asked us to define the term "controlled drugs."

Response: In this regulation we intend controlled drugs to mean those substances identified under schedules II, III, IV, and V of the Federal Controlled Substances Act (PL 91-513) and FDA regulations (see 21 CFR Part 290) issued thereunder.

Comment: A few commenters suggested that we should require hospices to use pharmacists to participate in the drug review. Other commenters suggested that we should require a pharmacist as a member of the IDG to help identify and prevent drug-related complications such as duplication, improper dosing, and drug interactions. Still other commenters suggested that the requirements for pharmacist and pharmaceutical services at proposed §418.110(m) and §418.110(n) should apply to the entire hospice, rather than only to the hospice inpatient facility. The commenters stated that, since drugs are prescribed to virtually all

hospice patients, these patients should benefit from the expertise of a pharmacist and the additional level of drug oversight required by these regulatory standards. One commenter suggested that we should retain the existing requirements for drugs found at §418.96(b), which requires the hospice to have a policy for the disposal of controlled drugs maintained in the patient's home when those drugs are no longer needed by the patient.

Response: Many hospices, particularly those with hospice inpatient facilities, have already realized the benefits of actively involving pharmacists in patient care planning. Hospices are seeking to use drugs more effectively and efficiently to improve patient outcomes and reduce costs. In the last years of life, patients typically use five drugs or more at any one time, increasing the risk of duplicative drug therapy, drug interactions, or drug side effects, as well as the risk of dispensing or dosing errors. (Steinman, M., Landefeld, C.S., Rosenthal, G., Berthenthal, D., Sen, S., et al., "Polypharmacy and prescribing quality in older people," Journal of the American Geriatrics Society, 2006; Koh, N.Y., Koo, W.H., "Polypharmacy in palliative care: Can it be reduced," Singapore Medical Journal, 2002; Meredith, S., Feldman, P., Frey, D., Hall, K., Arnold, K., et al., "Possible medication errors in home

healthcare patients," Journal of the American Geriatrics Society, 2001; Twycross, R., Bergl, S., John, S., and Lewis, K., "Monitoring drug use in palliative care," Palliative Medicine, 1994.) The need for the use of drugs in caring for hospice patients, coupled with the risk of negative patient outcomes, warrants an additional focus on drug management for all hospice patients, regardless or whether they receive care in their place of residence or in an inpatient facility. Therefore, we have moved and modified the requirements of proposed §418.110(m) and §418.110(n) to §418.106 and have reorganized the requirements in standards (a) through (e).

In new standard (a), "Managing drugs and biologicals," we combined some of the requirements of proposed §418.110(m) and §418.110(n), such as the proposed requirement that a qualified licensed pharmacist direct the inpatient hospice's pharmaceutical services, including evaluation of a patient's response to drug therapy, and identification of adverse drug reactions. New standard (a) requires the hospice to ensure that the interdisciplinary group confers with an individual with education and training in drug management as defined in hospice policies and procedures and State law, who is an employee of or under contract with the hospice to ensure that drugs and biologicals meet each patient's needs.

Hospices may choose to use a licensed pharmacist, an individual who has an extensive and up-to-date knowledge of drugs, to fulfill this role. Approximately 1,600 hospices already contract with pharmacy benefit management companies to provide drugs and pharmacist services to each of their patients. Hospices may also choose to use other individuals with specialized education and training in drug management, including evaluating the effectiveness of drug therapies, identifying drug side effects, identifying actual or potential drug interactions, identifying redundant drugs, and taking appropriate corrective actions. All hospices must be able to demonstrate an individual's knowledge, skills, and abilities in managing the use of drugs in accordance with accepted standards of practice and all applicable State and local requirements, including State licensure requirements.

Standard (a)(2) also incorporates the proposed requirements of §418.110(m) and §418.110(n) that a pharmacist must oversee an inpatient hospice's pharmacy program. The provided pharmacist services must include evaluation of a patient's response to medication therapy, identification of potential adverse drug reactions, and recommended appropriate corrective action.

New standard (b), "Ordering of drugs," relocates the

requirements of proposed §418.110(n)(1). This new standard indicates who may order drugs for a hospice patient and how verbal or electronic drug orders should be documented.

New standard (c), “Dispensing of drugs and biologicals,” combines some of the requirements of proposed §418.110(m), with proposed §418.110(n)(4)(ii). This new standard requires a hospice to have a written policy that promotes dispensing accuracy, to maintain current and accurate records of the receipt and disposition of all controlled drugs, and to obtain drugs and biologicals from community or institutional pharmacists or from its own stock.

New standard (d), “Administration of drugs and biologicals,” combines the requirements of proposed §418.106(a)(2) and §418.110(n)(2). The new standard addresses drug administration in both the home and hospice inpatient facility environments to ensure that drugs and biologicals are administered to a patient by an individual who is competent to do so, regardless of the patient’s current environment.

New standard (e), “Labeling, disposing, and storing of drugs and biologicals,” combines and revises the requirements of proposed §418.106(b) and §418.110(n)(3), (n)(4)(i), (n)(4)(iii), and (n)(5). This new standard ensures that drugs are safely labeled, stored, and disposed of in

accordance with accepted standards of practice and applicable Federal and State laws and regulations. It also ensures that patients and families are properly educated about drug disposal.

We understand that the revised drug requirements may have some financial impact on hospices. However the cost saving achieved through a more efficient and effective use of drugs in the hospice, as well as improved patient outcomes and satisfaction, will, we believe, offset a portion of this financial impact. Additionally, we believe that the new standards (for example, development of hospice-wide policies and procedures, patient and family education) will help hospices create partnerships with patients and families to ensure that controlled drugs are used and disposed of in a safe manner.

Comment: Numerous commenters suggested that we should address the issue of hospice patients bringing their own drugs from their homes into a hospice inpatient facility.

Response: This rule does not prohibit patients from bringing their own drugs into a hospice inpatient facility. If patients do so, the transportation and use of these drugs must be in accordance with any applicable Federal, State, and local laws and regulations, as well as with the hospice’s own policies and procedures.

Comment: A commenter suggested that we should delete the requirement that drugs and biologicals must be obtained from a community or institutional pharmacist or stocked by the hospice.

Response: We assume that the commenter seeks to obtain drugs and biologicals from sources outside of the United States. Due to concerns about the safety of drugs and biologicals obtained from sources that are outside of the purview of the Food and Drug Administration, we believe it it necessary to continue to require hospices to obtain drugs and biologicals from a community or institutional pharmacist or from its own stocks.

Comment: A commenter requested that the following statement be added to proposed §418.106(a) (now located at §418.106(d)(1)):

"If the patient and/or family are determined to be unable to safely administer drugs and biologicals, the patient and family will be encouraged to relocate the patient to a setting where administration assistance can be routinely offered. However, it is recognized that the patient, if competent, and the patient's surrogate if the patient is not competent, can refuse to relocate. Given patient rights and the home setting, [the] hospice will be expected to provide reasonable assistance. [The] hospice

will not be expected to restrict the provision of medications unless there is a blatant safety issue for non-competent adults or children in the home."

Response: If a patient and all family members are unable to safely administer drugs themselves, then it is incumbent upon the hospice to identify alternatives to ensure safe administration. Depending on the circumstances, alternatives may include friends and neighbors of the patient and family who are competent to administer medications with appropriate training from the hospice, the hospice's own paid employees and volunteers, paid caregivers, and, lastly, patient relocation. We do not believe that it is necessary to include the suggested language because the options mentioned above are already available to hospices. Furthermore, we do not believe that it is necessary to establish in this regulation criteria for restricting the placement of drugs in a patient's home. We believe that hospices should be able to assume the responsibility to determine when it is or is not appropriate to place drugs in a patient's home.

Comment: A few commenters suggested changes regarding who is permitted to administer medications to patients in a hospice inpatient facility. One commenter suggested that licensed practical nurses (LPN) and licensed vocational

nurses (LVN) should be allowed to administer medications, while other commenters suggested that the patient's family or caregiver should be allowed to administer medications.

Response: In accordance with §418.106(d)(2) of this final rule, licensed nurses are permitted to administer medications in accordance with their scope of practice. If an LPN's or LVN's scope of practice permits him or her to administer medications, then it is appropriate to allow them to administer medications in accordance with this rule. However, it is not appropriate to allow the family or primary care giver of a patient to administer medications in an inpatient facility. Patients enter hospice inpatient facilities for two primary reasons, respite and general inpatient care. If a patient is in an inpatient facility for respite care, it is because the family/care giver needs a temporary break from care giving duties. It would not be appropriate to expect the family/caregiver to administer medications to the patient in the inpatient facility. If a patient is in an inpatient facility for general inpatient care, it is because the patient is experiencing pain or symptoms which cannot be managed in the patient's home by the patient's caregivers in conjunction with the hospice staff, in which case it is not appropriate to expect the family/caregiver to handle the complex medication regimen

the patient likely requires. This is the job of the hospice inpatient staff.

Comment: Numerous commenters expressed concern regarding our proposal in §418.52(a)(3) that hospices inform patients and families about their drug policies before hospice care is furnished. Commenters believed that providing the drug policy information at that time would overwhelm patients and families with information that was not urgent. Some commenters suggested that a hospice should be required to provide information about its drug policy in the admission package of information that is left with the patient. The content of the admission package, including the drug policy, could be discussed with the patient and family at some time during the comprehensive assessment period. Other commenters suggested that hospices be required to discuss their drug policies when patients are prescribed drugs to which the hospice's policy applies. Other commenters requested clarification regarding the form of the drug policy notice, noting the difficulties involved in furnishing the notice in obscure or otherwise uncommon languages. As with the general notice of patient rights in §418.52, many commenters requested that we explicitly allow the use of translators when providing the drug policy notice. Additionally, as with the general notice of patient

rights, a few commenters requested that we clarify how hospices should document the fact that patients and families were informed of the hospice's drug policies.

Response: We agree that providing controlled drug policy information before the start of care may not be appropriate in all cases because not all patients are taking controlled drugs at the start of care. We also agree that providing such information may unnecessarily overwhelm patients and families. Therefore, we have replaced the proposed requirement at §418.52(a)(3), with a requirement set out at §418.106(e)(2) that, at the initial time that controlled drugs are ordered by the hospice for the patient's use at home, the hospice must provide a copy of its written policies and procedures on the management and disposal of controlled drugs to the patient or representative, and the family.

While we are requiring hospices to provide drug policy and procedure information to patients and families, we are not prescribing the manner in which they must document this information sharing. The drug policy and procedure information, unlike the notice of patient rights in §418.52, is more of an educational effort. The hospice's drug policies and procedures will help patients learn how to safely use controlled substances and avoid negative

outcomes. The drug policies and procedures will also help the hospice explain its own role in controlled drug management. We do not believe that it is necessary to dictate the method for educating patients and families about the hospice's drug policies and procedures, nor is it necessary to prescribe how hospices should document that patients and families have received such education. Hospices should decide for themselves, in their own policies and procedures, how staff will document the discussion of the hospice's drug policies and procedures. Obtaining a patient or family member signature would be appropriate, as would any number of other documentation methods.

As previously discussed in the notice of patient rights section, it is acceptable to use translators, either professional or family members, to ensure that patients and families fully understand the hospice's controlled drugs policies and procedures.

Comment: In §418.106(b) we proposed that hospices have a written policy for tracking, collecting, and disposing of controlled drugs maintained in the patient's home. The majority of commenters who submitted comments on this CoP asked us to remove this requirement. The commenters were concerned that the tracking requirement would require hospice staff to conduct pill counts. They were also

concerned that these proposed requirements would compel hospice employees to remove drugs from the patient's home, which employees are prohibited from doing because the drugs are the patient's property.

Response: While it was not our intent to imply that hospices would be required to conduct pill counts or remove drugs from patient homes, we understand that the terms "tracking", "collecting" and "disposing" implied precisely that. Therefore, we have removed these terms and replaced them with a requirement at new §418.106(e)(2) that hospices have written policies and procedures for management and disposal of controlled drugs maintained in the patient's home. The intent of this revised requirement is to ensure that hospices have a clear picture of what drugs have been prescribed and delivered to the patient, and are therefore present in the patient's home, at any time. Through the written policies and procedures, hospices will have a plan detailing how they can assist a family in safely disposing of controlled drugs after a patient's death.

Comment: The majority of commenters who submitted comments on this CoP asked us to replace the proposed requirement that hospices must discuss the potential dangers of controlled drugs with a requirement that hospices must

discuss the “safe use,” “appropriate use,” or “risks/benefits” of controlled drugs.

Response: Our intent in the proposed standard was to ensure that hospices educate patients and families on how controlled drugs are used and the risks associated with abusing and/or improperly disposing of them. We agree that requiring hospices to discuss the “safe use” of controlled drugs accomplishes this intent without the negative connotations that may be associated with the language of the proposed rule. The safe disposal of controlled drugs should also be part of the patient and family education effort. Therefore, we revised §418.106(e)(2)(B) to require that, when controlled drugs are first ordered for use in the patient’s home, the hospice must, “[d]iscuss the hospice policies and procedures for managing the safe use and disposal of controlled drugs with the patient or representative and the family in a language and manner that they understand to ensure that these parties are educated regarding the safe use and disposal of controlled drugs.”

Comment: A commenter suggested that we should require hospices to educate patients and families about drug policies in a language and manner that the patient and family understand.

Response: HHS guidance on Title VI, “Guidance to

Federal Financial Assistance Recipients Regarding Title VI, Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons," August 8, 2003 (68 FR 47311), related to limited English proficiency persons, presents guidelines for developing and implementing communication strategies in a variety of settings, including hospice. Since hospices are already expected to meet these guidelines, we agree that it is appropriate to re-enforce the existing guidance by requiring the discussion of drug policies to occur in a language and manner that the patient and family understand.

Comment: A few commenters wanted to know where drug discrepancy investigation reports should be sent to. One of these commenters suggested that sending drug discrepancy investigation reports to State and Federal officials should be done only when required by law.

Response: We agree that such reports should only be sent to the appropriate agencies when required by a specific Federal or State law or regulation. These State specific laws and regulations may vary, and describe the appropriate reporting mechanism, timeframe, and recipient. We have added the phrase "if required by law or regulation" to the end of the reporting requirement, which is now located at §418.106(e)(3)(ii).

Comment: A commenter asked us to clarify the relationship between the requirement that hospices must provide drugs for patients and the Medicare Part D benefit.

Response: Hospices are required by section 1861(dd)(1)(E) of the Act to furnish all drugs and supplies related to the terminal illness and related conditions. Hospices may not expect patients to obtain drugs related to the terminal illness and related conditions through the Medicare Part D benefit. If a patient requires drugs that are not related to the terminal illness and related conditions, then it may be possible for the patient to obtain those unrelated drugs through the Medicare Part D benefit.

Comment: A commenter suggested that hospices should note in the patient’s clinical record any drugs that are prescribed for the patient that are not standard treatment for that patient’s symptoms. The commenter further suggested that the patient’s clinical record should include an explanation for such unconventional use.

Response: Hospices are free to determine the type, dose and administration methods for any drugs that they choose to prescribe. We would expect hospices to confer with a individual with education and training in drug management and use current practices to select the most appropriate

drugs for a particular patient, and to be able to explain drug choices to those providing patient care, the patient or representative, the family, and any authorities having jurisdiction, as necessary. Hospices may find it appropriate to document those drugs that are prescribed for uncommon or unconventional reasons, and the rationale behind such decisions; however, we do not believe that it is necessary to require such additional documentation.

Comment: Numerous commenters stated that, when durable medical equipment (DME) is provided under contract, the contracted DME provider is responsible for DME maintenance. As such, the commenters stated that hospices should not be held responsible for DME maintenance when it is provided under contract.

Response: We understand that the majority of hospices contract with outside entities for DME equipment. We also understand that, as part of that contract, most hospices require the DME company to provide maintenance services. This is an acceptable arrangement. However, requiring a DME company to maintain the equipment that it provides does not absolve the hospice of its ultimate responsibility to ensure that all services provided on its behalf, whether by its employees or through a contract, are safe and effective. An improperly or inadequately maintained piece of DME is

neither safe nor effective. Thus, it is the hospice's ultimate responsibility (as it is with respect to all of its contracted services) to ensure that maintenance is performed on DME equipment, regardless of the source of such equipment. A written statement from the DME supplier and signed by a person of authority stating that equipment has been serviced according to manufacturer recommendations or other comparable standards would be one way that the hospice could assure that the equipment is safe and performs as required. If a hospice does not ensure that such maintenance is performed, it is not in compliance with the requirement that it must maintain professional management responsibility for all services provided or this requirement at new §418.106(f)(1).

At the same time, we understand that the proposed requirements should be clarified to ensure that hospices may provide DME maintenance services under contract. We have revised new §418.106(f)(1) to state that hospices must ensure that manufacturer maintenance recommendations are followed. If there are no manufacturer recommendations, hospices must ensure that maintenance policies are developed. We believe that adding the term "ensure" will clarify that hospices must make sure that such maintenance is complete, but that hospices are not necessarily required

to handle maintenance through their employees.

Comment: Numerous commenters stated that the contracted entity that supplies the DME is best suited to instruct the patient and family in the safe use of the DME provided.

Response: In the proposed rule at §418.106(c)(2), we stated that hospices must ensure that patients and families receive DME instruction. Our intent was to allow hospices to provide such instruction through a contracted DME supplier. We agree that this intent should be further clarified. We have added a provision to the final rule at §418.106(f)(2) to clarify that, "[t]he hospice may use persons under contract to ensure patient and family instruction."

Comment: A few commenters asked for clarification about the role of the Medicare Supplier Standards and accreditation in contracting for DME services. Some of these commenters suggested that any DME supplier who furnished DME equipment as part of the Medicare hospice benefit be required to meet the Medicare Supplier Standards and be accredited by a national accrediting body. Another commenter suggested that by contracting with a DME supplier that met the Medicare Supplier Standards, hospices would have more assurance that the DME provider would safely and effectively perform its maintenance and instruction duties.

Response: We believe that Medicare beneficiaries should receive the same high quality DME service whether they receive such DME through Medicare Part B or through the Medicare hospice benefit. In order to ensure continuous DME service quality, we agree that hospices should contract with those DME suppliers who meet the Medicare Supplier Quality and Accreditation Standards. A provision to this effect has been added at new §418.106(f)(3).

Comment: A commenter suggested that the National Safety Council should be involved in conducting site inspections of DME suppliers to determine compliance with the Medicare Supplier Standards.

Response: As part of the effort to ensure quality DME services for Medicare beneficiaries, the Medicare Supplier Quality and Accreditation Standards require DME suppliers to be accredited by national accrediting organizations. (See 42 CFR 424.58.) Accreditation requires regular surveys by CMS-approved accrediting bodies. The existing DME accreditation regulations, we believe, respond to the commenter’s concern.

Other Issues

We are aware that the appearance of a conflict of interest or an actual conflict of interest could exist when a pharmacist or pharmacist service under contract to the hospice recommends one brand name drug over another, favors

one drug in a therapeutic class over another, or recommends an increase in the utilization of a specific drug. For example, a conflict of interest exists when a pharmacist under contract to the hospice is employed by the pharmacy that supplies drugs to the hospice and that pharmacy accepts access/performance rebates or other price concessions designed to or likely to influence or impact utilization of drugs in the hospice. The term “access/performance rebates” refers to rebates manufacturers provide to pharmacies that are designed to prefer, protect, or maintain that manufacturer’s product selection by the pharmacy or to increase the volume of that manufacturer’s products that are dispensed by the pharmacy under its formulary (referred to as “moving market share”). If a conflict of interest exists, it has the potential to compromise the judgment of the pharmacist which could affect the care of a patient. The hospice IDG retains responsibility for all patient care decisions independent of others, and it is inappropriate for a pharmacist or any other member or consultant of the IDG to drive patient care decisions based on financial or business incentives. It is incumbent upon a hospice to obtain assurance that a contracted pharmacist or pharmacist service is free of any potential or real conflicts of interest or financial incentives.

19. Condition of Participation: Short-term inpatient care (§418.108)

Under §418.108, we proposed to retain the requirement that hospices make inpatient care available for pain control, symptom management, and respite purposes, and that care be provided either in the hospice or in a participating Medicare or Medicaid facility. We proposed to recodify the current standard found at §418.98(a), ”Inpatient care for symptom control,” as §418.108(a), “Inpatient care for symptom management and pain control.” We proposed to recodify the current standard found at §418.98(b), “Inpatient care for respite purpose”, as §418.108(b), with the same title and only minor terminology changes.

We proposed to eliminate the existing requirement found at §418.100(a)(2), requiring that a registered nurse provide direct patient care on each shift. In its place, we proposed that the patient’s plan of care and the patient’s condition should determine the amount and skill level of nursing care required, as well as the skill level and State licensing requirements of the staff required to provide requisite care.

Under proposed §418.108(c), “Inpatient care provided under arrangement,” we proposed to incorporate the requirements of existing standard 418.56(e),”Inpatient

care." In particular, we proposed to require that, if a hospice chose to contract with another type of facility to provide inpatient care, the hospice would have to include in its contract a provision that it would train the personnel who would be providing hospice patient care in the inpatient facility (currently at §418.56(e)(5)). We believe the training is necessary because the hospice palliative model of patient care is very different from the curative model of patient care in which medical personnel are routinely trained. We also proposed that, as part of the contract, a copy of the inpatient clinical record and discharge summary would have to be available to the hospice at the time of discharge from the inpatient facility.

Under proposed §418.108(d), "Inpatient care limitation," and §418.108(e), "Exemption from limitation," we proposed to re-codify the existing parallel requirements at §418.98(c) and (d) respectively, without changes, because these requirements are derived directly from section 1861(dd) of the Act.

Comment: Many commenters believe that a reference to the psychosocial/family crisis situations should be added to the opening paragraph of the CoP as an additional reason to admit a patient to inpatient care. Adding psychosocial and family crisis situations would, according to the commenters,

conform to the requirements of Chapter 9, section 40.1.5 of the Medicare benefit policy manual. Another commenter asked that we allow inpatient care to be used for acute caregiver breakdown. One commenter stated that the hospice should have the option of placing the patient in a general inpatient level of care for a short period of time while developing a more appropriate plan of care.

Response: We believe that caregiver and family status should be considered in the comprehensive assessment process. This allows families and hospices time to develop back-up plans for any family or caregiver breakdowns that may occur in the future. As this issue primarily relates to Medicare payment rules, we refer readers to the FY 2008 hospice wage index (72 FR 50214, August 31, 2007) for additional discussion of the appropriate use of the respite and general inpatient levels of care in situations where a caregiver breakdown has occurred.

Comments: One commenter requested that we change the language in proposed §418.108(b)(2) from “Medicare/Medicaid approved” to “Medicare/Medicaid participating.” Two commenters requested that we use the phrase “Medicare certified.”

Response: We have amended the language to read “Medicare or Medicaid-certified.”

Comment: One commenter asked for clarification of whether or not a freestanding hospice inpatient facility operated by a Medicare-certified hospice would qualify as a participating Medicare or Medicaid facility.

Response: Yes, the facility would qualify if it met all applicable requirements of the hospice regulations at 42 CFR part 418.

Comment: One commenter stated that a hospice should not be able to send its own nursing staff to supplement contracted facility staff to meet inpatient care staffing requirements.

Response: We understand the commenter’s view; however, this issue is related to a hospice’s contractual agreement with its providers. A hospice must set up its own polices and guidelines, as well as its own written contract with an inpatient provider. We would not prohibit a hospice from sending in its own staff to care for the hospice patient, if it is permitted within the provisions of its contractual arrangement and the statutory and regulatory requirements applicable to the contracted inpatient provider.

Comment: One commenter requested that we allow up to four patients per room for inpatient respite purposes.

Response: We do not agree with the commenter. The level of care provided to the patient should not determine

the level of patient and family privacy. Therefore, we believe that no more than two patients per room should be permitted.

Comment: Many commenters thanked us for proposing to remove the 24 hour nursing requirement for respite care. The commenters felt it was not always necessary to have an RN on duty 24 hours a day for respite care and that the proposed nurse staffing requirement allowed for greater staffing flexibility and improved coordination of care between hospices and nursing homes where respite care may be provided.

Response: We agree that it is not automatically necessary to have a registered nurse on every shift to provide direct patient care if the only hospice patients in a facility are receiving the respite level of care. We believe that respite care is meant to give the family time to rest and re-energize before the patient returns to the home. The care needs of a respite patient are equivalent to those of the patient in his or her home and therefore may not necessitate registered nursing care on a 24-hour basis. Rather, staffing for a facility solely providing the respite level of care to hospice patients should be based on each patient’s care needs. The requirements for nursing services for respite care are now at §418.108(b)(2).

Comment: A few commenters requested that that we define nursing services in inpatient facilities as care provided by an RN or LPN.

Response: Because Congress was not specific about what level of nursing services were required, we believe that the intent of section 1861(dd) of the Act has always been for hospices to furnish nursing services from a variety of different categories of nurses, ranging from nurse practitioners to licensed vocational nurses to registered nurses. Since hospices have not, to our knowledge, had any difficulty in determining what constitutes nursing services, we see no reason to establish a definition for the term at this time.

Comment: One commenter stated that the respite level of care should be able to be provided in any facility that meets the general nursing requirements that apply to all hospice care; that is, that the nursing services provided must meet patient needs without CMS issuing specific regulations prescribing the exact level of nursing services that must be available at all times (such as 24-hour RN services). A few commenters requested that assisted living facilities and licensed group homes providing 24-hour care (but not necessarily nursing care) that meet the needs of the patient should be authorized for inpatient respite

purposes.

Response: To meet each patient's nursing needs the facility would need to be a Medicare/Medicaid certified nursing facility, a Medicare-certified hospice or a Medicare-certified hospital or skilled nursing facility because these facilities already maintain the requisite staff to meet hospice patient's needs at the respite level of care.

While we understand that care of the respite patient is much different than care of the general inpatient, we do not have regulatory authority over assisted living facilities or group homes. Therefore, to maintain continuity and safe care of the respite patient, we require that all respite care be provided in Medicare or Medicaid certified inpatient facilities. This in no way prohibits a hospice patient from residing in an assisted living facility or licensed group home.

Comment: One commenter requested that we add language that states that general inpatient care and respite care are coordinated by the hospice in a Medicare or Medicaid facility.

Response: We agree with the commenter in that care of the general inpatient and respite patient must be coordinated by the hospice. The standard at §418.108(c),

"Inpatient care provided under arrangements" has been modified to read: "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, coordinated by the hospice… ."

Comment: A few commenters suggested that the inpatient clinical record should be provided by the inpatient facility only if requested by the hospice, and that a discharge summary would be routinely provided to the hospice at the time of discharge.

Response: We agree with the commenters, and the amended language at §418.108(c)(3) requires the written agreement to specify, "[t]hat the hospice patient's inpatient clinical record includes a record of all inpatient services furnished and events regarding care that occurred at the facility; that a copy of the discharge summary be provided to the hospice at the time of discharge; and that a copy of the inpatient clinical record is available to the hospice at the time of discharge."

Comment: One commenter requested that we replace the word "individual" with "position" in proposed §418.108(c)(4). This would have the effect of permitting more than individual holding that position to implement the provisions of the agreement.

Response: Identifying a single individual, rather than a position that may be shared by more than one individual, in the inpatient facility that is responsible for implementing the contract, ensures that accountability is clearly assigned. Therefore, we are not accepting the commenter's suggestion and are finalizing this requirement as proposed.

Comment: A few commenters stated that, since inpatient facilities provide services to more than one hospice, the hospice should retain responsibility for ensuring the training of all personnel who will be providing care to the patients in facilities for which it has responsibility, rather than the hospice actually arranging such training. In addition, a description of the training and the names of those giving the training would be documented. Another commenter noted that hospices have no control over the staff of facilities, and therefore, requiring hospice responsibility for training will pose problems for hospices.

Response: The training of personnel who will be furnishing care must be specified in the contractual agreement. The hospice must ensure that facility personnel are trained. Through the contractual agreement, the hospice is responsible for ensuring that the facility makes its staff available for these trainings. We agree with the

commenters that hospices are responsible for ensuring that training occurs, but not necessarily arranging for or providing such training; therefore, we are amending the language at §418.108(c)(5) and §418.108(c)(6) to require the agreement between the hospice and the inpatient facility to state: “that the hospice retains responsibility for ensuring that the training of personnel who will be providing the patient’s care in the inpatient facility has been provided and that a description of the training and the names of those giving the training is documented; and (6) A method for verifying that the requirements in paragraphs (c)(1) through (c)(5) of this section are met.”

Comment: A few comments were submitted regarding the proposed requirement in §418.108(d), “Inpatient care limitation.” The commenters stated that the 20 percent limitation is problematic because patients who reside a great distance from the hospice must be admitted to the hospice, making their entire hospice stay an inpatient stay.

Response: We believe that there may be some confusion about the proposal in this section. Hospices are permitted to admit patients to their own facilities if the patient lives a long distance from the hospice, cannot stay at home, or for any number of other reasons. However, if the patient is admitted for a reason other than the need for short-term

respite care, or for symptom management or pain control, then the patient is not receiving an inpatient level of care that counts toward the 20 percent inpatient cap. Patients admitted for reasons other than short-term respite care, symptom management, or pain control receive the routine home care level of payment.

20. Condition of participation: Hospices that provide inpatient care directly (§418.110)

We proposed to recodify most of the requirements of existing §418.100 at §418.110, with some revisions. We proposed to recodify, without change, the requirements of §418.100(d), “Fire protection,” at §418.110(d); §418.100(e), “Patient areas,” at §418.110(e); §418.100(f), ”Patient rooms and toilet facilities,” at 418.110(f) and (g); §418.100(g), “Bathroom facilities,” at §418.110(h); §418.100(h), “Linen,” at §418.110(k); and §418.100(k), “Pharmaceutical services,” at §418.110(m) and (n).

We proposed to replace existing §418.100(a) with §418.110(a), “Staffing,” and §418.110(b), “24-hour nursing services.” The existing regulation requires that a registered nurse must provide direct patient care on each shift. The two proposed standards provide some flexibility and would require hospices that provide inpatient care in their own inpatient facilities to ensure that staffing for

all services, including nursing services, is adequate, based on the volume of patients, their acuity, and the level of services they need. These standards further proposed that staffing must meet the needs of patients to ensure that each patient's plan of care is adhered to and that the outcomes described in each patient's plan of care are achieved. Finally, these standards proposed that nursing services must be adequate to ensure that each patient is kept comfortable, clean, well-groomed, and protected from accident, injury, and infection. We believe that this outcome-based approach meets the needs of patients and hospices without using prescriptive requirements.

At §418.110(c), "Physical environment," we proposed that the hospice maintain a safe physical environment that was free of hazards for patients, staff, and visitors. In §418.110(c)(1), "Safety management," we proposed that the hospice prevent situations that posed a real or potential threat to the health and safety of the patients, others, and property. The hospice would be required to promptly investigate, correct, and report to appropriate State and local bodies with jurisdiction all breaches of safety. The hospice would be required to take steps to prevent equipment failures, and correct and report any equipment failures promptly.

In addition, §418.110(c)(1)(iii) proposed to retain the existing requirement at §418.100(b) that the hospice periodically rehearse with staff a disaster preparedness plan for managing the consequences of natural disasters and other emergencies that affect the hospice's ability to provide care. In developing and rehearsing their disaster preparedness plans, we believe that it is important for hospices to be engaged with their local and state disaster preparedness planning counterparts. Although this disaster preparedness requirement applies only to hospice inpatient facilities, we encourage all hospices to be aware of the need for disaster planning at the hospice, local, and State levels, and to actively engage in the planning process. We also proposed, at §418.110(c)(2), that the hospice develop procedures for managing trash and medical waste disposal; light, temperature and ventilation; emergency gas and water supplies; and equipment maintenance and repairs. We believe that these basic precautions and actions will help the hospice ensure that buildings, as well as the equipment inside of them, are fully and safely functioning at all times to ensure patient and family comfort and satisfaction.

Proposed §418.110(f), "Patient rooms," would recodify and revise the requirements of existing 418.100(f). We

proposed in §418.110(f)(3)(iv) that each room accommodate no more than two patients because we believe that hospice patients and families need the additional privacy that a two-patient room affords them in order to help preserve the patient’s comfort and dignity during the dying process. We believe this is the standard accommodation in most facilities. We proposed to allow existing hospice facilities with more than two patients in each room to receive a waiver of this requirement. This waiver would be based on whether the hospice was already providing direct inpatient care in a non-compliant facility when this regulation became effective. That is, if a hospice was providing direct inpatient care in a non-compliant building on the day before the effective date of the final rule and could demonstrate that the imposition of a two-patient-per-room requirement would result in unreasonable hardship or jeopardize its ability to continue to participate in Medicare or Medicaid, then the hospice operating in the non-compliant building could qualify for a waiver of the proposed requirement. A hospice would have to demonstrate to CMS that the waiver served the needs of its patients and did not adversely affect their health and safety. I f that same hospice moved into a non-compliant building after the effective date of this final rule, then the hospice would be

deemed out of compliance with our rules. If a hospice chose to begin operating its own inpatient unit after the effective date of this final rule, then it would not qualify for the proposed waiver, and would be required to have no more than two patients per room. The remaining paragraphs in this standard would be virtually the same as in the current requirement, with only minor revisions to the language that would not change the substantive requirements of the regulation.

In §418.110(i), “Infection control,” we proposed to revise the infection control standards to conform to those required of other provider types, such as home health agencies and hospitals. We proposed to require a hospice to establish an infection control program that would protect patients, families, and staff against communicable diseases and would prevent and control the spread of infections. The infection control program would be required to follow professionally established infection control standards and be part of the hospice’s overall quality assurance and performance improvement and education program. We did not propose any specific approaches to meeting the infection control requirement.

In §418.110(l), “Meal service and menu planning,” we proposed to revise the existing §418.100(j). We proposed to

make this standard less restrictive by eliminating several structural requirements, such as serving at least three meals at regular times, with no more than 14 hours between substantial evening and breakfast meals, and having a staff member trained in food management or nutrition. In place of these prescriptive requirements, we proposed that a hospice should focus on meeting the individual patient's nutritional and plan of care needs.

We proposed a new standard at §418.110(o) to address the use of seclusion and restraints in hospice inpatient facilities. Anecdotal evidence indicates that seclusion and restraints are occasionally used in hospice inpatient facilities ostensibly to protect patients, visitors, and/or staff. The proposed requirements, modeled on those for hospitals issued by CMS in 1999, and on the requirements of section 3207 of the Children's Health Act (P.L. 106-310), would ensure that, when seclusion or restraints are used, they are used in a safe manner for the shortest time necessary to ensure patient and staff safety.

The proposed standard, divided into seven elements, focused on the proper use of seclusion and restraints, and on the need for hospice personnel to receive training and education both in the proper use of seclusion and restraint application and techniques, and in the use of alternative

methods for handling situations that arise. The standard proposed specific requirements for physician orders for seclusion or restraint (for example, consultation with the hospice medical director, 1 hour face-to-face evaluation of the patient, and time limits on the length of orders). The proposed standard also included a requirement that a hospice would have to report to its CMS regional office any death that occurs while a patient is restrained or in seclusion, or that occurred within 24 hours of a patient being removed from seclusion or restraint.

Comment: A commenter asked us to clarify that the requirements in §418.110 would apply only to facilities operated by the hospice and not to nursing facilities or hospitals with which the hospice has a contract for inpatient care.

Response: The commenter is correct that, with the exception of §418.110(b) and §418.110(f), the requirements of this CoP only apply to hospice operated inpatient facilities. These facilities may be in a building owned wholly by the hospice, or may be in space leased from a company or health care provider, such as a designated hospice inpatient facility leasing and occupying a floor in a hospital. In order to clarify our longstanding intent that this CoP only applies to inpatient facilities operated

by a hospice, we have added the term “in its own facility” to the stem statement, which now reads, “[a] hospice that provides inpatient care directly in its own facility must demonstrate compliance with all of the following standards.” We believe that restricting the majority of the requirements of §418.110 to hospice-operated inpatient facilities, and permitting contracted facilities to comply with their own applicable regulations, will help avoid and potential regulatory conflicts between the hospice regulations and the regulations pertaining to a contracted facility (for example, a hospital or skilled nursing facility). A contracted facility would nonetheless be required to comply with (b) and (f), because these requirements are necessary to ensure appropriate staffing levels to care for seriously ill patients receiving the general inpatient level of hospice care and to ensure that hospice patients and families receive the care in a comfortable environment.

Comment: A commenter suggested that we should define the term “nursing services” as it is used in proposed §418.110(b) to include the services of licensed practical nurses within their scope of practice.

Response: The nursing services, as well as all other services, furnished by a hospice inpatient facility must meet the needs of the patients in the facility. Hospices may

choose to use registered nurses, licensed practical nurses, licensed vocational nurses, and any other level of nurse to meet the needs of their patients. We expect all nurses, as well as other professionals, to always act within the scope of their training and licensure. We do not believe that a statement to this effect needs to be in regulation because we require in §418.114 that all professionals must obtain the license offered by their State. In order to obtain and maintain the license, these providers are required by their State to practice only within the scope of their license.

Comment: The majority of commenters who submitted comments on this CoP made suggestions regarding the 24-hour nursing services requirement at proposed §418.110(b). An overwhelming number of commenters suggested that, if a hospice is providing general inpatient care, the hospice should be required to have a registered nurse (RN) on duty at all times. These same commenters stated that it is not necessary to have a registered nurse on duty at all times if the hospice is only providing respite care. Other commenters agreed with our proposal to require that the nursing services provided by the hospice must meet patient needs rather than requiring hospices to have a registered nurse on duty at all times. Still other commenters suggested that, if a registered nurse is not present in the

facility, one must be available for on-call consultation and direct care, if needed.

Response: We proposed to eliminate the 24-hour registered nurse requirement in order to make it easier for providers to care for respite patients. We continue to believe that it is not necessary to require a registered nurse on duty for all shifts if patients in the facility are receiving respite care only, and we therefore did not include a 24-hour RN requirement in §418.108(b)(2), which pertains to nurse staffing levels in facilities that are only providing respite level care to hospice patients. At the same time, we agree that the needs of patients receiving general inpatient care, who are in distress to such a degree that their pain and symptoms cannot be managed in their homes, necessarily require care from a registered nurse on all shifts. Therefore, we have incorporated a requirement for 24-hour RN services at §418.110(b)(2), and have cross-referenced this requirement at §418.108(a)(2). All facilities providing the general inpatient level of care, whether operated by the hospice or under arrangement with the hospice, must provide 24-hour RN care if at least one hospice patient is receiving general inpatient care.

Comment: Numerous commenters asked us to define and provide examples of the terms “breach of safety” and

“equipment failures” as they are used in proposed §418.110(c)(1)(i) and (ii), respectively. Commenters asked us to clarify the relationship between the requirements for equipment failures and the requirements of the Safe Medical Devices Act of 1990 (P.L. 101-629). Furthermore, commenters asked us to clarify which State and local bodies should receive reports of safety breaches and equipment failures.

Response: The intent of these proposed requirements was to ensure that the proper authorities were alerted by hospices regarding situations that may jeopardize patient health and safety. We agree that this goal has already been accomplished both through the requirements of the Safe Medical Devices Act, with which health care providers are required to comply (21 USC §360L), and the requirements of final §418.110(c)(2)(iv), which requires hospices to have procedures for controlling the reliability and quality of their emergency maintenance and repair program for their equipment. Therefore, we have deleted the proposed requirements.

Comment: A commenter was confused about the requirements for chapter 9 of the Life Safety Code, as included in proposed §418.110(d)(4).

Response: In January 2003 we published a final rule adopting the 2000 edition of the Life Safety Code. The 2000

edition of the Life Safety Code requires health care facilities, including hospices, to have emergency lighting systems meeting certain specifications. We allowed hospices a 3-year phase-in period after the effective date of the Life Safety Code rule to purchase and install their emergency lighting systems. That phase-in period expired March 13, 2006. Therefore all hospices must now have emergency lighting systems that comply with the specifications of chapter 9 of the 2000 edition of the Life Safety Code. Since the phase-in date has now passed, we have removed the phase-in language in this final hospice rule. We believe that removing the phase-in language will make it clearer that hospices must comply with all of the requirements of the 2000 edition of the Life Safety Code.

Comment: Some commenters suggested that we should define the terms “home-like” and “equipped for nursing care” as they are used in proposed §418.110(e) and (f).

Response: Hospice inpatient facilities have been required, since the inception of the Medicare hospice benefit, to have a home-like environment for patients and families to enjoy. Hospices should take all appropriate steps to minimize a cold, clinically sterile environment by incorporating materials and items typically found in private residences where appropriate. We understand that certain

standards of hygiene may preclude the use of certain materials or objects. We also understand that certain machines and devices needed to provide medical care to patients may need to be present and that such machines and equipment may not appear "home-like." We expect hospices to take appropriate steps, where feasible, to create a soothing, inviting atmosphere within the context of creating an environment where nurses and other hospice staff are able to effectively provide care and services.

Comment: Many commenters submitted comments regarding our proposal at §418.110(f), "Patient rooms." Some suggested that hospices should be allowed to have more than two patients in a room during community disasters or evacuations. Others suggested that patient rooms should be required to accommodate families as well as patients. Still others supported our proposal to waive the maximum two patients per room requirement for existing hospice facilities.

Response: We appreciate the support and thoughtful comments that we received in this area. We agree that the two-patient rooms should accommodate patients and family members, and we have specified this in revised §418.110(f)(3)(iv). We also agree that hospices should be allowed to place more than two patients in a room during

community disasters or evacuations. This situation is already addressed through separate waiver authority in section 1135 of the Act. Furthermore, we agree that the two-patient-per-room waiver for existing facilities should remain. Requiring a hospice to reduce the number of beds per room without the opportunity for a waiver may reduce the number of overall beds available and could create a hardship for affected facilities and problems for patients requiring access to inpatient care.

Comment: All commenters who submitted comments on proposed §418.110(l), “Meal service and menu planning,” supported our proposal to replace prescriptive food planning and service requirements with requirements based on patient needs and goals.

Response: We thank the commenters for their support of this change. The final rule will require that food service in a hospice inpatient facility be based on the needs and wants of the patient in the facility, rather than on prescriptive regulatory requirements.

Comment: Numerous commenters who submitted comments on our proposed seclusion and restraint requirements at §418.110(o) were confused about the applicability of the proposed standard. Commenters seemed to believe that the proposed standard would apply to patients in their homes or

to hospice patients who reside in long term care facilities.

Response: This standard is located in the CoP that governs hospice inpatient facilities operated by the hospice. It only applies to care furnished to hospice patients in the hospice's inpatient facility. This requirement does not apply to care furnished to hospice patients outside of the hospice's inpatient facility. If a hospice contracts with another facility (for example, hospital, or SNF) for inpatient care, we believe that it is preferable for the seclusion and restraint requirements for that provider to apply to the hospice patient.

Comment: A single commenter suggested that we should convene an expert task force to examine the use of drug restraints in hospice care.

Response: Under the revised definition of "drug restraints" previously described, we believe that it will be a rare situation for a hospice to use a drug restraint on a patient. Since the situation is likely to be very rare, we do not believe that it is necessary to convene an expert panel to examine the issue. Moreover, we are following the statutory definition, which applies to hospices through the Children's Health Act (42 USC 290ii(d)(1)(B)).

Comment: Many commenters made suggestions to modify proposed §418.110(o)(3)(ii) regarding orders for seclusion

and restraint. One commenter sought clarification about the prohibition on standing or as needed orders for seclusion and restraint. Other commenters stated that it would be difficult for a hospice physician to get to the inpatient facility in time to complete the one-hour visit and evaluation of a patient in seclusion or restraint. A commenter questioned the role and responsibility of the attending physician ordering restraints or seclusion. Other commenters suggested that orders be allowed to be written for eight or even 24-hour periods, rather than only for four hours as proposed. One commenter suggested that there should be no maximum length of time for a seclusion or restraint order.

Response: An order for seclusion or restraint must be specific to the patient, time, and place where the intervention will be used. A physician may not order restraint for a patient unless the patient requires such intervention at that very moment. In other words, orders based on future contingencies are not acceptable.

Hospices may authorize their medical director, physician designee, other hospice physician employees, and/or attending physicians to issue restraint or seclusion orders. If an order for seclusion or restraint is not ordered by the attending physician, medical director, or

physician designee, then the medical director or physician designee must be consulted as soon as possible after the order is issued.

Once an order for seclusion or restraint is issued and implemented, the patient must be seen within one hour to evaluate the need for continuing the intervention. We agree that it may be difficult for a hospice physician to arrive at the inpatient facility and actually see the patient within this one-hour window. Therefore, we have added a provision permitting a registered nurse trained in the proper use of seclusion and restraint to conduct the one-hour face-to-face evaluation of the patient.

In addition to the one-hour evaluation, we believe that it is necessary to regularly re-evaluate the patient's status and need for the ordered intervention. To ensure a thorough re-evaluation, we are requiring orders for seclusion or restraint to last no more than four hours each for a total of up to 24 hours. We believe that frequently re-ordering the intervention will ensure that patients remain in seclusion or restraint for the shortest time possible to control their distress.

Comment: A commenter asked us to clarify the meaning of the term "continually" as it is used in proposed §418.110(o)(4)(i). The commenter specifically asked if this

term meant that patients would need to be constantly monitored when restraint and seclusion are used simultaneously.

Response: If restraint and seclusion are used simultaneously, the patient must be continually monitored, face-to-face, by an assigned, trained staff member or continually monitored by trained staff using both video and audio equipment. This monitoring must be in close proximity to the patient. For the purposes of this provision, “continually” means ongoing without interruption.

Comment: Some commenters expressed concern that the presence of seclusion and restraint requirements would seem to discourage their use, even when medically necessary and appropriate. Other commenters suggested that the requirement proposed at §418.110(o)(7), regarding the reporting of seclusion and/or restraint-related deaths, would discourage the use of seclusion and/or restraint because hospices would fear that the reports would result in State surveys. They therefore suggested deleting the seclusion and restraint requirements in their entirety, while other comments suggested that hospices should only be required to report unexpected deaths or deaths that occur by hanging due to physical restraints.

Response: Seclusion and restraint requirements are needed to protect a patient from harm by ensuring that professionals will be able to appropriately use seclusion and restraint methods. These regulations also implement sections 591-593 of the Public Health Service Act, as added by section 3207 of the Children's Health Act. In order to further the goal of safe and appropriate implementation of seclusion and restraint techniques, we clarified the training requirements for hospice inpatient staff. Staff must be trained in techniques to identify behaviors, events, and environmental factors that may trigger the need for seclusion and restraint techniques. Staff must also be trained in the following: using nonphysical intervention skills, choosing the least restrictive intervention, safely implementing all types of restraint and seclusion, recognizing and responding to distress signs, identifying behavioral changes that indicate that seclusion and restraint are no longer necessary, monitoring patient well-being, and using first aid and cardiopulmonary resuscitation techniques. We believe that this staff training will minimize the likelihood of a patient death related to the use of seclusion or restraint for a patient, and will thus minimize the number of deaths that hospices must report. These regulations are similar to those that we

plan for other facility types, as required by section 593(b) of the PHS Act.

Should a seclusion or restraint-related death occur, our intent is to ensure that hospices fully investigate the death and notify CMS of the death and the investigation findings. We have clarified that the seclusion and restraint investigation and reporting requirements in final standard §418.110(o), “Death reporting requirements,” only apply to those patients who die unexpectedly.

Section 592 of the PHS Act requires facilities to report all deaths within 24 hours after a patient is removed from restraint or seclusion, or where it is reasonable to assume that a patient’s death is a result of such seclusion or restraint. Therefore, we have also clarified that unexpected deaths occurring within 24 hours of a patient being removed from seclusion and/or restraints would need to be investigated. We believe that unexpected deaths require a full investigation by the hospice to determine the presence or lack of a relationship between the seclusion and/or restraint and the patient’s death. We also believe that CMS must be apprised of such situations because a patient death related to seclusion and/or restraint use may indicate the presence of patient safety issues within the hospice that require additional guidance from the State or

CMS. It is important to remember that we are in no way seeking to discourage the use of seclusion and restraint if, within these regulatory boundaries, their use will benefit a patient. Our goal is to ensure that seclusion and restraint, when used, are used in a safe manner for the shortest amount of time necessary, as required by the PHS Act.

21. Condition of participation: Hospices that provide hospice care to residents of a SNF/NF or ICF/MR (§418.112)

We currently do not separately address the provision of hospice care to a hospice-eligible resident of a facility. This includes hospice care provided to residents who choose to live in skilled nursing facilities, nursing facilities, intermediate care facilities, and many other types of facilities. The provision of, and questions related to, hospice care for residents of those facilities has come under scrutiny as a result of a variety of report findings, including Operation Restore Trust (ORT) activities, Inspector General (OIG) reports from 1996, 1997, and 1998, and a 2000 report from the Department’s Assistant Secretary for Planning and Evaluation (ASPE) Office of Disability, Aging and Long-Term Care Policy and the Urban Institute. (U.S. D.H.H.S. OIG, “Hospice and Nursing Home Contractual Relationships,” Nov. 1997, OEI–05–95–00251; OIG Special

Fraud Alert, "Fraud and Abuse, Nursing Home Arrangements with Hospices," Mar. 1998; "Synthesis and Analysis of Medicare Hospice Benefit Executive Summary and Recommendations." (Harvell, J.; Jackson, B.; Gage, B.; Miller, S.; and Mor, V., Mar. 2000)). The relationship between hospices and nursing facilities was also addressed by the Secretary's Advisory Committee on Regulatory Reform. The committee focused on clarifying the responsibilities of each provider and on patient access to the hospice benefit while residing in a facility.

Based on the recommendations of the committee, as well as the reports from Operation Restore Trust, the Office of the Inspector General, and ASPE, we proposed to add a new condition at §418.112, "Hospices that provide care to residents of a SNF/NF, ICF/MR, or other facilities." We are also preparing a separate regulatory document to address long-term care facility obligations regarding residents receiving hospice services.

Under §418.112(a), "Resident eligibility, election and duration of benefits," we proposed that the hospice ensure that the resident met all the same Medicare eligibility requirements for hospice care (found at §418.20 to §418.30), as a patient who resides in his or her home in the community.

At §418.112(b), “Professional management,” we proposed that the hospice assume full responsibility for all of the hospice care provided to the patient. This would include making arrangements for any inpatient care that the patient would require in accordance with §418.100. This standard would reinforce the necessity of continuity of care for patients who reside in a SNF/NF, ICF/MR, or other facility. In §418.112(c), “Core services,” (and in accordance with sections 1861(dd)(1) and (2)(A) of the Act), we proposed that the hospice be required to provide all necessary core services to its patients residing in a SNF/NF, ICF/MR, or other facility in the same manner that it would provide such core services to a patient residing in a home in the community. It is not reasonable for the hospice to delegate any of its standard hospice core services to the nursing or residential facility staff.

In §418.112(d), “Medical director,” we proposed that a hospice medical director would be expected to communicate with all facility physicians, including the facility’s medical director, and the attending physician and other professionals involved in developing and/or implementing the patient’s plan of care. This standard was designed to ensure that all physicians, including those in leadership positions, were in agreement regarding the patient’s care to

ensure that duplicative and/or conflicting physician orders are not issued for patient care.

Under §418.112(e), “Written agreement,” we proposed that a comprehensive written agreement be developed between the hospice and facility, and that it be in effect before any hospice care was provided to a facility resident. The purpose of the written agreement would be to ensure that the duties and responsibilities of the hospice and facility were clearly articulated and executed in a manner that ensured that the patient would receive quality hospice care. The written agreement would be required to include the following:

(1) Written consent and documentation of the patient or the representative’s desire for hospice services.

(2) Identification of the services that the hospice and the facility would provide.

(3) The manner in which the facility and the hospice would communicate to ensure that the needs of the patient were addressed and met 24 hours a day.

(4) A requirement that the facility immediately notify the hospice when:

(A) A significant change in the patient’s physical, mental, social or emotional status

occurred;

(B) Clinical complications appeared that suggested a need to alter the plan of care;

(C) A life threatening condition(s) appeared;

(D) A need to transfer the patient from the facility arose; or

(E) The patient died.

(5) A provision stating that the hospice assumed responsibility for determining the appropriate course of care, including the determination to change the level of services provided. (An agreement that it was the facility's primary responsibility to furnish room and board.)

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

(7) A provision that the hospice could 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, but only to the extent that the hospice would routinely use the services of a hospice patient's family in implementing the plan of care.

These would be mandatory agreement provisions, but would not otherwise limit the scope or content of the relationship between the hospice and the facility. Additional provisions could be added subject to mutual agreement.

Under §418.112(f), "Hospice plan of care," we proposed that the content of the plan of care for a patient residing in a SNF/NF, ICF/MR, or other residential facility would be similar to the content of the plan of care for a patient residing in a home in the community. The plan would have to reflect the hospice philosophy in all aspects, be based on an assessment of the patient's needs and unique living situation in the facility, and be updated at least every 14 calendar days. In addition to the standard plan of care requirements, the plan of care for a patient residing in a SNF/NF, ICF/MR, or other facility would be required to be coordinated with and developed by the hospice IDG and SNF/NF, ICF/MR, or other facility in collaboration with the

attending physician. Furthermore, the plan of care would have to specify which provider would be responsible for providing a particular form of care. The performance of the functions would reflect the participation of the hospice, SNF/NF, ICF/MR, or other facility, and the patient and family to the extent possible.

At §418.112(g), “Coordination of services,” we proposed that the hospice designate a member of the IDG to coordinate the implementation of the plan. The hospice would provide the residential facility with the plan of care, hospice consent form, contact information for hospice personnel involved in the care of the resident, instructions on accessing the hospice 24-hour on-call system, medication information specific to the patient, physician orders, and any advance directives. We believe that these requirements would ensure effective communication between the hospice and the facility.

Under §418.112(h), “Transfer, revocation, or discharge from hospice care,” we proposed to cross-reference the proposed requirement for discharge or revocation at §418.104(e). In addition, we proposed that discharge or revocation of the hospice care would not impact the eligibility to continue to reside in a SNF/NF, ICF/MR, or other facility.

At §418.112(i), “Orientation and training of staff,” we proposed that the hospice staff would be required to train facility staff who provided care to hospice patients on aspects of the hospice philosophy and unique program features, including policies and procedures, methods of comfort, pain control and symptom management, general principles about death and dying and individual responses, patient rights, appropriate forms, and record keeping requirements.

Comment: Many commenters suggested that the phrase “other facilities” be removed from the title and text of this CoP. The commenters stated that this phrase was too broad and imprecise to enable hospices to effectively determine when they would have to comply with the additional requirements of this CoP. Some commenters suggested that “other facilities” should only apply to those that were Medicare- or Medicaid-approved, while others suggested that assisted living facilities could be included as well.

Response: We agree that the phrase “other facilities” is ambiguous and difficult to objectively determine. We also agree that this requirement should be limited to those facilities that can be Medicare-certified so as not to impose a de facto burden upon facilities that do not receive Medicare funds. Therefore, this final requirement applies

only to those types of residential facilities that are eligible to be Medicare-certified, that is SNFs, NFs, and ICFs/MR. Hospices are permitted to use the structure and content of this section when establishing and managing their relationships with other facility types such as assisted living facilities.

Comment: A commenter asked us to clarify that the requirement of proposed §418.112(a) regarding eligibility criteria would apply to residents of ICFs/MR in addition to residents of SNFs and NFs.

Response: We agree that this clarification would be helpful, and we have made the suggested change.

Comment: Many commenters asked us to specify in §418.112(b) that hospices would only be responsible for making the necessary arrangements for inpatient care related to a patient's hospice care (that is, the terminal illness and related conditions).

Response: We agree that is it helpful to clarify that the hospice is responsible for hospice-related inpatient care for the patient, and we have made this change. In addition, we have clarified that the arrangements for hospice inpatient care must be in accordance with the requirements of §418.108, "Short term inpatient care," as well as the requirements of §418.100(e), "Professional

management responsibility." We believe that the new reference to the requirements of §418.108 will ensure that hospices make arrangements with the appropriate facilities and ensure proper staffing to meet the needs of the patient.

Comment: Numerous commenters sought clarification on proposed §418.112(b), "Professional management." Commenters were confused by the proposed requirement that the hospice must assume full responsibility for professional management of the resident's hospice care. They believed that this requirement could create conflicts with long term care facility responsibilities. One commenter suggested that, in order to further clarify the hospice's responsibility, we should add a statement that the hospice is responsible for those services that are included in the hospice plan of care. Another commenter suggested that deleting the word "full" would clarify the scope of the hospice's responsibility.

Response: We agree that further clarification is warranted in this standard. Hospices are only responsible for furnishing and managing a patient's hospice care related to the terminal illness and related conditions. They are not responsible for managing all of a patient's care. We believe that requiring hospices to take responsibility for the care they furnish is not in conflict with the long term

care facility regulations at 42 CFR part 483. To ensure that our intent is clear in the requirement, we have removed the word “full” and have added a provision that the hospice is responsible for services provided in accordance with the plan of care. Revised standard (b) now reads, “[t]he hospice must assume responsibility for professional management of the resident’s hospice services provided, in accordance with the hospice plan of care and the hospice conditions of participation, and make any arrangements necessary for hospice-related inpatient care in a participating Medicare/Medicaid facility according to §418.100 and §418.108.”

Comment: A commenter sought additional clarification on the distinction between coordination of care and responsibility for the provision of care as the latter appears in the proposed rule at §418.112(b).

Response: Hospices are responsible for furnishing all care and services related to the terminal illness and related conditions as those services are identified in the plan of care, regardless of where the patient resides. Hospices are required by section 1861(dd) of the Act to provide some of these services directly, while other services may be provided under arrangement. Regardless of whether the hospice services are provided directly or under

arrangement, hospices are required to assume full professional management responsibility for those services. In addition, hospices are required to designate a registered nurse who is a member of the hospice's IDG to coordinate the implementation of the patient's hospice care and services. Furthermore, hospices are required to have a system of communication to ensure that all disciplines furnishing hospice care to patients communicate with each other about patient needs. This system of communication must also include a sharing of information with health care providers that are simultaneously caring for the same patients that the hospice is caring for to ensure that the hospice is able to coordinate its care with that being provided by others.

Through these mechanisms, the hospice maintains responsibility for all of its care and services for all of its patients and ensures that the care it is providing complements the care being provided by others. In addition to these mechanisms used for all patients, hospices are required to establish written agreements and communication systems with SNFs, NFs, and ICFs/MR when hospices are furnishing hospice care to residents of those facilities. Clear communication between the hospice and the SNF/NF or ICF/MR will help hospices ensure that they are meeting their

responsibility to furnish the care necessary to meet the needs of its patients.

Comment: Many commenters suggested that we should revise or remove the proposed requirement at §418.112(e)(4)(iii) that the written agreement between a hospice and a SNF/NF or ICF/MR must contain a provision that the facility notifies the hospice if a life-threatening condition appears in a hospice patient. Some commenters stated that this should be clarified to state that the life-threatening condition is only required to be reported if it is unrelated to the terminal illness and related conditions. Other commenters stated that this should be removed because the requirement at proposed §418.112(e)(4)(i), stating that the facility must notify the hospice if a significant change in a patient's status occurs, would apply to life-threatening conditions as well.

Response: We agree that proposed §418.112(e)(4)(i), now located at 418.112(c)(2)(i), applies to life threatening conditions, and, as a result, we have deleted the proposed requirement at §418.112(e)(4)(iii).

Comment: Many commenters asked us to clarify or remove the proposed requirements of §418.112(e)(6), which would require the agreement between the hospice and the residential facility to state that it would be the

residential facility's primary responsibility to furnish room and board. Commenters stated that, although SNFs/NFs and ICFs/MR do provide room and board, describing these functions as their primary responsibility ignores the other functions that the facilities perform. Commenters also stated that the services provided by the SNF/NF or ICF/MR should not be assumed by the hospice. Rather, the commenters stated, the SNF/NF or ICF/MR should furnish services in the role of the primary caregiver at the same level that would have been provided if the resident had not elected to receive hospice care.

Response: We agree that the term "primary" unnecessarily excludes the other functions that SNFs/NFs and ICFs/MR perform for their residents, and it has been deleted. Nonetheless, the responsibility of room and board will be deemed to be that of the residential facility. In addition, we have expanded this requirement to clarify that hospices should not be expected to assume the functions of the SNF/NF or ICF/MR. The revised requirement, located at new §418.112(c)(4), requires the agreement to state that "it is the SNF/NF or ICF/MR's responsibility to continue to furnish 24 hour room and board care, meeting the personal care and nursing needs that would have been provided by the primary caregiver at home at the same level of care provided

before hospice care was elected." This expanded requirement clarifies that hospices are not required to assume the functions that the SNF/NF or ICF/MR performed for the patient before the patient elected to receive hospice care. This requirement is not, however, meant to imply that the SNF/NF or ICF/MR is required to automatically increase its level of services simply because the resident has elected to receive hospice care. All Medicare and Medicaid approved facilities, be they SNFs/NFs or ICFs/MR are responsible for providing services to their residents in accordance with their respective laws and regulations.

Comment: Numerous commenters suggested that the written agreement between the hospice and the SNF/NF or ICF/MR should contain a provision that the SNF/NF or ICF/MR will continue to provide services at the same level as those services would have been provided before the patient elected the hospice benefit.

Response: We agree that it is beneficial for hospice patients to continue to receive the same level of services provided by the SNF/NF or ICF/MR upon entry into the hospice program. These facilities often function as a patient's family, and, just as hospices are not expected to replace the role of the family in caring for hospice patients, we do not expect hospices to replace the role of the SNF/NF or

ICF/MR staff in caring for hospice patients who reside in those facilities. We have clarified proposed §418.112(e)(6) to this effect, and have relocated the requirement to new §418.112(c)(4). To further clarify this issue, we have also added a new requirement for the written agreement, located at §418.112(c)(5), that it is the hospice's responsibility to provide services to residents of a SNF/NF or ICF/MR at the same level and to the same extent as those services would be provided to patients residing in their own private homes. Regardless of where a patient resides, a hospice is continually responsible for furnishing core services, and may not delegate these services to the staff of a SNF/NF or ICF/MR. We believe that this new requirement will help to ensure consistent, high quality hospice care for all hospice patients, regardless of their place of residence.

Comment: Numerous commenters sought clarification on our proposal at §418.112(e)(8) that a hospice may use the nursing personnel of the SNF/NF or ICF/MR, where permitted by law and as specified by the facility, to assist in administering hospice care, to the extent that the hospice would routinely use a patient's family to implement the plan of care. Some commenters suggested that hospices should be allowed to use the nursing personnel of SNFs/NFs or ICFs/MR to a greater extent than family members would be used,

because the nursing personnel have more training and education in furnishing medical care than family caregivers typically do. Other commenters wanted to know how this provision would affect the long term care facility requirement that long term care facility staff must provide care to residents as needed to maintain resident well-being. Other commenters were concerned that utilizing facility nursing personnel could be a “slippery slope” whereby hospices would delegate essential tasks to the facility’s personnel. Still other commenters sought clarification regarding which laws would apply to hospices utilizing facility personnel to implement the plan of care. These commenters suggested that State laws would most appropriately apply. A single commenter suggested that the personnel of the SNF/NF or ICF/MR should be expected to provide all nursing care unless the facility specifically asks the hospice to perform a nursing function.

Response: The utilization of SNF/NF or ICF/MR personnel in implementing the hospice plan of care for a patient is difficult to address because both hospices and these facilities provide varying levels of care based on the needs of the patient/resident. We agree that State laws are best suited to governing the use of facility personnel by hospice staff, and we have specified this in the final rule.

This provision is not intended to preempt any State laws that may apportion duties between hospice and residential facility staff.

We proposed that hospices may only use the staff of the SNF/NF or ICF/MR as specified in the written agreement signed by the SNF/NF or ICF/MR. This is being retained in the final rule at §418.112(c)(7). It recognizes that facilities must give consent for their staff to be used in caring for the hospice patient and must determine the extent of staff involvement. This consent allows facilities and hospices to match their corresponding levels of available personnel service to the needs of the patients being served. As stated above, hospices are not responsible for assuming the functions that the SNF/NF or ICF/MR performed for the patient before the patient elected to receive hospice care. Likewise, SNFs/NFs and ICFs/MR are not responsible for assuming the functions that the hospice would provide for a patient residing in his or her own home.

The hospice benefit is not designed so that hospice personnel routinely provide 24-hour care or serve as the patient’s primary caregiver. Hospice patients in their private homes have private caregivers, be they family members, friends, hospice volunteers, paid assistants, or any of a number of other combinations. These caregivers are

trained by the hospice to administer care in accordance with the patient's plan of care. Caregivers may help patients with a variety of duties, such as medication administration, bathing, and housekeeping.

Hospice patients in SNFs/NFs and ICFs/MR depend, at least in part, on facility staff to provide caregiver services. As such, we believe that it is reasonable to allow hospices to use facility staff who act as caregivers in the same manner and to the same extent that hospices would use family members, friends or other caregivers who care for patients in their private residences. For example, hospices typically instruct home caregivers in how and when to administer medications to hospice patients. Therefore, it would be appropriate to instruct facility staff caregivers in how and when to administer medications. Hospices typically do not instruct home caregivers in how to draw blood to monitor medication levels; thus it would not be appropriate to expect facility staff to draw blood, even though some members of the facility's staff may be competent to do so. Hospices are to use facility staff in the same way that they would use home caregivers to implement the patient's plan of care. While facility staff presumably possess more sophisticated health care skills than home caregivers, they may not be used to perform functions more

frequently, or with a greater degree of complexity, than the hospice would utilize home caregivers under similar circumstances.

We understand that, in times of crisis, it may be necessary for a hospice to direct staff of the SNF/NF or ICF/MR to perform more sophisticated functions than caregivers would typically perform in order to ensure patient comfort while the hospice staff are in route to the patient. A hospice should, in the contract between it and the facility, address potential crisis situations, and how they would be handled, with facility staff. Potential crisis situations specific to the circumstances of individual patients should also be included in individual plans of care. The temporary emergency measures should be undertaken at the direction of the hospice, which maintains responsibility for ensuring that all hospice care is provided in accordance with the patient's plan of care.

We understand that this does not provide the exact specificity of what functions may or may not be performed by facility caregivers that some commenters sought. We cannot provide an absolute list because such a list is subject to many variables (for example, patient needs, provisions of the written agreement, staff skill levels, etc.).

Comment: Some commenters supported, while others

demurred, on our proposal, originally at §418.64(d), to require hospices to provide bereavement services to facility personnel when appropriate and identified in the patient's plan of care.

Response: We appreciate the support that we received regarding bereavement services furnished to facility personnel. There are times when facility employees fulfill the role of a patient's family, providing caregiver services, being companions, and generally supporting the patient. In order to ensure that the needs of these individuals are met in a manner that accommodates the needs and responsibilities of the hospice and the SNF/NF or ICF/MR, we moved the requirements concerning bereavement care for staff from 418.64, "Core services," to 418.112(c), which governs the written agreement between a hospice and a facility. The relocated requirement at 418.112(c)(9) requires the written agreement to include a provision delineating the responsibilities of the hospice and the facility with regard to providing bereavement services to facility staff that fulfill the role of a hospice patient's family.

Comment: Numerous commenters suggested that the proposed written agreement requirements at §418.112(e) should be clarified. A primary concern of the commenters

was the proposed requirement that the written agreement must include the written consent of the patient or the patient's representative that hospice services are desired. Commenters stated that this proposed requirement implies that a new written agreement must be developed for each resident who receives hospice services. Commenters then noted that, if a written agreement is necessary per patient, it may be difficult to secure the agreement before furnishing care to the patient.

Response: We agree that the proposed requirement implied that a new written agreement must be developed for each resident who receives hospice services. We also agree that such a requirement would be difficult to fulfill before any hospice services are furnished to a specific patient. As a proxy for the written consent of the patient or representative, we will use the requirement at new §418.112(e)(3)(ii), which requires hospices to provide SNFs/NFs, ICFs/MR, and assisted living facilities with each patient's hospice election form, to ensure that each provider is aware of the patient's choice to receive hospice care. In this way, the election form is not linked to the content of the written agreement. We believe that this will help to clarify that the written agreement does not need to be completed for each and every patient who is a resident of

a SNF/NF or ICF/MR. In addition, we believe that this will make it easier for hospices to secure agreements before furnishing care to the patient because they will be required to secure the agreements less often than was implied.

We would like to clarify that the written agreement requirements only apply to hospice patients who are residents of SNFs/NFs and ICFs/MR. The written agreement, and the remaining requirements of §418.112, do not apply to hospice patients who are placed in SNFs/NFs for general inpatient or respite care by the hospice itself. Rather, the requirements for the written agreement between a hospice and a facility that furnishes general inpatient or respite care are described in §418.108(c).

Comment: Several commenters suggested that we should add a provision requiring the written agreement to contain information about the services to be provided by the SNF/NF or ICF/MR.

Response: The services provided by the SNF/NF or ICF/MR will vary based on the plan of care which will identify the resident's needs. The written agreement established between the hospice and the SNF/NF or ICF/MR is not the appropriate place for a list of the services to be provided by the SNF/NF or ICF/MR. The services provided by the facility are

included in the plan of care and coordinated by the hospice and the facility in accordance with new §418.112(d).

Comment: Some commenters expressed confusion about the proposed hospice plan of care requirements at proposed §418.112(f). Commenters questioned if the standard required hospices and SNFs/NFs and ICFs/MR to have a single plan of care that applied to both providers. If so, commenters stated that updating the plan of care every 14 days would be burdensome to long term care facilities that otherwise would be required to update the resident's plan of care only every three months.

Response: Hospices and SNFs/NFs and ICFs/MR must have a single plan for each patient. We would expect the hospice and the facility to develop and update this plan in full consultation with each other. The hospice portion of the plan of care governs the actions of the hospice and describes the services that are needed to care for the patient. The patient's single, coordinated plan of care must identify which provider (hospice or facility) is responsible for performing a specific service. The plan of care may be divided into two portions, one of which is maintained by the long term care facility and the other of which is maintained by the hospice. These two sections must work together to ensure that the needs of the patient for

both hospice care and long term care facility care are met at all times. The facility is required to update its portion of the plan of care in accordance with any Federal, State or local laws and regulations governing the particular facility just as hospices would need to update their plans of care according to §418.56(d) of these CoPs.

Comment: As with the proposed update of the plan of care requirements in §418.56, many commenters suggested changes to the update timeframe for the hospice plan of care for residents of SNFs/NFs and ICFs/MR. Commenters suggested that the update timeframe be changed from “at least every 14 days” to “at least every 15 days” or “at least twice a month.”

Response: We agree that the update timeframe should be lengthened to at least every 15 days to correspond with the lengths of the Medicare hospice benefit periods. This change has been made by referencing the requirements of §418.56, which includes an every-15-day update timeframe.

Comment: A commenter suggested that we should clarify that the hospice plan of care must be based on a comprehensive assessment of the patient’s needs.

Response: We agree that the plan of care must address those needs identified in the comprehensive assessment of the patient. This requirement is included in §418.56, and

the revised hospice plan of care standard at new §418.112(d) references the requirements of §418.56.

Comment: Numerous commenters suggested that the proposed requirement at §418.112(f)(4) should be clarified. Specifically, these commenters expressed concern about the proposed requirement that changes in the plan of care must be discussed "among all caregivers." These commenters stated that the phrase "among all caregivers" was very broad, considering that multiple facility staff may act as caregivers for a resident on any given day. Some commenters suggested that "between both providers" or "discussed by the IDG, facility representatives and the patient/family" should replace the phrase "among all caregivers."

Response: We agree that discussing plan of care changes with "all caregivers" should be replaced by a more definite requirement. Therefore, the final rule at §418.112(d)(3) requires changes in the hospice portion of the plan of care to be "discussed with the patient or representative, and SNF/NF or ICF/MR representatives… ." This revised requirement allows the facility to identify those with whom plan of care discussions must occur and provides hospices with a defined list of those individuals who must be consulted before a change in the hospice portion of the plan of care is implemented. The revised requirement

still states that the hospice must approve any changes to the hospice portion of the plan of care before those changes are implemented. We believe that this enables hospices to maintain control over the hospice portion of the plan of care while allowing facilities to have their voices heard before final decisions are made about hospice care.

Comment: A commenter wanted to know what forms of communication are acceptable between the hospice and the residential facility concerning care planning.

Response: Hospices are free to use any form of communication that best suits their needs in accordance with their established system of communication as required by §418.56(e). In accordance with 418.112(c)(1) of this final rule, hospices must document that this communication has occurred to ensure that the hospice has made all necessary efforts to consult facility representatives in hospice care planning activities.

Comment: A large number of commenters requested clarification of the proposed medical director requirement at proposed §418.112(d). The overall response of commenters was that the proposed requirements were overly burdensome. Many of these commenters suggested that the medical director requirement should be entirely deleted. Others suggested that the communication responsibilities assigned to the

hospice medical director would be more appropriately handled by all physicians in the hospice, the hospice IDG, or the RN member of the IDG who is assigned the care plan coordinator role. Still others expressed concern that the proposed medical director communication requirement would overwhelm SNF/NF and ICF/MR medical directors with information about the care of patients that they are not actively involved with.

Response: Our intent in proposing the medical director requirement was to ensure that there was communication and agreement among the clinical leadership of both providers. The purpose of this communication was to ensure that these senior physicians did not issue incompatible care orders for the same patient or otherwise disagree on the approach to patient care. However, as some commenters noted, hospice and facility medical directors are not necessarily involved in actively caring for all patients and facility residents. Some hospices and facilities have multiple physicians, and one of these physicians, rather than the medical director, could potentially be the most knowledgeable with respect to the care of a particular patient or resident. For this reason, we agree that it is appropriate to remove the medical director requirement. We also agree that it is appropriate to reassign communication responsibilities to

the IDG responsible for caring for the resident of a SNF/NF or ICF/MR. New §418.112(e) requires the hospice IDG to designate one of its members to coordinate the patient's hospice care with representatives of the SNF/NF or ICF/MR. The designated IDG member must also communicate with representatives of the SNF/NF or ICF/MR and any other health care providers to ensure quality care for the patient.

Additionally, the designated IDG member must ensure that the hospice IDG communicates with the SNF/NF or ICF/MR medical director, the patient's attending physician, and any other physicians caring for the patient as needed to coordinate the patient's hospice care with the care provided by other entities. We believe that this new requirement will alleviate the demand on the hospice and facility medical directors while actively involving all members of the patient's care team, both within the hospice and the facility, in care planning and delivery.

Comment: Commenters expressed general support for the coordination of services requirement at proposed §418.112(g), stating that it would have the greatest potential for strengthening the partnerships between hospices and SNFs/NFs and ICFs/MR. Several commenters suggested that we specify that the hospice provide the SNF/NF or ICF/MR with a copy of the hospice plan of care.

The commenters believe that requiring this would reinforce the fact that the hospice and the facility have separate, but coordinated plans of care for each patient. Other commenters suggested that, in addition to the original hospice plan of care, facilities should also be provided with updated plans of care. Still other commenters suggested that hospices should provide SNFs/NFs and ICFs/MR copies of each patient's initial certification and recertification of terminal illness forms.

Response: We appreciate the general support of this requirement. We agree that this standard, now at §418.112(e), should specify that hospices provide facilities with the most recent hospice plan of care. This will ensure that facilities have the most current plan for what services the hospice is providing as well as what services they are committed to providing. We also agree that it is helpful for the hospice to provide the facility with a patient's certification and recertification forms. Having these forms on file will serve as a reminder to the facility that the patient is terminally ill and that he or she is a Medicare hospice beneficiary.

Comment: A few commenters sought clarification about what kind of physician orders hospices would provide to facilities. Other commenters suggested that we should take

action to require SNFs/NFs and ICFs/MR to accept hospice physician orders.

Response: Although a large amount of the care decided upon by the hospice IDG does not require specific physician orders, certain elements of the plan of care, such as medications and laboratory work, do require physician orders. Whenever physician orders are issued, whether by the hospice physician or the attending physician in coordination with the hospice, a copy of those orders must be provided to the SNF/NF or ICF/MR in a timely manner. Providing a copy of physician orders to the SNF/NF or ICF/MR allows the staff of the facility to implement any portions of the order for which they may be responsible. Providing a copy of orders is simply another way in which the hospice keeps the SNF/NF or ICF/MR abreast of its hospice care activities. In the final rule at §418.112(e)(3)(vii) we clarified that the “physician orders” supplied by the hospice are those issued by the hospice physician(s) and the patient’s attending physician (if any). The acceptance of hospice physician orders by residential facility staff is not within the purview of this rule. In its contract with the residential facility, the hospice is responsible for ensuring that the management of the residential facility communicates with its staff regarding the acceptability of

hospice physician orders.

Comment: A majority of commenters who submitted recommendations on this CoP recommended that we revise the proposed requirement at §418.112(i) regarding the training of staff of a SNF/NF or ICF/MR in hospice philosophy. Most of these commenters noted that a SNF/NF or ICF/MR may work with several different hospices and that facility staff should not be required to be oriented to hospice philosophy by every hospice. The commenters suggested that hospices be required to assure that the staff of the SNF/NF or ICF/MR has received the required training, rather than requiring each hospice to provide the training. One commenter suggested that the responsibility for orienting facility staff in hospice philosophy should fall to the facility, rather than the hospice.

Response: The intent of this proposed standard was to ensure that facility staff who furnish care to patients are provided information on the hospice philosophy and approach to care, much in the same way that home caregivers are routinely provided information on the hospice philosophy and approach to care. We agree that facility staff should not be oriented multiple times using the same basic information. Therefore, we have amended this requirement at new

§418.112(f) of the final rule to state that hospices must assure the orientation of facility staff.

At the same time, we note that the entire purpose for using outside hospices to furnish hospice care to facility residents is to fulfill a need that the facility is not able to fulfill on its own. If a facility is unable to provide hospice care because it lacks the capability to do so, then the facility is certainly not qualified to orient its staff in hospice philosophy. Furthermore, the facility would not be qualified to orient its staff in a particular hospice's policies and procedures, patient rights, forms, and record keeping requirements. In that case, the hospice working with the facility needs to provide information, guidance and/or staff to assure orientation of the facility staff.

Comment: Several commenters asked how frequently hospices are to be involved in offering training to facility staff, considering the high staff turnover rates of some facilities. Commenters also questioned who might be in the best position to coordinate the training sessions.

Response: It is the hospice's responsibility to coordinate the trainings with representatives of the facility. It is also the hospice's responsibility to determine how frequently training needs to be offered in order to ensure that the staff furnishing care to hospice

patients are oriented to the philosophy of hospice care. Facility staff turnover rates should certainly be a consideration in determining training frequency.

Comment: A commenter disagreed with our proposed requirement that facility staff should be trained by hospices in hospice philosophy and care. The commenter stated that there is a “spillover effect,” whereby the training received by staff affects the care furnished to non-hospice patients as well as hospice patients. The commenter further stated that this “spillover effect” may not be desirable for those patients who do not choose to receive hospice care.

Response: While there may be a “spillover effect” when facility staff are oriented to hospice philosophy, we do not believe that the effect is inherently negative. The hospice philosophy focuses on using multiple treatment modes to make patients physically, emotionally, and spiritually comfortable. Providing comfort to residents, regardless of whether those residents receive hospice care or not, would positively impact their well-being. Therefore, we do not view a “spillover effect” as a problem that would warrant removal of the proposed facility staff orientation requirements.

Comment: A commenter suggested that hospices be

required to educate the facility staff regarding the individualized plan of care for each hospice patient who resides in the facility.

Response: We agree with this suggestion. Section 418.56(b) of this rule, “Plan of care,” requires hospices to ensure that each patient and his or her primary caregiver(s) receives education and training provided by the hospice as appropriate to their responsibilities for the care and services identified in the plan of care. Facility staff members acting as the patient’s primary caregivers are expected to receive education specific to each patient’s hospice plan of care and the caregiver’s role in implementing the content of the hospice portion of the plan of care.

Comment: A commenter suggested that hospices should be required to orient facility administrative staff as well as the staff who furnish care to hospice patients that reside in the facility.

Response: With the facility’s consent, hospices may orient facility administrative staff as well as hands-on care staff. However, we do not believe that this orientation should be required because it is unlikely to improve patient care or outcomes.

Comment: A commenter asked for a definition of the term "nursing facility."

Response: Our use of the abbreviation "SNF/NF" refers to the long term care facilities referenced at 42 CFR part 483, where skilled nursing facilities (SNF) and nursing facilities (NF) are described.

Comment: Many commenters stated that this section of the rule should require SNFs/NFs and ICFs/MR to contract with any hospice that a resident chooses. Many other commenters stated that hospices should be prohibited from contracting with SNFs/NFs and ICFs/MR that do not contract with all interested hospices.

Response: As noted above, these CoPs regulate hospices, not SNFs/NFs and ICFs/MR. We are not proposing mirroring requirements for Medicare/Medicaid facilities at this time. We also note that we do not have jurisdiction or authority to regulate facilities that do not participate in Medicare or Medicaid. In addition, even though these CoPs do regulate hospices, we do not believe that it is appropriate to preclude hospices from contracting with certain SNF/NF or ICF/MR because the facility chooses to be selective in its contracting decisions. Indeed prohibiting hospices from contracting with selective SNFs/NFs and ICFs/MR could deny residents of those facilities any access

to hospice care furnished by Medicare-approved hospices. We believe that this would be a disservice to those residents.

Comment: Some commenters took issue with the requirement that, when hospice services are furnished to Medicaid eligible SNF/NF residents, the hospice receives payment from Medicaid for room and board care and is responsible for paying the SNF/NF for this service.

Response: Payment and billing procedures are not within the scope of these CoPs. We have shared this comment with the appropriate officials within CMS, and it will be taken under advisement.

Comment: A commenter suggested that hospices should be required to notify hospice patients who reside in a SNF/NF or ICF/MR that Medicare does not pay for room and board for a patient who is receiving the routine home care level of hospice care.

Response: The commenter is correct that Medicare does not pay for room and board. We believe that Medicare coverage of services under the hospice benefit is already addressed by §418.52(c)(7), stating that patients have the right to "[r]eceive information about the services covered under the hospice benefit." We do not believe that it is necessary to require hospices to provide a separate notice

in writing regarding Medicare non-coverage of a patient's room and board in a SNF/NF or ICF/MR.

Comment: Many commenters had questions about the proposed core services requirement at §418.112(c), which would have required hospices to routinely provide all core services to hospice patients who are residents of SNFs/NFs or ICFs/MR. Some commenters wanted to know if this requirement was the same as proposed §418.64, "Core Services." If so, the commenters suggested that it should be deleted because it is duplicative and unnecessary. Other commenters asked if it would be permissible to use staff of the SNFs/NFs or ICFs/MR to furnish core services to hospice patients. A single commenter suggested that, for clarity, we should add the word "work" to the term "medical social" to clarify that hospices must provide medical social work services to patients who reside in SNFs, NFs, or ICFs/MR.

Response: Hospices that furnish hospice services to residents of a SNF/NF or ICF/MR are required to furnish core services to those residents under the same requirements and in the same manner as those services are furnished to patients residing in their own homes. The core services requirement at §418.64 applies equally to both facility and community residents. We agree that it is not necessary to state the same requirements in both §418.64 and §418.112.

Therefore, the core services standard in §418.112 has been removed.

Since the core services requirement at §418.64 applies, regardless of where services are provided, hospices are not permitted to routinely delegate hospice services to the staff of a SNF/NF or ICF/MR. Hospices are required to routinely provide substantially all core services directly. Hospices may only provide core services under arrangement if they meet the conditions for an extraordinary circumstance exemption described in §418.64, the nursing services waiver described in §418.66, or the nursing shortage waiver described in CMS S&C letter 05-02.

Comment: Numerous commenters asked us to clarify or delete the proposed requirement at §418.112(h), “Transfer, revocation, or discharge from hospice care.” Most of these commenters stated that this requirement should be deleted because hospices have no authority to govern the discharge actions of SNFs/NFs and ICFs/MR, thereby making it very difficult for hospices to comply with the requirement. Some commenters suggested that the intent of the standard should be clarified. One commenter suggested that we should add the following statement to the end of the requirement: “It is believed that patients should not experience the trauma of an external move because they perhaps have stabilized and

may not continue to be eligible for hospice."

Response: We agree that resident eligibility is not within the control of the hospice, and this requirement has been removed. Absent this requirement, the discharge requirement set forth in §418.104(e) continues to apply to any hospice patients who reside in a SNF/NF or ICF/MR. The requirements of §418.104(e) do not place any requirements on residential facilities serving as a patient's home.

Comment: A large number of commenters stated that it would be difficult for hospices to implement the requirements of this CoP without the inclusion of complementary requirements in the long term care CoPs at 42 CFR part 483. Some commenters suggested that we should not issue this CoP until the complementary requirements are included in the long term care CoPs, while other commenters suggested that we should add a phase-in period for this CoP to allow the long term care CoPs to "catch-up" to this hospice CoP. Still other commenters suggested that this CoP should be issued as planned, but that survey enforcement of its requirements should understand that not all provisions can be adequately implemented until the long term care CoPs agree with those for hospices.

Response: Upon issuance of this final rule we intend to issue a proposed rule to add a new requirement to the long

term care CoPs at §483.75(r). This proposed rule would describe:

- The manner in which long term care facilities may furnish hospice services to their residents;
- The minimum content of the written agreement between the long term care facility and the hospice;
- The conditions under which the long term care facility must contact the hospice;
- The participation and coordination of the long term care facility in care planning and delivery; and
- The information that the long term care facility must obtain from the hospice.

We agree that, without this requirement in the long term care facility regulations, it will be challenging for hospices to comply with the requirements of this CoP. We will work with the hospice and long term care industries to address any situations that may occur during the intervening time period.

Comment: Several commenters sought clarification about how surveyors would determine accountability for negative patient outcomes when patients were both hospice patients and residents of a SNF/NF or ICF/MR.

Response: Hospices are responsible for all hospice care and services provided to a patient, regardless of where that

patient resides. Hospices are also responsible for coordinating the plan of care for a particular patient with representatives of the facility where the patient resides to ensure that both the hospice and facility are aware of their respective patient care responsibilities. Furthermore, hospices are responsible for ensuring that the terms of the arrangement established between the hospice and the facility are met to ensure patient care and safety at all times. We expect hospices to fulfill their responsibilities at all times and for all patients. If a hospice does not fulfill its responsibility and take all appropriate actions to ensure the health and safety of its patient in accordance with the requirements of this final rule, then that hospice will be held accountable for its actions. We note that these final provisions do not propose to judge hospices on "negative patient outcomes" except to the extent that those outcomes are connected with regulatory non-compliance.

Comment: Several commenters noted that the interpretive guidelines that surveyors will use to ensure compliance with this CoP needs to provide further detail regarding provider responsibilities for individual aspects of hospice care.

Response: We agree that additional detail is needed and we will take this suggestion under advisement as we develop interpretive guidelines for this regulation.

Comment: A commenter suggested that frequent onsite verification of hospice agency compliance with this proposed CoP is the best way to ensure that hospices are fulfilling their regulatory obligations.

Response: State surveyors are required to survey long term care facilities annually. These surveyors have already been directed to report issues involving long term care facility residents who are hospice patients to their hospice surveyor counterparts for follow-up with the hospice. We believe that using hospice survey resources to focus on potential problems is preferable to randomly surveying hospices where issues involving long term care facility residents have not appeared.

Comment: Several commenters suggested that we address the responsibilities of the attending physician in caring for residents of a SNF/NF or ICF/MR who receive hospice services. The commenters suggested that the attending physician be responsible for coordinating the patient’s care and communicating with hospice and facility physicians.

Response: We do not have the authority to regulate the actions of a patient’s attending physician who is not an employee of or under contract with the hospice through this hospice rule. If a patient has an attending physician who is actively involved in his or her care, then the hospice is

required to consult the attending physician in developing and updating the patient's hospice plan of care. The hospice may use this consultation with the attending physician to gather information about other care and services the patient is receiving from the facility where the patient resides and from any other health care providers. The hospice may not delegate its responsibility to coordinate the patient's hospice care to the attending physician.

Comment: A commenter asked if the medical director of a SNF/NF or ICF/MR may also be the medical director of a hospice.

Response: These regulations do not prohibit this arrangement.

Comment: A commenter suggested that the interpretive guidelines should allow the medical director of the SNF/NF to relinquish or assume secondary professional responsibility for coordinating the medical care for residents who elect the hospice benefit.

Response: As discussed above, we have deleted the proposed medical director requirement at proposed §418.112(d), including the requirement that the hospice medical director must provide overall coordination of the medical care of the hospice patient residing in a SNF/NF or

ICF/MR. We have replaced it with the requirement of the final rule at §418.112(e)(1) that a member of the IDG coordinate the patient care and services with the facility.

22. Condition of participation: Personnel qualifications (§418.114)

We proposed significant revisions to the personnel qualifications for hospice employees. Specifically, we proposed to provide that in cases where personnel requirements are not statutory, or do not relate to a specific payment provision, personnel would only be required to meet State certification or licensure requirements.

In §418.114(a), “General qualifications,” we proposed that licensed professionals who provide hospice services directly, either as employees or under individual contract, or under arrangement with a hospice must be licensed, certified, or registered to practice by the State in which they perform the functions, as applicable. All personnel who fall into this category must act exclusively within the scope of the State license, certification or registration. In proposed §418.114(b), “Personnel qualifications for physicians, speech-language pathologists, and home health aides,” we proposed to include those personnel requirements that are included in the Act.

When a State does not have a licensure, certification,

or registration requirement, the hospice would apply the qualifications in proposed §418.114(c), “Personnel qualifications when no State licensing laws or State certification or registration requirements exist.” This category would consist of all personnel qualifications specified in existing §418.3, “Definitions,” including a requirement that a social worker have a baccalaureate degree from a school of social work accredited by the Council on Social Work Education (proposed §418.114(c)(7)).

In §418.114(d), we proposed a new requirement that a hospice obtain a criminal background check for all hospice and contract employees before employment at the hospice. We believe that this is an important safety measure to protect both patients and the hospice. We did not propose any specific type, scope, or frequency requirements for completing the background check.

Comment: A commenter noted that the proposed title of this CoP is “Personnel qualifications for licensed professionals,” and that this title could be interpreted as to apply only to those individuals for whom licensure is available. As such, the commenter reasoned, the criminal background check requirement would not apply to unlicensed individuals.

Response: Our intent, as stated in the proposed rule,

is for all appropriate individuals to have background checks. We have removed the phrase “for licensed professionals” from the title of this CoP to avoid any confusion in this area.

Comment: Several commenters supported the proposed requirement that, if a State offers licensure for any discipline, including social workers, the individuals practicing within that discipline must obtain State licensure. One commenter even suggested that social workers should be required to obtain the highest level of State licensure available to them. However, a few commenters disagreed, stating that social workers should not be required to obtain State licensure.

Response: The existing hospice requirements at §418.72 require employees who provide services to be licensed, certified, or registered in accordance with applicable Federal and State laws. We believe that it is necessary to maintain this requirement in this final rule to ensure that the individuals furnishing services to hospice patients are legally authorized to furnish care in their respective disciplines. We believe that State licensure, certification and/or registration, where required by State law or regulation, help to ensure that individuals are qualified to furnish safe and effective care to patients and families.

As professionals and equals among the IDG members, we believe that it is necessary to require social workers to meet the same licensure qualifications that all other hospice professionals are required to meet.

Comment: The majority of commenters who submitted comments on our proposed personnel qualifications section made suggestions to revise the requirements for social workers. While some of these commenters agreed with our proposal to defer to State requirements for social workers, the majority of commenters believed that all hospice social workers should be required to meet the same basic qualifications. Of these commenters, many suggested that hospice social workers should be required to have a baccalaureate degree in social work from an accredited higher education institution. Other commenters suggested that a baccalaureate or higher degree in a field related to social work, such as psychology, would be an appropriate qualification for hospice social workers, while some commenters explicitly disagreed with this suggestion. Numerous other commenters suggested that hospice social workers should be required to have a Master of social Work (MSW) degree from an accredited university. Of these commenters, several suggested that a waiver should be granted for hospices in rural areas to allow them to use the

services of a social worker with a baccalaureate degree under the supervision of an MSW or a licensed mental health professional with a graduate degree. Still other commenters suggested that, regardless of the degree that the social worker holds, he or she should be required to have one or two years of social work experience in a health care setting. Some commenters explicitly disagreed with this suggestion.

Response: The large number of public comments submitted in reference to the personnel requirements for social workers, coupled with the divergent views expressed in the comments, leads us to believe that there is no standard or consensus in the hospice industry on this issue. Our goal is to balance the needs of patients and families at a very stressful time and the needs of hospices that may have difficulty employing personnel who meet appropriate personnel standards. We believe that all hospices should strive to employ the most qualified individuals possible to provide social work services to patients and families. In order to ensure that hospices employ a qualified individual as a social worker, we are requiring that a hospice social worker must at least meet one of the following options:

- Have a Master of Social Work (MSW) degree from a school of social work accredited by the Council on Social

Work Education, and one year of experience in a health care setting;

- Have a baccalaureate degree in social work (BSW) from a school of social work accredited by the Council on Social Work Education, and one year of experience in a health care setting; or
- Have a baccalaureate degree in psychology, sociology, or other field related to social work, and at least one year of social work experience in a health care setting.

If a hospice chooses to employ a social worker with a baccalaureate degree in social work, psychology, sociology, or other field related to social work, the services of that baccalaureate social worker must be provided under the supervision of a social worker with an MSW from a school of social work accredited by the Council on Social Work Education and one year of experience in a health care setting. We believe that requiring MSW supervision of BSW services will help ensure that patient and family needs are met in a complete and timely manner. The MSW supervisor role is that of an active advisor, consulting with the BSW on assessing the needs of patients and families, developing and updating the social work portion of the plan of care, and delivering care to patients and families. This

supervision may occur in person, over the telephone, through electronic communication, or any combination thereof.

Social workers with a baccalaureate degree from a school of social work accredited by the Council on Social Work Education and who are employed by the hospice before the effective date of this final rule are exempted from the MSW supervision requirement. Therefore, if a hospice currently employs a BSW, unsupervised by an MSW, it is not required to hire an MSW to supervise the BSW. If a hospice hires a new social worker with a baccalaureate degree and one year of experience in a health care setting, then the new baccalaureate social worker must be supervised by an MSW who has one year of experience in a health care setting.

Comment: Many commenters suggested that the final rule should include personnel qualifications for chaplains. Commenters suggested that education (that is, a baccalaureate and graduate-level divinity or theological degree from a university accredited by the Council of Higher Education Accreditation and/or 4 units of clinical pastoral education), experience in the medical field, certification from a national organization, or any combination thereof would be appropriate to qualify a chaplain to care for hospice patients. Other commenters explicitly disagreed with this suggestion, stating that the final rule should not

include personnel qualifications for chaplains or require them to be licensed or certified.

Response: Hospices may choose to employ the individual(s) best suited to meet the needs of the hospice and its patients. If a hospice chooses to employ a chaplain, it may choose to use any criteria in selecting the appropriate candidate. We do not believe that it is appropriate to require hospices to use specific criteria to guide the selection of a spiritual counselor. Rather, the needs of the hospice's patient population should drive the selection of the appropriate person.

Comment: A commenter suggested that, if physical therapist assistants furnish care to hospice patients, they should be required to be under the supervision of a physical therapist.

Response: As a general statement, hospices are required to furnish physical therapy services in a manner consistent with accepted standards of practice. In addition, physical therapists and assistants are required to act only within the scope of their State license, certification, or registration. We believe that these requirements ensure that physical therapy services are provided in a safe and effective manner by and under the supervision of the appropriate personnel.

In this final rule we are incorporating changes made by a separate final rule (72 FR 66222, 66406, November 27, 2007) to the personnel qualifications for physical therapists, physical therapist assistants, occupational therapists, occupational therapist assistants, and speech-language pathologists. That final rule amended §418.92 of the existing hospice regulations to cross reference the revised personnel requirements contained in 42 CFR Part 484.4, thereby requiring physical therapists, physical therapist assistants, occupational therapists, occupational therapist assistants, and speech-language pathologists subject to the requirements of the hospice conditions of participation to meet the same personnel requirements as therapists subject to the requirements of the home health agency conditions of participation. In this final rule, we continue to require therapists who are subject to the requirements of the hospice conditions of participation to meet the same personnel requirements as therapists subject to the requirements of the home health agency conditions of participation, as was required by the November 27, 2007 final rule.

We believe that these revised requirements, which went through the notice-and-comment rulemaking process separate from and more recently than the hospice conditions of

participation continue to allow hospices the flexibility to employ or contract with individuals who are well qualified to provide therapy services to hospice patients. However, we are replacing the cross reference to the requirements of 42 CFR Part 484 with a duplicate of the requirements of §484.4. We believe that duplicating the relevant requirements of §484.4 in §418.114(b)(4)-(8) will make it easier for hospices to know the personnel requirements that their therapists must meet in order to be considered qualified to provide services to hospice patients.

Comment: A commenter suggested that we should incorporate the definition of the term “licensed professionals” from the home health regulations at 42 CFR part 484 in the personnel requirements for registered nurses at §418.114(c).

Response: The home health regulations at 42 CFR part 484 do not define the term “licensed professionals”; therefore we cannot incorporate this suggestion into the final rule.

Comment: Some commenters suggested that we should add personnel qualifications for nurse practitioners.

Response: Section 1861(aa)(5) of the Act describes a nurse practitioner for purposes of Medicare as an individual “who performs such services as such individual is legally

authorized to perform (in the State in which the individual performs such services) in accordance with State law (or the State regulatory mechanism provided by State law), and who meets such training, education, and experience requirements (or any combination thereof) as the Secretary may prescribe in regulations." A Medicare-participating hospice that employs a nurse practitioner is expected to comply with these statutory requirements, and we believe that they are sufficient.

Comment: Numerous commenters sought clarification about who was required to have a criminal background check. Some commenters suggested that volunteers should not be required to have a background check, while others suggested that only those individuals who provide direct patient care and/or who have access to patient financial information should be required to have background checks. Furthermore, some commenters suggested that only unlicensed hospice personnel should be required to have criminal background checks. Other commenters wanted to know if hospices would be required to obtain background checks on current employees, or only for employees hired after the effective date of this final rule. Still other commenters wanted to know if background checks were needed for individuals employed by a DME supplier or pharmacy that the hospice has a contract

with. Some commenters suggested that, if background checks are required for contractors, the contracted entity would be the most appropriate entity to complete criminal background checks for its employees.

Response: We believe that any individual who has direct patient contact or has access to a patient's records, clinical, financial or otherwise, should have a criminal background check because these individuals are in a position that enables them to violate patient rights to both safety and privacy. This includes all current paid hospice employees, volunteers, and contracted employees, as well as any new employees. If an office employee, such as a receptionist, does not have access to patient records, and does not make patient visits, then that employee is not required to have a criminal background check. If a volunteer is a homemaker, and thus has direct patient contact, he or she is required to have a background check. We understand that hospices would likely not actually conduct background checks on contracted employees. We have added a statement to §418.114(d)(1) that hospices must require, as part of their written agreement with a contractor, that the contractor provides the hospice a background check for each contracted employee who has direct hospice patient contact or access to hospice patient records. We believe that requiring all

individuals who have direct patient contact or access to patient records to have background checks will help hospices assure that patient rights are protected at all times.

Comment: Many commenters suggested that the requirements for criminal background checks (that is, scope, frequency, timing, etc.) should apply only in the absence of State requirements. Other commenters suggested that the timeframe for completing a criminal background check should be lengthened because it may take a few weeks to receive a background check from the State police and/or FBI. Still other commenters suggested that the scope of this requirement should be clarified.

Response: We agree that if a State has particular laws or regulations requiring criminal background checks for hospice employees and contractors, then hospice compliance with such State requirements satisfies the intent of this requirement. If a State does not have any requirements, or does not have requirements for a specific discipline, then the requirements of this final rule must be met. In this final rule, we require hospices to obtain a criminal background check within three months of the date of employment for all states that the individual has lived or worked in for the past three years. We believe that it is essential to gather information on the individual’s

activities in several states to ensure that the criminal background check presents a complete and accurate picture of the individual's compliance with the law. In order to gather such information while allowing hospices to fill vacant positions in a timely fashion, we believe that it is necessary to alter the proposed time frame from "before employment" to "within three months of the date of employment… ." Therefore, if a State requires a registered nurse to have a State police background check completed within six months of employment, and the hospice complies with this State requirement when conducting background checks on its nurses, then the hospice is in compliance with this final rule even though the state standard is not as stringent. If that same State does not have requirements for background checks of physicians, then the hospice must obtain a criminal background check within three months of the date of employment for all states that the physician (paid, volunteer, or contracted) has lived or worked in for the past three years.

Comment: A few commenters sought clarification on the relationship between the background check obtained by the hospice and the background check conducted by the State licensing body.

Response: Many States require a criminal background

check before a health care practitioner can obtain a State license, and some of these states require background checks to be updated when the license is renewed. However, not all states have a background check requirement in place for licensing. As described above, if a State has criminal background check requirements for a specific discipline, and the hospice complies with the State requirements for that discipline, then the hospice is in compliance with this Federal criminal background check requirement. This means an individual does not need a criminal background check if his or her license is current and State licensure requires a background check. If a State does not have such criminal background check requirements, then the hospice must comply with the Federal requirements described above.

Comment: One commenter suggested that we should delay implementing the criminal background check requirement until completion of the background check demonstration project called for by the MMA.

Response: While the results of the MMA background check demonstration project may provide further clarification on the particulars of implementing background check requirements in health care, we do not believe that it is appropriate to delay this important requirement. Hospices must make informed decisions regarding the staff (paid,

volunteer, and contracted) that they use to care for patients. Without such vital information patients become vulnerable, and this can lead to negative patient outcomes.

Comment: Some commenters noted that obtaining background checks will have a financial impact on hospices, while others noted that requiring volunteers to submit to background checks may decrease the number of willing volunteers.

Response: We understand that obtaining background checks will have some degree of financial impact on hospices. We believe that this impact will be offset by a decreased level of hospice liability. Hospices will be able to exclude those individuals who may pose a threat to hospice patients, thereby decreasing the likelihood of patient’s rights violations and/or criminal and civil litigation.

We also understand that some volunteers may perceive a criminal background check as an affront. However, we believe that explaining that background checks are a precaution that everyone must take, and that background checks are not meant to single anyone out, will ease volunteer concerns and not deter them from offering their time and services to hospices.

Comment: A few commenters asked us to prescribe the exact offenses that would preclude a hospice from employing a certain individual. A commenter also asked us to include a waiver for individuals who have been reformed as well as protections for hospices to choose to terminate an individual's employment based on the results of the criminal background check.

Response: We do not believe that it is appropriate to prescribe the circumstances under which an individual must be precluded from hospice employment on the basis of his or her criminal background check results. Hospices should consult applicable labor laws and regulations when developing their own policies and procedures for implementing the criminal background check requirement. In addition, hospices should inform current and prospective direct employees (including volunteers) and contracted employees about their criminal background check policy. We believe that a well-designed and openly implemented policy will help hospices choose the individuals best suited for hospice employment and service.

Comment: A commenter suggested that the section for personnel requirements should be re-located to the beginning of the rule, rather than its proposed location at the end of the rule.

Response: This rule is organized into two subparts, Subpart C – Patient Care, and Subpart D – Organizational environment. Subpart C contains the conditions of participation related to providing direct patient care, while Subpart D contains the conditions of participation related to the administration of a hospice. Since the requirements for personnel qualifications relate more to the administration of a hospice than to the delivery of direct patient care, we believe that it is appropriate to keep the personnel qualifications section in its proposed location.

23. Condition of Participation: Compliance with Federal, State, and local laws and regulations related to the health and safety of patients (§418.116)

The provisions concerning licensure requirements for hospices are currently located at §418.72, "Condition of participation: Licensure." We proposed to expand this condition by making a minor revision to the language at existing §418.72(a), requiring the hospice and its staff to operate and furnish services in compliance with all Federal, State, and local laws and regulations applicable to hospices related to the health and safety of patients.

Under §418.116(b), "Satellite locations," we proposed to continue to require that the hospice comply with the requirements of §420.206 regarding disclosure of ownership

and control information. We also proposed that the hospice and any other satellite locations operated under the same provider number be licensed in accordance with applicable State licensure laws before the hospice could be reimbursed for Medicare services. This proposed provision would apply to the hospice as an entity, as well as to any personnel furnishing services to hospice patients.

We proposed to recodify the current requirements at §418.92(b), regarding laboratory services, at §418.116(c).

Comment: We received a minimal number of comments on the proposed rule concerning multiple location requirements in this section. The commenters requested that hospices be allowed to have multiple locations (previously known as satellite locations) and also asked about the procedures for the approval of such locations.

Response: As previously noted in this preamble, we have deleted the term “satellite” and replaced it with “multiple locations.” Hospices are permitted to operate in multiple locations if they meet the requirements set forth in §418.3 and §418.100(f). The definition of “multiple location” as defined in §418.3 is “a Medicare-approved location from which the hospice provides the same full range of hospice care and services that is required of the hospice issued the certification number. A multiple location must meet all of

the conditions of participation applicable to hospices." The multiple location is part of the hospice and shares administration, supervision, and services with the hospice that was issued the certification number. In §418.100(f) we state that all multiple locations must be approved by Medicare before providing hospice care and services to Medicare patients. 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. Procedures for requesting CMS approval of a multiple location will be set forth in the hospice interpretive guidelines, which will be made available after this final rule has been published. The interpretive guidelines will provide sub-regulatory instructions and parameters which will apply to multiple locations.

III. Provisions of the Final Regulations

In this final rule we are adopting the provisions as set forth in the May 27, 2005 proposed rule with the following revisions. We have --

Definitions (§418.3)

- Deleted proposed revisions to the definition of the term "attending physician."

- Amended the definition of “bereavement counseling” by adding the term "before and".
- Revised the definition of “clinical note.”
- Added a definition of the term “comprehensive assessment.”
- Added a definition of the term “dietary counseling.”
- Deleted the definition of the term “drug restraint.”
- Added a definition of the term “initial assessment.”
- Amended the definition of “licensed professional.”
- Amended the name and definition of “satellite location,” now referred to as “multiple location.”
- Added a definition of the term “physician.”
- Added a definition of the term “physician designee.”
- Revised the definition of “restraint,” incorporating definitions of the terms “restraint”, “drug restraint”, and “physical restraint” into a single definition.
- Revised the definition of “seclusion.”
- Deleted the definitions of the terms “physical restraint” and “progress note.”

2. Condition of Participation: Patient’s rights (§418.52)

- Renamed 418.52(a) “Notice of rights and responsibilities.”
- Revised the phrasing of §418.52(a)(1).

- Redesignated and revised proposed §418.52(a)(3) to §418.106(e)(2)(i).
- Redesignated and revised proposed §418.52(a)(4) as §418.52(a)(3).
- Revised §418.52(b)(4) to clarify the hospice's responsibility for investigating and reporting violations of patient rights.
- Renamed and revised section 418.52(c) "Rights of the patient" to include several new patient rights.
- Deleted §418.52(d) "Confidentiality of clinical records" (now at 418.52(c)) and §418.52(e), "Patient liability."

3. Condition of Participation: Initial and comprehensive assessment of the patient (§418.54)

Revised the stem statement.

Revised §418.54(a) to clarify the assessment timeframe.

Revised §418.54(b) to clarify the role of the patient's attending physician, and expand the time frame for completing the comprehensive assessment.

Revised §418.54(c) to include new factors that must be considered during all comprehensive assessments. The new factors are functional status, imminence of death, and severity of symptoms.

Renumbered §418.54(c)(3)(ii) as §418.54(c)(6), and revised the title of this section as "Drug Profile." We also

revised the factors that hospices must consider in the drug profile assessment.

Revised the requirements for the "bereavement assessment" now at §418.54(c)(7) to require that a hospice incorporate information gathered from the initial assessment into the patient’s plan of care and consider such information when developing the bereavement plan of care.

Revised §418.54(d) to require an update of the comprehensive assessment at least every 15 days. We also deleted the requirement that the comprehensive assessment be updated at the time of each recertification.

4. Condition of Participation: Interdisciplinary group, care planning, and coordination of services (§418.56)

Revised the stem statement.

Revised §418.56(a)(1) to maintain consistent terminology throughout the rule. In addition, we retained the existing hospice rule provision that requires the hospice to designate a registered nurse that is a member of the IDG to coordinate patient care, assessment, and care plan implementation.

Revised the IDG requirements at §418.56(a)(1)(i) to require that the physician member of the IDG be an employee of or under contract with the hospice. We also revised §418.56 (a)(1)(iv), to retain the existing hospice requirement that

the hospice IDG must include a pastoral or other counselor.

Revised §418.56(a)(2) regarding the members of the IDG responsible for developing day-to-day hospice policies and procedures.

Revised §418.56(b) to clarify that a patient's plan of care must be individualized to his or her needs and circumstances. Additionally, we revised this section to require a hospice to involve the patient and primary caregiver in developing the plan of care in accordance with the patient's needs. We also clarified which individuals must be educated and trained by the hospice in implementing the plan of care, as well as the extent of that education and training.

Revised §418.56(c) to specify that the written plan of care must be individualized. We also added a provision that the plan of care must reflect patient and family goals.

Revised §418.56(c)(1) to simplify the phrasing of the requirement.

Removed the term "targeted" from §418.56(c)(3) to simplify its phrasing.

Revised §418.56(c)(6) by changing "family" to "representative."

Revised §418.56(d). We removed specific mention of the role of the hospice medical director or physician designee in

updating each patient’s plan of care. We also revised the time frames for updating the plan of care to at least every 15 days. Additionally, we added a requirement that the IDG must note the patient’s progress toward specified goals when updating in the plan of care.

Made several minor revisions to §418.56(e) that do not change the intent of the proposed and added a new requirement that hospice coordination and communication systems must ensure that information is shared with non-hospice health care providers furnishing services to patient.

5. Condition of Participation: Quality assessment and performance improvement (§418.58).

Removed the phrase “focuses on the end-of-life support services provided” from §418.58.

Replaced the phrase “end-of-life support services” with “hospice service” in §418.58(a). In addition, we replaced the phrase “for which there is evidence that improvement in those indicators will improve palliative outcomes” with the phrase “related to improved palliative outcomes.”

Revised §418.58(b) to clarify our intent. In §418.58(b)(2)(ii), we incorporated a requirement that quality indicator data must be used to identify priorities, as well as opportunities, for improvement. In

§418.58(b)(3), we replaced the term “specified” with the term “approved” to clarify that the governing body is not necessarily the entity that establishes data collection specifications.

Added a 240-day phase-in period to §418.58(d) to allow hospices more time to collect the initial program data.

Revised §418.58(e) by adding a requirement that the governing body annually evaluates the hospice’s QAPI program. We also added a requirement that the hospice governing body must identify at least one individual who is responsible for operating the QAPI program.

Deleted proposed §418.58(e)(3) regarding expectations for patient safety.

6. Condition of Participation: Infection control (§418.60).

Expanded the scope of the hospice’s infection control program to protect visitors as well as patients, families and hospice personnel.

Replaced the term “staff” in proposed §418.60(c) with the terms “employees” and “contracted providers.”

7. Condition of Participation: Licensed professional services (§418.62)

Revised §418.62(b) to clarify that licensed professionals providing care to hospice patients must

actively participate in the coordination of all aspects of the patient's hospice care.

8. Condition of Participation: Core services (§418.64)

Revised §418.64 to permit hospices to utilize contracted staffing sources under extraordinary or other non-routine circumstances (for example, unanticipated periods of peak patient loads, short-term staffing shortages that interrupt patient care, and patient travel).

Deleted the proposed requirement at §418.64(a) that hospice physicians be responsible for meeting a patient's general (that is, non-hospice) medical needs.

Replaced the term "nurse practitioner" with "registered nurse" in §418.64(b)(2). We also deleted the proposed requirement at §418.64(b)(2) that the role and scope of nurse practitioner services be separately specified in the plan of care.

Revised the requirements in §418.64(d) to clarify the role of counseling services, requiring that hospices make available counseling services, "…to assist the patient and family in minimizing the stress and problems that arise from the terminal illness, related conditions, and the dying process."

Revised §418.64(d)(1)(i) to permit individuals with education (as well as experience) in grief/loss counseling

to supervise a hospice's bereavement program.

Furthermore, we revised §418.64(d)(1)(ii) by removing the term "other facility" and removing the requirement that hospices must offer bereavement services to facility staff. We also revised §418.64(d)(1)(iv) by changing "provided" to "offered."

Revised §418.64(d)(2), renaming it "Dietary counseling," to be more consistent with the terminology used throughout the rest of the rule.

Revised section 418.64(d)(3)(iii) by removing the statement that hospices are not required to go to extraordinary lengths to facilitate clergy, pastoral, or other visits from this section. We added language that indicates that hospices must make all reasonable efforts to facilitate such visits.

9. Condition of Participation: Nursing services—Waiver of requirement that substantially all nursing services be routinely provided directly by a hospice (§418.66).

Removed the requirement at proposed §418.66(d) that CMS may approve a maximum of two 1-year extensions for each initial waiver.

10. Condition of Participation: Waiver of requirement-- Physical therapy, occupational therapy, speech-language pathology, and dietary counseling (§418.74).

Revised §418.74(d) by removing the requirement at 418.66(d) that CMS may approve a maximum of two 1-year extensions for each initial waiver.

11. Condition of Participation: Hospice aide and homemaker services (§418.76)

Revised §418.76 by changing its name from “Home health aide and homemaker services” to “Hospice aide and homemaker services.”

Revised §418.76(a)(ii) to clarify that the evaluation program used to measure aide competency must meet the specific requirements of §418.76(c) of this section.

Clarified that the training or competency evaluation programs referred to in §418.76(a)(2) are those programs described in §418.76(a)(1).

Added an option in §418.76(a)(1), that a hospice aide may be considered qualified if the aide has completed a training and competency evaluation program in accordance with the content and specifications of the nurse aide training program requirements for long term care facilities at 42 CFR part 483.

Revised the language in §418.76(b)(1) to describe the training that hospice aides must complete. The revised requirement states that, “[h]ospice aide training must include classroom and supervised practical training.”

Revised §418.76(c)(1) to clarify that a competency evaluation program is required to address the areas identified in §418.76(b)(3) of this section, rather than the requirements of §418.76(b)(1) through §418.76(b)(3).
Revised the requirement in §418.76(c)(4) to specify that an aide is not considered to have successfully completed a competency evaluation if the aide has an “unsatisfactory” rating in more than one required area.
Deleted the proposed requirement in §418.76(d) that an organization excluded by §418.76(f) would be excluded from offering in-service training to hospice aides. This paragraph continues to exclude certain organizations from initially training hospice aides.

Revised §418.76(e) to clarify that the requirements of this section apply to instructors providing both classroom and supervised practical training. We are no longer applying the requirements of this standard to those individuals performing competency evaluations or in-service trainings. Third, we clarified the description of the training instructor by rearranging the language and clarifying that one year of the trainer’s health care experience would be in the broad home care environment (that is, hospice or home health care), rather than in the more specific home health care environment.

Revised §418.76(f) to state that any home health agency that, within the last two years, was out of compliance with the requirements of paragraphs §418.76(b) or §418.76(c) of this section was not eligible to train hospice aides, except with respect to in-service training.

Deleted the proposed language in 418.76(g)(1) that an appropriate qualified therapist may make hospice aide assignments or supervise hospice aides. Also in section 418.76(g)(1), we added a new specification requiring the nurse who makes aide assignments for a specific aide and patient to be a member of that patient's hospice IDG.

Revised §418.76(g)(2) to indicate that the hospice IDG as a whole may order aide services.

Revised §418.76(h) by removing references to qualified therapists.

Clarified the purpose of the every 14 day aide supervision visit in §418.76(h)(1)(i).

Added a provision in §418.76(h)(1)(ii) stating that if during the supervision visit the nurse supervisor notes a potential area of concern regarding the way in which hospice aide services are being furnished, then the supervising registered nurse must make an on-site visit to the patient when the hospice aide is present, to observe and assess the aide while he or she is performing care.

Added §418.76(h)(1)(iii) to clarify these problems identified during any hospice aide supervisory visits that cannot be resolved at that time by the supervising registered nurse, the hospice aide must complete a competency evaluation in accordance with §418.76(c). We also redesignated §418.76(h)(2) as §418.76(h)(3). We added a new section 418.76(h)(2) to require a hospice registered nurse to make an annual on-site visit to observe each hospice aide furnishing aide services to at least one patient. Hospices may determine the appropriate location to document this annual aide evaluation in accordance with their own policies and procedures.

Deleted proposed 418.76(h)(3).

Added a provision in §418.76(i)(2) that the individuals providing Medicaid personal care aide services may only be used by the hospice in implementing a patient’s plan of care to the same extent that the hospice would routinely use a patient’s family in implementing the plan of care.

Added a provision in §418.76(i)(3) that a hospice must coordinate its hospice aide and homemaker services with the personal care aide services provided by Medicaid to ensure that patient needs are met.

Reorganized §418.76(j) to clarify that homemakers must either meet the standards of §418.202(g) (in 42 CFR 418

Subpart F – Covered Services) and complete hospice orientation, or meet the requirements for hospice aides at §418.76 as indicated in revised §418.76(j)(2). There are no substantive changes to this paragraph.

Revised the qualifications for the supervision of homemakers in §418.76(k) to require that such services be supervised by the same member of the IDG who coordinates the services.

12. Condition of Participation: Organization and administration of services (§418.100).

Revised the requirements of §418.100(a) and §418.100 (a)(1) to make clear that hospices must structure their operations to fully serve patients and families at the end of life.

Clarified then relationship between a hospice's governing body and administrator in §418.100(b) by adding a provision that the administrator must be appointed by the governing body.

Revised the requirement in §418.100(e) to state that hospices must maintain oversight responsibility for services furnished under contract.

Revised the requirement in §418.100(e)(2) that contracted services be provided by personnel having at least the same qualifications as hospice employees with a requirement that contracted services by provided by qualified personnel.

Revised and reorganized §418.100(f) by replacing the term “satellite location” with the term “multiple location,” and adding new requirements for Medicare approval.

Revised §418.100(g) by adding (g)(1) and (2) to address the orientation of patient care employees in the hospice philosophy and the initial orientation of a hospice employee to his or her specific job duties. We also redesignated proposed paragraph (g) as (g)(3).

13. Condition of Participation: Medical Director (§418.102)

Revised **§**418.102 by describing the employment relationship between the medical director and the hospice. We clarified that the medical director is either an employee of the hospice (paid or volunteer) or is an individual under contract with the hospice. We also revised the requirement to state that the hospice is responsible for designating the individual who fulfills the physician designee role in the medical director’s absence.

Inserted a new §418.102(a) to address contracting for medical director services, and redesignated the other paragraphs accordingly. The new paragraph specifies that hospices may choose to make arrangements for medical director services to be met through a contract with a self-employed doctor or through a contract with a professional

entity or physicians group. Revised §418.102 (a)(2) specifies that if a hospice chooses to contract with a professional entity or physicians group for medical director services, the contract must identify a particular physician who will fulfill the hospice medical director's role and responsibilities.

Redesignated §418.102(a) as §418.102(b) and revised it to delete the term "criteria."

Deleted proposed §418.102(b)(2), which would have required the medical director to review the patient's and family's expectations and wishes for the continuation of hospice care at the time of each recertification.

Redesignated and revised §418.102(c) as §418.102(d). The revision requires the hospice medical director to assume responsibility for the medical component of the hospice's patient care program. We deleted references to the joint responsibility of the IDG.

13. Condition of participation: Clinical records (§418.104)

Revised §418.104(a) to clarify which documents must be included in the clinical record.

Revised §418.104(a) to specify that all versions of the plan of care (initial and updated) must be in the clinical record. Likewise, we clarified that all assessments

(initial, comprehensive, and updated comprehensive) must be included in the patient's clinical record. In addition, we removed the language that separate progress notes must be included in the clinical record because all notes, including notes that document a patient's progress, are included under the broad heading of "clinical notes." Furthermore, we removed the requirement that the clinical record must contain a patient's informed consent from this section. In its place, we require that the clinical record contain a copy of the notice of patient rights (in accordance with §418.52(a)(3)), which requires a hospice to obtain the patient's or representative's signature confirming that he or she has received a copy of the notice of rights.

Deleted the requirement in section §418.104(b) that, "[a]ll 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." We are requiring authentication and dating in accordance with hospice policy and accepted standards of practice.

Revised §418.104(d) to specify the length of time that a hospice is required to retain a patient's clinical record after death or discharge from five years to six years in accordance with the HIPAA requirements.

Revised §418.104(e) by replacing the term

"Medicare/Medicaid-approved facility" with "Medicare/Medicaid-certified facility."

Revised §418.104(e)(1) and (2) by requiring only that the discharge summary be sent to the receiving facility/physician, and that the clinical record be made available only upon request.

14. Condition of Participation: Drugs and biologicals, medical supplies, and durable medical equipment (§418.106)

Revised this CoP by combining the requirements of proposed §418.106 and proposed §418.110(m) and §418.110(n).

Revised §418.106(a) to now require the hospice to ensure that the IDG confers with a qualified individual with education and training in drug management who is an employee of, or under contract with, the hospice to ensure that drugs and biologicals meet each patient's needs. This section also requires a hospice that provides inpatient care directly in its own facility to provide pharmacy services under the direction of a qualified licensed pharmacist who is an employee of, or under contract with, the hospice.

Incorporated the proposed requirements of §418.110(n) in section 418.106(b). Drug orders must only be given by a physician or nurse practitioner. If a drug order is given verbally or electronically, it must be given to a licensed nurse, nurse practitioner, pharmacist, or physician, and

must be recorded and signed immediately by the receiver. The prescribing individual must sign the order in accordance with State and Federal regulations.

Inserted new section 418.106(c), “Dispensing of drugs and biologicals,” to incorporate elements of proposed §418.110(m) and (n). This new standard requires a hospice to have a written policy to promote dispensing accuracy, maintain current and accurate records of the receipt and disposition of all controlled drugs, and obtain drugs and biologicals from community or institutional pharmacists or its own stock. Some of these requirements (that is, policy for dispensing accuracy and controlled drug records) only apply to those hospices that choose to maintain their own drug and biological stocks.

Revised §418.106(d) to combine proposed standards §418.106(a)(2) and §418.110(n)(2). Revised §418.106(d) is divided into two elements, one for patients receiving care in their home and another for patients receiving care in a hospice inpatient facility. If a patient is receiving care in his or her home, the hospice IDG must determine the patient’s and/or family’s ability to safely administer drugs and biologicals in the home. If a patient is receiving care in an inpatient facility operated by the hospice, then drugs may only be administered to the patient by a designated list

of individuals working in the inpatient facility. Revised §418.106(e) to combine and revise the requirements of §418.106(b) and §418.110(n)(3), §418.110(n)(4), and §418.110(n)(5). A hospice must ensure that all drugs and biologicals are labeled with appropriate use and cautionary instructions, as well as an expiration date, in accordance with accepted standards of practice. In addition, a hospice must have written policies and procedures for the management and disposal of controlled drugs in a patient's home, and must provide and discuss them with the patient and family at the time when controlled drugs are initially ordered. Furthermore, a hospice that operates its own inpatient facility must dispose of controlled drugs in compliance with State and Federal requirements and its own policies and procedures. It must also store drugs and biologicals in a secure area. Certain controlled drugs must be stored in locked compartments within the secure area, and access to those locked compartments must be restricted to those individuals who are permitted to administer these drugs. Any discrepancies in the acquisition, storage, dispensing, administration, disposal, or return of controlled drugs in the hospice's inpatient facility must be investigated immediately, and reported, if necessary. An investigation report must be made available to State and/or federal

officials, if required.

Revised §418.106(f) to clarify the hospice's responsibility for durable medical equipment and medical supplies and the hospice's contractual relationship with a durable medical equipment supplier. Specifically, section 418.106(f)(1) and (2) have been revised to state that, regardless of whether the hospice provides durable medical equipment and medical supplies directly or under contract, the hospice must ensure the following: that manufacturer recommendations for routine and preventive maintenance are followed; that maintenance policies are developed when no manufacturer recommendations exist; that equipment is safe; that equipment works as intended; that patients, families, and other caregivers receive instruction in the safe use of equipment and supplies; and that patients, families, and other caregivers are able to demonstrate the safe and appropriate use of equipment and supplies.

Added §418.106(f)(3) to state that, if a hospice chooses to contract with an entity for durable medical equipment, it may only contract with a durable medical equipment supplier that meets the Medicare Supplier Quality and Accreditation Standards at 42 CFR §424.57.

15. Condition of participation: Short-term inpatient care (§418.108)

Revised 418.108(b)(2) to require a facility providing only the respite level of care to meet the 24-hour nursing needs of all patients in accordance with each patient's plan of care. A facility providing only the respite level of care is not required to automatically have registered nurse present on all shifts to provide direct patient care.

16. Condition of participation: Hospices that provide inpatient care directly (§418.110)

Revised the opening paragraph of this CoP to clarify that the requirements of §418.110 apply only to those inpatient facilities operated by a hospice. Where a hospice has its "own inpatient facility," either in a freestanding building or as a section located in the building of another provider type, the requirements of §418.110 apply to the building or applicable portion thereof as if it were physically located with the hospice administrative offices, as well as to the hospice patients receiving care within that building.

Added a requirement at §418.110(b)(2), originally at §418.100(a) of the existing hospice regulations, that at least one registered nurse must provide direct patient care on each shift. However, unlike the current §418.100(a), this requirement only applies if the hospice inpatient facility is providing general inpatient care to one or more

patients.

Removed the proposed requirements §418.110(c)(1)(i) and (ii), that a hospice must report safety breaches and that hospices must prevent, report, and correct equipment failures.

Deleted §418.110(d)(4) and §418.110(d)(5), the phase-in provisions requiring hospices to comply with certain emergency lighting and door latching requirements as of March 13, 2006.

Redesignated proposed paragraph §418.110(d)(6) as paragraph §418.110(d)(4).

Added an exception to §418.110(f)(1)(iv) with respect to the number of patients that may occupy a single room.

Redesignated proposed §418.110(o) as §418.110(m), and revised it to correspond with the seclusion and restraint requirements for hospitals.

Revised proposed §418.110(o)(6) as §418.110(n) to provide more detailed guidance regarding the role of staff training in safely and successfully implementing restraint or seclusion techniques. These changes conform to the requirements of the hospital conditions of participation.

Redesignated proposed §418.110(o)(7) as §418.110(o) to provide more detailed requirements regarding death reporting requirements.

16. Condition of participation: Hospices that provide hospice care to residents of a SNF/NF or ICF/MR (§418.112)

Deleted the term “other facilities” throughout this section.

Revised §418.112(b) to clarify a hospice’s responsibility for care furnished to hospice patients who reside in a SNF/NF or ICF/MR. A hospice assumes all responsibility for the professional management of all hospice services furnished to residents, including hospice-related inpatient care. All services furnished by the hospice must be in accordance with the individualized plans of care.

Deleted §418.112 (c) and (d), and redesignated the remaining sections accordingly.

Redesignated §418.112(e) as §418.112(c), deleted some provisions, clarified other provisions, and incorporated new provisions regarding the written agreement between a hospice and a SNF/NF or ICF/MR.

Redesignated §418.112(f) as §418.112(d) and replaced some of the detailed plan of care requirements included in the proposed standard with a cross reference to the requirements of §418.56. We also clarified that the hospice must discuss changes in a patient’s plan of care with the patient or the patient’s representative, as well as with representatives of the SNF/NF or ICF/MR where the patient resides.

Revised §418.112(g) (redesignated as §418.112(e)) to clarify the hospice's patient care coordination responsibility.

Deleted proposed §418.112(h).

Revised §418.112(i) and redesignated it as §418.112(f) to clarify that a hospice is not required to provide orientation training itself if another hospice has already done so.

17. Condition of participation: Personnel qualifications (§418.114)

Revised §418.114(a) by combining the requirements of proposed standards §418.114(a) and §418.116(a). The revised §418.114 requires that all professionals who furnish hospice services be currently licensed, certified or registered to provide services in accordance with applicable Federal, State, and local laws. Furthermore, all professionals must act only within the scope of their license, certification, or registration.

Revised §418.114(b) by replacing the proposed term "home health aides" with the final term "hospice aides." We also added revised personnel requirements for social workers at §418.114(b)(3).

Revised personnel requirements for physical therapists, physical therapy assistants, occupational therapists, occupational therapy assistants, and speech-language

pathologists to incorporate changes made to these sections in a separate final rule (72 FR 66222, November 27, 2007)

Revised §418.114(d) to provide more specificity about the timing and scope of the criminal background check requirement.

18. Condition of participation: Compliance with Federal, State, and local laws and regulations related to the health and safety or patients (§418.116)

Moved proposed §418.116(a) to a similar provision at final §418.114(a).

Replaced the term “satellite locations” with the term “multiple locations” in final §418.116(a) (proposed §418.116(b)) to conform to other sections of the final rule.

IV. Crosswalk

Provisions not cited in the crosswalk are unchanged in the final rule.

Proposed Citation	Proposed Condition	Final Citation	Final Condition
418.3	**Definitions**	Same	**Definitions**
	New	418.3	Initial assessment, Comprehensive assessment, Physician designee, and Dietary counseling
	Satellite location	Same	Multiple location, New and amended language

	Bereavement counseling, Clinical note, Employee, Hospice care, Licensed professional, Restraint, Seclusion	Same	**New and amended language**
	Attending physician, Cap period, Drug restraint, Physical restraint, Progress note, Terminally ill		**Deleted**
418.52	**Patient Rights**	Same	**Patient Rights**
418.52(a)(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.	Same	New and amended language
418.52(a)(3)	The hospice must	418.106(e)(2)(i)	Relocated and

	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.		amended language
418.52(a)(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.	418.52(a)(3)	New and amended language
418.52(b)(4)(i)	The hospice must--Ensure that all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries	418.52(b)(4)(i) and 418.52(b)(4)(iv)	New and amended language

	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.		
418.52(b)(4)(ii)	Immediately investigate all alleged violations and immediately take action to prevent further potential abuse while the alleged violation is being verified;	Same	New and amended language
418.52(4)(iv)	Investigate complaints made by a patient or	418.52(b)(4)(ii)	Amended language

	the patient's family or representative regarding treatment or care that is (or fails to be) furnished, lack of respect for the patient or the patient's property by anyone furnishing services on behalf of the hospice, and document both the existence of the complaint and the steps taken to resolve the complaint.		
418.52(c)	Pain management and symptom control	418.52(c)(1)	New and amended language
	New	418.52(c)(2)	New
	New	418.52(c)(3)	New
		418.52(c)(4)	New
		418.52(c)(6)	New
	New	418.52(c)(7)	New
		418.52(c)(8)	New
418.52(d)	Confidentiality of clinical records	418.52(c)(5)	Same
418.52(e)	Patient liability	Deleted	Deleted

418.54	**Initial and Comprehensive Assessment of the Patient**	Same	Same
418.54(a)	Initial assessment: The hospice registered nurse must make an initial assessment visit within 24 hours after the hospice receives a physician's admission order for care (unless ordered otherwise by the physician), to determine the patient's immediate care and support needs.	Same	New and amended language
418.54(b)	Time frame for completion of the comprehensive assessment: The hospice interdisciplinary group in consultation with the individual's attending physician, must complete the	Same	New and amended language

	comprehensive assessment no later than 4 calendar days after the patient elects the hospice benefit.		
418.54(c)	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—	Same	New and amended language
418.54(c)(1)	The nature and condition causing admission (including	Same	New and amended language

	the presence or lack of objective data and subjective complaints);		
418.54(c)(3)	Factors that must be considered in developing individualized care plan interventions, including—	Same	New and amended language
418.54(c)(3)(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.	418.54(c)(7)	New and amended language
418.(c)(3)(ii)	Drug therapy. A review	418.54(c)(6)	New and amended

	of the patient's prescription and over-the-counter drug profile, including but not limited to identification of the following--		language
418.54(c)(3)(ii)(A)	Ineffective drug therapy;	418.54(c)(6)(i)	New and amended language
418.54(c)(3)(ii)(B)	Unwanted drug side and toxic effects; and	418.54(c)(6)(ii)	New and amended language
418.54(c)(3)(ii)(C)	Drug interactions.	418.54(c)(6)(iii)	New and amended language
	New	418.54(c)(6)(iv)	Duplicate therapy
	New	418.54(c)(6)(v)	Laboratory monitoring
418.54(c)(4)	The need for referrals and further evaluation by appropriate health professionals.	418.54(c)(8)	Same
418.54(d)	Update of the comprehensive assessment	Same	New and amended language
418.54(d)(1)	As frequently as the patient requires, but no less frequently than every 14 days; and	418.54(d)	Amended language
418.54(d)(2)	At the time of each recertification	Deleted	Deleted

418.56	**§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	Same	Amended language

	illness and related conditions.		
418.56(a)(1)	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	Same	New and amended language

	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:		
418.54(a)(1)(i)	A doctor of medicine or osteopathy (who is not the patient's attending physician).	Same	Amended language
418.54(a)(1)(iv)	A pastoral, clergy, or other spiritual counselor.	Same	Amended language
418.56(a)(2)	If the hospice has more than one interdisciplinary group,	Same	Amended language

	it must designate in advance only one of those groups to establish policies governing the day-to-day provision of hospice care and services.		
418.56(b)	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	Same	New and amended language

	care.		
418.56(c)	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—	Same	New and amended language
418.56(c)(1)	Interventions to facilitate the management of pain and symptoms;	Same	Amended language
418.56(c)(3)	Measurable targeted outcomes anticipated from implementing and coordinating the plan of care;	Same	Amended language
418.56(c)(6)	The interdisciplinary group's documentation of patient and family	Same	Amended language

	understanding, involvement, and agreement with the plan of care, in accordance with the hospice's own policies, in the clinical record.		
418.56(d)	Review of the plan: 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	Same	Amended language

	assessment and the patient's progress toward outcomes specified in the plan of care.		
418.56(e)	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—	Same.	New and amended language.
418.56(e)(1)	Ensure the interdisciplinary group, through its designated professionals, maintains responsibility for directing, coordinating, and supervising the care and services provided;	Same	Amended language
418.56(e)(4)	Provide for and ensure the ongoing sharing of information between all disciplines providing	Same	Amended language

	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.		
	New	New 418.56(e)(5)	New
418.58	**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	Same	New and amended language

	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.		
418.58(a)(1)	Program scope: (1) The program must at least be capable of showing measurable	Same	Amended language

	improvement in indicators for which there is evidence that improvement in those indicators will improve palliative outcomes and end-of-life support services.		
418.58(b)(2)(ii)	Identify opportunities for improvement.	Same	Amended language
418.58(b)(3)	The frequency and detail of the data collection must be specified by the hospice's governing body.	Same	Amended language
418.58(d)(1)-(d)(2)	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.	Same	New and amended language

	(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.		
418.58(e)-(e)(1)	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;	Same	Amended language
418.58(e)(2)	That the hospice-wide quality assessment and performance improvement efforts address priorities for improved quality of care	Same	Amended language

	and patient safety, and that all improvement actions are evaluated for effectiveness; and		
418.58(e)(3)	That clear expectations for patient safety are established.	Deleted	Deleted
	New	418.58(e)(3)	New
418.60	**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.	Same	Amended language
418.60(b)(2)(ii)	A plan for the appropriate actions that are expected to result in improvement and disease prevention.	Same	Amended language
418.62	**Licensed professional services**	Same	Same

418.62(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	Same	Amended language
418.64	**Core Services:** A hospice must routinely provide substantially all core services directly by hospice employees. These services must be provided in a manner consistent with acceptable standards of	Same	New and amended language

	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.		
418.64(a)	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	Same	Amended language

	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.		

418.64(b)	Nursing services: (1) The hospice must provide nursing care and services by or under the supervision of a registered nurse. Nursing services must ensure that the nursing needs of the patient are met as identified in the patient's initial comprehensive assessment and updated assessments. (2) If State law permits nurse practitioners (NPs) to see, treat and write orders for patients, then NPs may provide services to beneficiaries receiving hospice care. The role and scope of the services provided by a NP that is not the individual's attending physician must be specified in the	Same	Amended language

	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.		
418.64(d)	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:	Same	New and amended language
418.64(d)(1)(i)	Bereavement counseling. The hospice must: Have an organized program for the	Same	Amended language

	provision of bereavement services furnished under the supervision of a qualified professional with experience in grief/loss counseling.		
418.64(d)(1)(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.	Same	Amended language
418.64(d)(1)(iv)	Develop a bereavement plan of care that notes	Same	Amended

	the kind of bereavement services to be provided and the frequency of service delivery. A special coverage provision for bereavement counseling is specified in §418.204(c).		
418.64(d)(2)	Nutritional counseling. Nutritional counseling, when identified in the plan of care, must be performed by a qualified individual, which include dietitians as well as nurses and other individuals who are able to address and assure that the dietary needs of the patient are met.	Same	Renamed: Dietary Counseling
418.64(d)(3)(i)-(iv)	Spiritual counseling. The hospice must: (i) Provide an assessment of the patient's and family's	Same	Amended language

	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.		
418.66	**Nursing services-Waiver of requirement that substantially all**	Same	Same

	nursing services be routinely provided directly by a hospice		
418.66(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	Same	Amended language

	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 hospice-type services were furnished to patients on or before January 1, 1983; and (iii) 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).		
418.66(d)	CMS may approve a	Same	Amended language

	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 waiver have not changed since the initial waiver was granted.		
418.74	**Waiver of requirement-Physical therapy, occupational therapy, speech-language pathology, and dietary counseling**	Same	Same
418.74(a)	A hospice located in a non-urbanized area may submit a written request for a waiver of	Same	Amended language

	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).		
418.74(d)	CMS may approve a maximum of two 1-year extensions for each initial waiver. If a hospice wishes to	Same	Amended language

	receive a 1 year extension, it must submit a request to CMS prior to the expiration of the waiver period and certify that conditions under which it originally requested the waiver have not changed since the initial waiver was granted.		
418.76	**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.	Same	New and amended language
418.76(a)(1)	Home health aide	Same	New and amended

	qualifications: (i) A training program and competency evaluation as specified in paragraphs (b) and (c) of this section respectively; or		language
418.76(a)(1)	(ii) A competency evaluation program; or	Same	New and amended language
418.76(a)(1)	(iii) A State licensure program that meets the requirements of paragraphs (b) and (c) of this section.	418.76(a)(1)(iv)	Same
New	New	418.76(a)(1)(iii)	New
418.76(a)	(2) 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	Same	New and amended language

	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.		
418.76(b)	Content and duration of home health aide classroom and supervised practical training: (1) Home health aide training must include classroom and supervised practical classroom	Same	Amended language

	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 l6 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:		

	(4) The hospice must maintain documentation that demonstrates that the requirements of this standard are met.		
418.76(c)	Competency evaluation: An individual may furnish home health services on behalf of a hospice only after that individual has successfully completed a competency evaluation program as described in this section.	Same	Amended language
418.76(c)(1)	(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)	Same	Amended language

	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.		
418.76(c)(2)	(2) A home health aide competency evaluation program may be offered by any organization, except as specified in paragraph (f) of this section.	Same	Amended language
418.76(c)(4)	(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	Same	New and amended language

	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.		
418.76(d)	In-service training: A home health aide must receive at least l2 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	Same	Amended language

	registered nurse. (2) The hospice must maintain documentation that demonstrates the requirements of this standard are met.		
418.76(e)	Qualifications for instructors conducting classroom supervised practical training, competency evaluations and inservice 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	Same	Amended language

	registered nurse.		
418.76(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 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);	Same	Amended language

	(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:		
418.76(g)	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.	Deleted	Deleted stem
418.76(g)(1)	Home health aides are assigned to a specific patient by a registered nurse or the appropriate qualified therapist. Written patient care instructions for a home health aide must be prepared by a registered nurse or other appropriate skilled professional (i.e., a physical therapist, speech-language pathologist, or	Same	New and amended language

	occupational therapist) who is responsible for the supervision of a home health aide as specified under paragraph (h) of this section.		
418.76(g)(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.	Same	Amended language
418.76(g)(3)	The duties of a home health aide include: (i) The provision of hands on personal care;	Same	Amended language

	(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.		
418.76(g)(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	Same	Amended language

	compliance with the hospice's policies and procedures		
418.76(h)	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.	418.76(h)(1) and (h)(2)	New and amended language
418.76(h)(2)	The supervising nurse	418.76(h)(3)	Amended language

	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.		
418.76(h)(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)(l) 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.	Deleted	Deleted
	New	418.76(h)(3)	New language

418.76(i)	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.	418.76(i) and (i)(1)	Amended language
		418.76(i)(2)	New language
		418.76(i)(3)	New language
418.76(j)	Homemaker	Same	New and amended

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

	(3) Homemakers must report all concerns about the patient or family to the member of the interdisciplinary group who is coordinating homemaker services.		
	Subpart D Conditions of Participation: Organizational Environment		
418.100	**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.	Same	New and amended language
418.100(a)	Serving the hospice patient and family. The	Same	New and amended language

	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.		
418.100(c)	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. (iv) Counseling services, including spiritual counseling,	Same	Amended language

	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.		
418.100(e)	Professional management responsibility. A hospice that has a written agreement with another agency, individual, or organization to furnish any services under arrangement, must retain administrative and financial management, and supervision of staff and services 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	Same	Amended language

	hospice; (2) Furnished in a safe and effective manner by personnel having at least the same qualifications as hospice employees; and (3) Delivered in accordance with the patient's plan of care.		
418.100(f)	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	Same	Renamed. Amended language

	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.		
418.100(g)	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	Same	Renamed.. New and amended language

	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.		
418.102	**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	Same	Amended language

	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.		
418.102(a)	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	418.102(b)	Amended language

	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.		
New		418.102(a)	New
418.102(b)	Recertification of the terminal illness. Before the recertification period for each patient, as described in §418.21(a), the medical director or physician designee must review: (1) The patient's clinical information; and	418.102(c)	Amended language

	2) The patient's and family's expectations and wishes for the continuation of hospice care.	Deleted	Deleted
418.102(c)	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.	Deleted	Deleted
New	New	418.102(d)	New
418.104{a)	**Clinical records.** Content. Each patient's record must include the following:	Same	New and amended language

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

	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.		
418.104(e)	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. (2) If a patient revokes the election of hospice care, or is discharged from hospice because	Same	New and amended language

	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.		
418.106(a)	**Drugs and biologicals, medical supplies, and durable medical equipment**.	418.106(d)	Partially deleted and moved to stem.

	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.		
418.106(a)	(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.	418.106(d)(1)	Renamed. New and amended language
New	New	418.106(a)	Renamed. New and amended language
418.106(b)	Controlled drugs: The hospice must have a written policy for tracking, collecting, and disposing of controlled drugs maintained in the patient's home. During	418.106(e)	Renamed. New and amended language

	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.		
418.110(n)(1)	New	418.106(b)	Renamed. New and amended language
418.106(c)	Use and maintenance of equipment and supplies. (1) The hospice must follow manufacturer recommendations for performing routine and preventive maintenance on durable medical	418.106(f)	New and amended language.

	equipment. The equipment must be safe and work as intended for use in the patient's environment. Where there is no manufacturer recommendation for a piece of equipment, the hospice must develop in writing its own repair and routine maintenance policy. The hospice may use persons under contract to ensure the maintenance and repair of durable medical equipment. (2) The hospice must ensure that the patient, where appropriate, as well as the family and/or other caregiver(s), receive instruction in the safe use of durable medical equipment and		

	supplies. The patient, family, and/or caregiver must be able to demonstrate the appropriate use of durable medical equipment to the satisfaction of the hospice staff.		
418.110(m)		418.106(c)	Renamed. New and amended language
418.110(n)(2)		418.106(d)(2)	Renamed. New and amended language
418.106(b) and 418.110(n)(3)-(5)		418.106(e)	Renamed. New and amended language
New	New	418.106.(f)(3)	amended language
418.108(a)	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	Same	Amended language

	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.		
418.108(b)	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	Same	New and amended language

	the standards specified in §418.110 (b) and (f).		
418.108(c)	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; (2) That the inpatient provider has established patient care policies consistent with those of the hospice and agrees to abide by the palliative care	Same	Amended language

	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(c)(1) through (c)(5) of this section have been met is established.		
418.110	**Hospices that provide inpatient care directly**		
418.110	A hospice that provides inpatient care directly must demonstrate compliance with all of the following standards:	Same	New language
418.110(b)	Twenty-four hour nursing services: The hospice facility must provide 24-hour nursing services that meet the nursing needs of all	Same	New language

	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.		
418.110(c)	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	Same	Amended language

	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.		
418.110(c)	(2) Physical plant and equipment. The hospice must develop procedures for managing the control, reliability, and quality of-- (i) The routine storage and prompt disposal of trash and medical waste; (ii) Light, temperature, and ventilation/air exchanges throughout the hospice;	Same	Amended language
418.110(d)	Fire protection	Same	Amended language
418.110(f)	Patient rooms: (1) The hospice must ensure that patient rooms are designed and equipped	Same	New and amended language

	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; (v) 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 (vi) Be equipped with an easily-activated, functioning device accessible to the patient, that is used for calling for assistance.		
418.110(f)(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	Same	New and amended language
418.110(m)	Pharmaceutical	418.106(a)	New and amended

	services: Under the direction of a qualified pharmacist, the hospice must provide pharmaceutical services such as drugs and biologicals and have a written process in place that ensures dispensing accuracy.		language
418.110(m)	The hospice will evaluate a patient's response to the medication therapy, identify adverse drug reactions, and take appropriate corrective action.	418.54(a)(6)	New and amended language
418.110(m)	Drugs and biologicals must be obtained from community or institutional pharmacists or stocked by the hospice.	418.106(c)	New and amended language
418.110(m)	The hospice must furnish the drugs and biologicals for each	418.106 Stem	New and amended language

	patient, as specified in each patient's plan care.		
418.110(m)	The use of drugs and biologicals must be provided in accordance with accepted professional principles and appropriate Federal, State, and local laws.	418.100(c) and 418.116	New and amended language
418.110(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.	418.106(a)	New and amended language
418.110(n)(1)	Orders for medications. (i) A physician as defined by section 1861(r)(1) of the Act, or	418.106(b)	New and amended language

	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.		
418.110(n)(2)	Administration of	418.106(d)(2)	New and amended

	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.		language
418.110(n)(3)	Labeling of drugs and biologicals. Drugs and biologicals must be labeled in accordance with currently accepted professional practice and must include appropriate accessory and cautionary	418.106(e)(1)	New and amended language

	instructions, as well as an expiration date (if applicable).		
418.110(n)(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.	418.106(e)(3)	New and amended language

	(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.		
418.110(n)(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.	418.106(e)(2)(ii)	New and amended language
418.110(o)(1)	Seclusion and restraint:	418.110(m)	Same

	(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.		
418.110(o)(1)	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	418.3	Same

	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.		
418.110(o)(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.	418.110(m) and 418.110(m)(1)	Same
418.110(o)(3)(i)	The use of restraint and seclusion must be- (i) Selected only when less restrictive	418.110(m)(2)	New and amended language

	measures have been found ineffective to protect the patient or others from harm;		
418.110(o)(3)(ii)	Carried out in accordance with the order of a physician. The following will be superseded by more restrictive State laws:	418.110(m)(4) and 418.110(m)(7)	New and amended language
418.110(o)(3)(ii)(A)	Orders for seclusion or restraints must never be written as a standing order or an as needed basis (that is, PRN).	418.110(m)(5)	Amended language
418.110(o)(3)(ii)(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.	418.110(m)(6)	Amended language
418.110(o)(3)(ii)(C)	A hospice medical director or physician	418.110(m)(11) and 418.110(m)(12)	New and amended language

	designee must see the patient and evaluate the need for restraint or seclusion within 1 hour after initiation of this intervention.		
418.110(o)(3)(ii)(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.	418.110(m)(7)	New and amended language

418.110(o)(3)(iii)	In accordance with the interdisciplinary group and a written modification to the patient's plan of care;	418.110(m)(3)(i)	Amended language
418.110(o)(3)(iv)	Implemented in the least restrictive manner possible not to interfere with the palliative care being provided;	418.110(m)(2)	Amended language
418.110(o)(3)(v)	In accordance with safe, appropriate restraining techniques	418.110(m)(3)(ii)	Amended language
418.110(o)(3)(vi)	Ended at the earliest possible time; and	418.110(m)(8)	Amended language
418.110(o)(3)(vii)	Supported by medical necessity and the patient's response or outcome, and documented in the patient's clinical record.	418.110(m)(15)	New and amended language
418.110(o)(4)	A restraint and seclusion may not be used simultaneously unless the patient is-- (i) Continually monitored face to face	418.110(m)(14)	Amended language

	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.		
418.110(o)(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.	418.110(m)(9)	New and amended language
418.110(o)(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	418.110(n)	New and amended language

	situations that traditionally have been treated through the use of restraints or seclusion.		
418.110(o)(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.	418.110(o)	New and amended language
418.112	**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	Same	New and amended language

	must abide by the following additional standards.		
418.112(a)	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.	Same	New and amended language
418.112(b)	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	Same	New and amended language

	care in a participating Medicare/Medicaid facility according to §418.100.		
418.112(c)	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	418.64	New and amended language

	non-routine circumstances, as described in §418.64.		
418.112(d)	Medical director: The medical director and physician designee of the hospice must provide overall coordination of the medical care of the hospice resident that resides in an SNF, NF, or other facility. The medical director and physician designee must communicate with the medical director of the SNF/NF, the patient's attending physician, and other physicians participating in the provision of care for the terminal and related conditions to ensure quality care for the patient and family.	418.112(e)	New and amended language
418.112(e)	Written agreement: The	418.112(c)	New and amended

	hospice and the facility must have a written agreement that specifies the provision of hospice services in the facility. The agreement must be signed by authorized representatives of the hospice and the facility before the provision of hospice services.		language
418.112(e)(1) and (e)(2)	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.	Deleted	Deleted
418.112(e)(3)	The manner in which the facility and the hospice are to	418.112(c)(1)	Amended language

	communicate with each other to ensure that the needs of the patient are addressed and met 24 hours a day.		
418.112(e)(4)(i) and (ii)	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;	418.112(c)(2), 418.112(c)(2)(i) and 418.112(c)(2)(ii)	Amended language
418.112(e)(4)(iii)	A life threatening condition appears;	Deleted	Deleted
418.112(e)((4)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	418.112(c)(2)(iii)	Amended language

	necessary related to the terminal illness; or		
418.112(e)(4)(v)	The patient dies.	418.112(c)(2)(iv)	Amended language
418.112(e)(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.	418.112(c)(3)	Amended language
418.112(e)(6)	An agreement that it is the facility's primary responsibility to furnish room and board.	418.112(c)(4)	New and amended language
New	New	418.112(c)(5)	New
418.112(e)(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	418.112(c)(6)	New and amended language

	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.		
418.112(e)(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	418.112(c)(7)	Amended language

	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.		
New	New	418.112(c)(8)	New
New	New	418.112(c)(9)	New
418.112(f)	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.	418.112(d)	New and amended language
418.112(f)	The plan must reflect	418.56(b) and (c)	New and amended

	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.		language
418.112(f)(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	418.112(d)(1)	Amended language

	upon and included in the plan of care.		
418.112(f)(2)	The plan of care reflects the participation of the hospice, the facility, and the patient and family to the extent possible.	418.112(d)(2)	Amended language
418.112(f)(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 days.	418.56(d)	New and amended language
418.112(f)(4)	Any changes in the plan of care must be discussed among all caregivers and must be approved by the hospice before implementation.	418.112(d)(3)	Amended language
418.112(g)	Coordination of services: The hospice must designate a member of its	418.112(e)(1)	New and amended language

	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.		
418.112(g)(2)-(g)(6)	(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.	418.112(e)(3)	New and amended language
418.112(h)	Transfer, revocation, or	Deleted	Deleted

	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.		
418.112(i)	Orientation and training: 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,	418.112(f)	Amended language

	appropriate forms, and record keeping requirements.		
418.114	**Personnel qualifications for licensed professionals**	Same	Renamed
418.114(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	Same	New and amended language

	registration. All personnel qualifications must be kept current at all times.		
418.114(b)	Personnel qualifications for physicians, speech-language pathologists, and home health aides: The following qualifications must be met:	Same	Renamed. New and amended language
418.114(b)(1)	Physicians.	Same and 418.3	New and amended language
418.114(b)(2)	Speech language pathologists.	418.114(b)(4)	New and amended language
418.114(b)(3)	Home health aides.	418.114(b)(2)	Renamed. New and amended language
418.114(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	Same	New and amended language

	following requirements must be met:		
418.114(c)(1)	Occupational therapist.	418.114(b)(5)	New and amended language
418.114(c)(2)	Occupational therapy assistant.	418.114(b)(6)	New and amended language
418.114(c)(3)	Physical therapist.	418.114(b)(7)	New and amended language
418.114(c)(4)	Physical therapist assistant.	418.114(b)(8)	New and amended language
418.114(c)(5)	Registered nurse. A graduate of a school of professional nursing.	418.114(c)(1)	New and amended language
418.114(c)(6)	Licensed practical nurse. A person who has completed a practical nursing program.	418.114(c)(2)	New and amended language
418.114(c)(7)	Social worker.	418.114(b)(3)	New and amended language
418.114(d)	Criminal background checks: The hospice must obtain a criminal background check on each hospice employee and contracted employee before	Same	New and amended language

	employment at the hospice.		
418.116(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.	418.114(a)	Relocated and amended
418.116(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	418.116(a)	Amended language

	services.		

V. Collection of Information

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

The need for the information collection and its usefulness in carrying out the proper functions of our agency.

The accuracy of our estimate of the information collection burden.

The quality, utility, and clarity of the information to be collected.

Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comment on each of these issues for the following sections of this document

that contain information collection requirements.

Condition of participation: Patient's rights (§418.52)

Section 418.52(a)(1) states that a hospice must provide the patient or representative with verbal and written notice of the patient's right and responsibilities. The notification must be presented in a manner and language consistent with the patient's ability to comprehend the information. Section 418.52(a)(2) requires a hospice to inform and distribute written information on its policies concerning advance directives. The information must include a description of applicable State laws. Section 418.52(a)(3) states that a hospice must obtain the patient's or representative's signature confirming that he or she has received a copy of the notice of rights.

The burden associated with the notification requirements contained in §418.52(a) is the time and effort necessary for a hospice to: develop the notification form; provide, both verbally and in writing, the patient or the patient's representative with a notice of patient's rights; inform and distribute information pertaining to its policies on advance directives and applicable State laws; obtain signatures from the either the patient or representative confirming receipt of a copy of the notice of rights. There are 2,872 hospices that must comply with the aforementioned

requirements. We estimate that it will take each hospice 8 hours to develop the form and 5 minutes to meet the requirements in §418.52(a)(1-3). We estimate that each hospice will on average provide 303 notifications per year for a total one time burden of 22,976 hours and annual burden of 72,518 hours.

Section 418.52(b) sets out the right of the patients to exercise these patient rights and requires hospices to show respect for property and person. Specifically, §418.52(b)(4)(i) states that a hospice is accountable for ensuring that all alleged violations involving mistreatment, neglect or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property by anyone furnishing services on behalf of the hospice are reported immediately to the hospice administrator. Section 418.52(b)(4)(ii) requires a hospice to immediately investigate all alleged violations involving anyone furnishing services on behalf of the hospice and immediately take preventative action to avoid additional violations. As part of the investigation, the hospice must document and maintain all records associated with the alleged violations in accordance with established procedures. Section 418.52(b)(4)(iv) further requires that a hospice report all confirmed violations to the State and

local bodies having jurisdiction within 5 working days of becoming aware of the violation.

The burden associated with the recordkeeping and reporting requirements described in §418.52(b) is the time and effort necessary to report all alleged violations to the hospice administrator, to conduct and document an investigation and to maintain record of the documented investigation. There is also burden associated with reporting all verified allegations to the State and local bodies that have jurisdiction. We anticipate that each of the 2,872 hospices will investigate, document, and report 15 violations per year. We estimate that it will take each hospice 60 minutes per event to satisfy the requirements contained in §418.52(b). The estimated annual burden associated with the requirements contained in §418.52(b) is 43,080 hours.

Condition of participation: Initial and Comprehensive assessment of the patient (§418.54)

Section 418.54 contains the information collection requirements associated with the Initial and comprehensive assessment of the patient. Section 418.54(a) requires a hospice to conduct the initial patient assessment within 48 hours after the patient or representative elects the hospice benefit. Section 418.54(b) states that the hospice IDG must

complete the patient’s comprehensive assessment no later than 5 calendar days after the patient or representative elects the hospice benefit. Section 418.54(c) sets out the content of the assessment. Section 418.54(d) requires that the comprehensive patient assessment be updated as needed based on the patient’s condition, but no less frequently than every 15 days.

The burden associated with the requirements in §418.54 is the time and effort necessary to document and maintain the patient assessment. While these requirements are subject to the PRA, the associated burden is exempt as stated in 5 CFR 1320.3(b)(2); conducting patient assessments is a usual and customary business practice. The time, effort, and financial resources necessary to comply with a collection of information that would be incurred by a person in the normal course of their activities are considered to be usual and customary and is exempt from the PRA.

Condition of participation: Interdisciplinary group care planning and coordination of services (§418.56)

Section 418.56(a) requires a hospice that has more than one IDG to designate a group to establish policies governing the day-to-day provision of hospice care and services. The burden associated with this requirement is the time and effort necessary to draft, implement, and maintain the

policies governing the day-to-day provision of hospice care services. While this requirement is subject to the PRA, the burden is considered to be usual and customary and is exempt as stated under 5 CFR 1320.3(b)(2).

Section 418.56(b) requires all hospice care and services furnished to patients and their families to follow an established plan of care established by the hospice IDG and the patient’s caregivers. In addition, a hospice must ensure that each patient and the primary caregiver(s) receive education and training provided by the hospice. The education and training must be specific to the individual’s responsibilities with respect to the care and services outlined in the plan of care. The burden associated with this requirement is the time and effort associated with educating and training the patient and patient caregiver(s). This requirement is currently approved under OMB control number 0938-0302. The expiration date for the approval is August 31, 2009.

Section 418.56(c) requires hospices to develop an individualized written plan of care for each patient. The plan of care must contain the information described in §418.56(c)(1)-(6). Section 418.56(d) states that the hospice interdisciplinary team must review, revise, and document the individualized plan of care as frequently as

the patient’s condition warrants, but no less frequently than every 15 days. The burden associated with these requirements is the time and effort associated with drafting, reviewing, revising, and maintaining the plan of care. This requirement is currently approved under OMB control number 0938-0302, with and expiration date of August 31, 2009.

Section 418.56(e) describes the standard for the coordination of hospice services. Specifically, it states that a hospice must develop and maintain a system of communication and integration to ensure the information contained in §418.56(e)(1)-(5). The burden associated with this requirement is the time and effort required to develop and maintain the system of communication in accordance with the hospice’s policies and procedures. While this requirement is subject to the PRA, the associated burden is considered to be usual and customary as stated in 5 CFR 1320.3(b)(2).

Condition of participation: Quality assessment and performance improvement (§418.58)

Section 418.58 states that a hospice must develop, implement, and maintain an effective, ongoing, hospice-wide data-driven quality assessment and performance improvement (QAPI) program. In addition, the hospice must maintain

documentary evidence of its quality assessment and performance improvement program and be able to demonstrate its operation to CMS. Section 418.58(a) describes the required scope of the QAPI program. Specifically, §418.58(a)(1) discusses the documentation requirements. The QAPI program must be able to demonstrate measurable improvement in indicators related to improved palliative outcomes and hospice services. Section 418.58(a)(2) states that the hospice must measure, analyze, and track quality indicators.

Section 418.58(b)(2) states that a hospice must use the data to monitor the effectiveness and safety of services and quality of care. As part of the monitoring process, the data must be used to identify improvement opportunities. The data must also be used to assist in the prioritization of the aforementioned opportunities for improvement.

Section 418.58(c)(2) states that as part of performance improvement activities, a hospice must track adverse patient events, analyze their causes, and implement preventative actions and mechanisms that include feedback and learning throughout the hospice. Section 418.58(c)(3) requires a hospice to measure its success and track performance in its performance improvement initiatives to ensure that the improvements are continuous.

Section 418.58(d) discusses that standard for performance improvement projects. Hospices are responsible for developing, implementing, and evaluating performance improvement projects. Section 418.58(d)(2) requires hospices to document their performance improvement projects, the reason for conducting each project, and the measurable progress achieved as a result of the projects.

The burden associated with the requirements contained in §418.58 is the time and effort necessary to develop, draft, and implement a QAPI program. As part of the QAPI program, there is also burden associated with recording quality data for performance improvement initiatives. We estimate that for all 2,872 hospices, 1 hour per hospice will be required to comply with the documentation of the domains and measures, 91 hours per hospice for data entry and 48 hours to aggregate the data. This is an annual burden of 140 hours per hospice to meet the requirement of this section. The estimated annual burden associated with the requirements in §418.58 is 402,080 hours annually.

Condition of participation: Infection control (§418.60)

Section 418.60(a) requires hospices to maintain and document an effective infection control program. The goal of the program is to protect patients, families, visitors, and hospice staff by preventing and controlling infectious

and communicable diseases. Section 418.60(b) provides the standard for effective hospice infection control programs. Section 418.60(c) describes the standard for education with respect to infection control. Hospices must provide infection control education to employees, contracted providers, patients, and family members and other care givers.

The burden associated with the requirements in §418.60(a)-(c) is the time and effort associated with developing, implementing, documenting, and maintaining an effective infection control program. There is also burden associated with providing infection control education. While these requirements are subject to the PRA, the burden is exempt as stated in 5 CFR 1320.3(b)(2). The existence of an effective infection control program is a usual and customary business practice in the hospice care industry.

Condition of participation: Core services (§418.64)

Section 418.64 states that hospices may contract for the physician services contained in §418.64(a). A hospice may also enter into a written agreement with another Medicare-certified hospice program for the provision of the core services. The burden associated with these requirements is the time and effort necessary to develop, draft, sign, and maintain contracts and written agreements.

The burden associated with these requirements is exempt from the PRA as stated in 5 CFR 1320.3(b)(2); the use of contracted physicians and the use of written agreements between two Medicare certified hospice programs for the provision of core services constitutes a usual and customary business practice.

Section 418.64(d) describes the standard for counseling services. Hospices are required to make counseling services available to patients and families to provide comfort and assistance with coping and stress management associated with the dying process. Specifically, section §418.64(d)(1)(iv) states that as part of bereavement counseling, a hospice must develop a bereavement plan of care that notes the kind of bereavement services to be offered and the frequency of service delivery. Section 418.64(d)(3) states that a hospice must provide an assessment of the patient’s and family’s spiritual needs, provide spiritual counseling to meet those needs in a manner that is accepted by the patient and family and is consistent with their respective beliefs, facilitate visits by individuals that can meet the patient’s spiritual needs, and advise the patient and family of the availability of the aforementioned bereavement counseling services. We believe the requirements in §418.64(d) are usual and customary business practices; and therefore, the

burden is not subject to the PRA as stipulated in 5 CFR 1320.3(b)(2).

Condition of participation: Nursing services—Waiver of requirement that substantially all nursing services be routinely provided directly by a hospice (§418.66)

Section 418.66(a) allows CMS to waive the requirement in §418.64(b) that a hospice provide nursing services directly, if the hospice is located in a nonurbanized area. To obtain a waiver, the hospice must provide evidence to CMS that it made good faith efforts to hire a sufficient number of nurses to provide services. As part of CMS' review process, the a hospice must meet the criteria outlined in §418.66(a)(1)-(3). To obtain an extension for a currently approved waiver, a hospice must submit its request to CMS prior to the expiration of the waiver period and certify that the conditions under which the hospice originally requested the waiver have not changed. The burden associated with this requirement is the time and effort associated with a hospice demonstrating good faith efforts for it staffing process and submitting a certified extension request to CMS stating that the circumstances that caused the original waiver request have not changed. We believe this requirement and the associated burden is exempt from the PRA under 5 CFR 1320.3(c)(4). We believe the

requirement will affect less than 10 entities on an annual basis.

Waiver of requirement-Physical therapy, occupational therapy, speech-language pathology, and dietary counseling (§418.74)

Section 418.74(a) allows CMS to waive the requirement for providing physical therapy, occupational therapy, speech-language pathology, and dietary counseling services (as needed) on a 24-hour basis for hospices located in non-urbanized areas. In addition, CMS can waive the requirement that a hospice provide dietary counseling directly. To obtain a waiver, a hospice must provide evidence to CMS that it made good faith efforts to meet the requirements for the aforementioned services prior to submitting a waiver request. As part of CMS' review process, a hospice's waiver request must meet the criteria outlined in §418.74(a)(1)-(2). To obtain an extension for a currently approved waiver as stated in §418.74(d), a hospice must submit its request to CMS prior to the expiration of the waiver period and certify that the conditions under which the hospice originally requested the waiver have not changed. The burden associated with this requirement is the time and effort associated with a hospice demonstrating good faith efforts for it staffing process and submitting a certified

extension request to CMS stating that the circumstances that caused the original waiver request have not changed. We believe this requirement and the associated burden is exempt from the PRA under 5 CFR 1320.3(c)(4). We believe the requirement will affect less than 10 entities on an annual basis.

Condition of participation: Hospice aide and homemaker services (§418.76)

Section 418.76(b) outlines the standard for the content and duration of hospice aide classroom and supervised practical training. A hospice aide training program must meet the criteria in §418.76(b)(1)-(3). Section 418.76(b)(4) requires that a hospice maintain documentation demonstrating that its training program meets the requirement of the standard contained in §418.76(b). We estimate that it will take each hospice 5 minutes to document and maintain records that its hospice aide training program met all of the requirements contained in this section, for a total annual burden of 239 hours.

Section 418.76(c) describes the standard for competency evaluations. In particular, §418.76(c)(5) states that a hospice must maintain documentation that all individuals furnishing hospice aide services on behalf of a hospice successfully completed a competency evaluation program. The

competency evaluation program must meet the requirements specified under §418.76(b)(3). The burden associated with this requirement is the time and effort necessary to maintain documentation that demonstrates all individuals furnishing hospice aide services on behalf of a hospice successfully completed a competency evaluation program. We estimate it will take each hospice 5 minutes to meet this requirement, for a total annual burden of 239 hours.

Section 418.76(d) discusses the standard for in-service training. Hospices are required to maintain documentation that all hospice aides have received at least 12 hours of in-service training during each 12-month period. The burden associated with this requirement is the time and effort necessary to document and maintain record of the required in-service training. We estimate it will take each hospice 2 hours annually to meet this requirement. The estimate total annual burden for this requirement is 5,744 hours.

Section 418.76(g) describes the standard for hospice aide assignments and duties. Specifically, §418.76(g)(1) states that written patient care instructions for a hospice aide must be drafted by a registered nurse responsible for the supervision of a hospice aide. The burden associated with this requirement is the time and effort necessary for a registered nurse responsible for supervising a hospice aide to draft written patient care instructions for the hospice aide. We believe this is a usual and customary business practice and is thereby exempt from the PRA under 5 CFR

1320.3(b)(2).

Section 418.76(h) explains the standard for the supervision of hospice aides. In particular, §418.76(h)(1)(i) stated that a registered nurse must make an onsite visit to a patient's home no less frequently than every 14 days to assess and document the quality of care and services provided by the hospice care aide and to ensure that the services ordered by the hospice's IDG meet the patient's needs. The burden associated with this requirement is the time and effort necessary for a nurse to conduct an onsite evaluation of a hospice care aide in the patient's home, to document the quality of care provided by the hospice care aide, and to evaluate the services ordered by the IDG to ensure that they are consistent with the patient's needs. We believe this is a usual and customary business practice and is thereby exempt from the PRA under 5 CFR 1320.3(b)(2).

Section 418.76(h)(2) states that a registered nurse must also make an annual onsite visit to the location to the location where a patient is receiving care to observe and evaluate each aide while he or she is performing care. Section 418.76(h)(3) details the contents of the registered nurse's assessment required in 418.76(h)(3). The burden associated with this requirement is the time and effort necessary for a registered nurse to make an annual on site visit to observe and evaluate each hospice aide while they

perform care. In addition, they must document the evaluation. We estimate to meet this requirement that 5 supervisory visits will be conducted at on an annual basis per hospice with a total of 14,360 visits annually. We believe it will take each nurse 5 minutes to document the onsite visit. The estimated total annual burden associated with this requirement is 1,197 hours.

Section 418.76(i)(1) contains the standard for individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit. Prior to furnishing personal care services, an individual must demonstrate competency in the services they are required to furnish. The burden associated with this requirement is the time and effort necessary to demonstrate competency. While this requirement is subject to the PRA, we believe the associated burden is exempt stated in 5 CFR 1320.3(b)(2). We believe this is a usual and customary business practice.

Section 418.76(k)(2) requires the instructions for homemaker duties to be prepared by a member of the hospice IDG. The burden associated with this requirement is the time and effort necessary for a member of the IDG to develop and draft instructions for homemaker duties. We believe this is a usual and customary business practice and is thereby exempt from the PRA under 5 CFR 1320.3(b)(2).

Section 418.76(k)(3) states that homemakers must report all concerns about the patient or family to the member of the IDG who is coordinating the homemaker's services. The burden associated with this requirement is the time and effort needed for the homemaker to report all concerns. We believe the burden is exempt as stated in 5 CFR 1320.3(b)(2); this is a usual and customary business practice.

Conditions of participation—Volunteers (§418.78)

Section 418.78(a) states that a hospice must document, maintain, and provide volunteer orientation and training that is consistent with hospice industry standards. We estimate on average that a hospice would provide orientation and training six times per year; we estimate that it will take no longer than five minutes to document each orientation section for a total of 30 minutes per year per hospice. The total annual burden associated with this requirement is 1,436 hours.

Section 418.78(c) requires hospices to document and demonstrate viable and ongoing efforts to recruit and retain volunteers. The burden associated with this requirement is the time and effort necessary to document and demonstrate the recruitment and retention efforts. We estimate that it will take each hospice 3 hours to document and demonstrate

its recruitment and retention efforts, for a total annual burden of 8,616 hours.

The cost-saving standard in §418.78(d) requires hospices to document the cost savings achieved through the use of volunteers. We estimate that complying with this requirement will take 3 hours per hospice per year, or 8,616 annual hours.

Section 418.78(e) requires hospices to document and maintain records on the use of volunteers for patient care and administrative services, including the type of services and time worked. The burden associated with this requirement is the time and effort necessary to document and maintain the volunteer records. We estimate that recording these examples would take approximately 600 hours per hospice for a total annual burden of 1,723,200 hours.

Condition of participation: Organization and administration of services (§418.100)

Section 418.100(e) describes the standard for professional management responsibilities. 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 oversight of staff and services for all arranged services, to ensure the provision of quality care. The burden

associated with this requirement is the time and effort necessary to develop, draft, execute and maintain the written agreements. We believe these written agreements are part of the usual and customary business practices of hospices and are thereby exempt from the PRA under 5 CFR 1320.3(b)(2).

Section 418.100(f)(2) states that a hospice must continually monitor and manage all services provided at all of its locations. The burden associated with this requirement is the time and effort necessary to monitor and manage all of the services provided at all of its locations. The burdens associated with this requirement is considered to be usual and customary as stated in 5 CFR 1320.3(b)(2) and is thereby exempt from the PRA.

Section 418.100(g) describes the standard for training. In particular, §418.100(g)(2) requires a hospice to provide an initial orientation for each employee that addresses the employee’s specific job duties. Section 418.100(g)(3) requires a hospice to have written policies and procedures describing its method(s) of assessment of competency. In addition, the hospice must maintain a written description of the in-service training provided during the previous 12 months. The burden associated with the requirements of this section is considered to be usual and customary under 5 CFR

1320.3(b)(2); usual and customary burdens are exempt from the PRA.

Condition of participation: Medical director (§418.102)

Section 418.102(b) requires hospice medical directors or physician designees to review the clinical information for each hospice patient and provide written certification that it is anticipated that the patient's life expectancy is 6 months or less if the illness runs its normal course. Prior to making a certification statement, the medical director or physician designee must consider the issues discussed in §418.102(b)(1)-(5). Section 418.102(c) states that before the recertification period for each patient, as described in §418.21(a), the medical director or physician designee must review the patient's clinical information.

The burden associated with the requirements contained in §418.102(b)-(c) is the time and effort necessary to review the written certification. We estimate this process requires 10 minutes per patient. We estimate the burden for each hospice to be 50 hours annually. The total annual burden associated with the requirements of this section is 143,600 hours.

Condition of participation: Clinical records (§418.104)

Section 418.104 requires a hospice to maintain a clinical record for each patient. The required contents of

the record are listed in §418.104(a). The burden associated with the requirement is the time and effort necessary to document and maintain the information listed in §418.104(a). The maintenance of clinical records is a usual and customary business practice; the burden associated with maintaining a clinical record is exempt form the PRA under 5 CFR 1320.3(b)(2).

Section 418.104(b) requires that all of the entries in a clinical record be authenticated. The entries must be legible, clear, complete, and consistent with hospice policy. The burden associated with this requirement is considered to be usual and customary under 5 CFR 1320.3(b)(2). This usual and customary burden is therefore exempt from the PRA.

Section 418.104(d) describes the standard for the retention of records. Clinical records must be retained for 6 years after the death or discharge of the patient, unless State law stipulates a longer period of time. If the hospice discontinues operation, hospice policies must provide for retention and storage of clinical records. The burden associated with these requirements is the time and effort necessary to maintain records for 6 years after the death or discharge of the patient, and to draft, implement, and maintain the record retention policy in the event that the HHA discontinues operation. While this requirement is

subject to the PRA, we believe the associated burden is exempt as stated in 5 CFR 1320.3(b)(2). The development and maintenance of a record retention policy is a usual and customary business practice.

Section 418.104(f) describes the standard for the retrieval of clinical records. Clinical records, whether in hard copy or electronic form, must be made readily available on request by an appropriate authority. The burden associated with this requirement is the time and effort required to disclose a clinical record to an appropriate authority. While this requirement is subject to the PRA, we believe the associated burden is exempt as stated in 5 CFR 1320.3(b)(2). Making clinical records available to the appropriate authority is part of the survey and certification process and imposes no additional burden as a usual and customary business practice.

Condition of participation: Drugs, controlled drugs and biologicals, medical supplies, and durable medical equipment (§418.106)

Section 418.106(b) describes the standard for the ordering of drugs. In particular, §418.106 (b)(2)(ii) states that the individual receiving a drug order must record and sign it immediately and have the prescribing person sign it in accordance with State and Federal regulations. The burden associated with this requirement is the time and effort necessary for the recipient of the order

record and sign the order and to have the prescribing person sign the prescription. The burden associated with this requirement is exempt under both 5 CFR 1320.3(b)(2) and 5 CFR 1320.3(b)(3). As defined in 5 CFR 1320.3(b)(2), this process is a usual and customary business practice. As defined in 5 CFR 1320.3(b)(3), a State requirement would exist even in the absence of the Federal requirement. The associated burden is thereby exempt from the PRA.

Section 418.106(c)(2) states that a hospice that provides inpatient care directly in its own facility must have a written policy in place that promotes dispensing accuracy. Additionally, this section requires that a hospice that provides inpatient care directly must maintain current and accurate records of the receipt and disposition of all controlled drugs. The burden associated with this requirement is the time and effort necessary to develop, draft, implement, and maintain a written policy that promotes dispensing accuracy and to maintain controlled drug records. The existence of this type of policy and these records are usual and customary business practices. The burden associated with this section is exempt from the PRA under 5 CFR 1320.3(b)(2).

Section 418.106(e) discusses the standard for labeling, disposing and storing of drugs and biologicals.

Specifically, §418.106(e)(2)(i) states that a hospice must have a written policy for the management and disposal of controlled drugs in the patient's home. As required by §418.106(e)(2)(i)(A), a hospice must provide a copy of the written policy required in §418.106(e)(2)(i) to the patient, and his/her representative and family. Additionally, the hospice must discuss the hospice policy for managing the safe use and disposal of controlled drugs with the patient or representative and the family in a language and manner they can understand to ensure that these parties are educated regarding the safe use and disposal of controlled drugs, as required by §418.106(e)(2)(i)(B). Section 418.106(e)(2)(i)(C) requires a hospice to document in a patient's clinical record that the written policy for managing controlled drugs was provided and discussed. Section 418.106(e)(2)(ii) states that a hospice maintain current and accurate records of the receipt and disposition of all controlled drugs.

The burden associated with the requirements contained in §418.106(e)(2) is the time and effort necessary to provide a written copy of the policy on the management and disposal of controlled drugs in the patient's home to the patient representative and family. There is also some burden associated with the hospice explaining the policy to

the patient or representative and the family. In addition, there is a burden associated with documenting in the patient's clinical record that the written policy for managing and controlled drugs was provided and discussed. We believe the burden associated with the aforementioned requirements is exempt from the PRA under 5 CFR 1320.3(b)(2), as they are part of the usual and customary business practice for hospices.

Section 418.106(e)(3)(ii) states that the hospice pharmacist and the hospice administrator are required to immediately investigate any discrepancies in the acquisition, storage, dispensing, administration, disposal, or return of controlled drugs. The event must be reported to the appropriate State authority. A written account of the investigation must be made available to State and Federal officials if required by law or regulation. The burden associated with this requirement is exempt under both 5 CFR 1320.3(b)(2) and 5 CFR 1320.3(h)(6). As defined in 5 CFR 1320.3(b)(2), documenting an investigation and reporting the investigation to the appropriate State authority is a usual and customary business practice. Additionally, the burden associated with making a written account of the investigation available to State and Federal officials upon request is exempt from the PRA under 5 CFR

1320.3(h)(6); the information will be collected from individual hospices on a case by case basis. As stated under in 5 CFR 1320.3(h)(6), information collection requests addressed to a single “person” as defined in 5 CFR 1320.3(b)(4), are exempt from the PRA.

Section 418.106(f)(1) states that a hospice must ensure that repair and routine maintenance policies are developed in situations when a manufacturer’s recommendation for a piece of equipment is nonexistent. Section 418.106(f)(2) requires a hospice to ensure that the patient, family, and other caregivers receive instruction in the safe use of durable medical equipment and supplies. After providing instruction, the patient, family, and/or caregiver must be able to demonstrate the appropriate use of durable medical equipment. The burden associated with the requirements in §418.106(f)(1)-(2) is the time and effort necessary to develop, draft, implement, and maintain repair and routine maintenance policies. There is also burden associated with providing proper instruction on the use of durable medical equipment to patient, family members, and caregivers. As defined in 5 CFR 1320.3(b)(2), providing proper instruction on the use of durable medical equipment to patient, family members, and caregivers is a usual and customary business practice.

Condition of participation--Short-term inpatient care (§418.108)

Section 418.108(c) requires the use of a written agreement if a hospice has an arrangement with a facility to provide short-term inpatient care. At a minimum, the agreement must address the issues outlined in §418.108(c)(1)-(6). The burden associated with this requirement is the time and effort necessary to develop, draft, execute, and maintain the written agreement. While this requirement is subject to the PRA, the burden is exempt under 5 CFR 1320.2(b)(2). The use of the written agreements between facilities is a usual and customary business practice.

Condition of participation: Hospices that provide inpatient care directly (§418.110)

Section 418.110(c)(1)(ii) states that a hospice must have a written disaster preparedness plan in effect to manage emergencies that might compromise the hospice's ability to provide care. Additionally, the plan must be periodically reviewed. The burden associated with this requirement is the time and effort necessary to develop, draft, implement, maintain, and periodically review the disaster preparedness plan. Section 418.110(c)(2) requires

hospices to develop procedures for managing physical plant issues.

The burden associated with the requirements in §418.108(c) is the time and effort necessary to draft, implement, maintain, and review the facility's disaster preparedness plans and procedures to address physical plant issues. While these requirements are subject to the PRA, we believe the associated burden is exempt as stated in 5 CFR 1320.3(b)(2).

Section 418.110(m)(3)(i) specifies that the use of restraint and seclusion must be used in accordance with a written modification to the plan of care. The use of restraint and seclusion must be implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospice policy in accordance with State law. The burden associated with this requirement is the time and effort necessary to modify the plan of care in writing to include the physician order for restraint and seclusion.

Section 418.110(m)(4) states that the use or restraint or seclusion must be done in accordance with a physician's orders. There is a burden associated with creating a physician's order. However, we believe the burden associated with the aforementioned requirements is exempt

from the PRA under 5 CFR 1320.3(b)(2), as they are part of the usual and customary business practice for hospices.

Section 418.110(m)(7)(ii) states that prior to writing a new order for the use of restraint or seclusion, a physician must see and assess the patient. The burden associated with this requirement is the time and effort necessary for the ordering physician to see and assess the patient.

Section 418.110(m)(15) states that when restraint or seclusion is used, a patient's clinical record must contain the documentation outlined in §418.110(m)(15)(i)-(v). The burden associated with this requirement is the time and effort necessary to compile the documentation specified in §418.110(m)(15)(i)-(v) in the patient's clinical record. We estimate the collective burden associated with the requirements contained in 418.110(m)(3)(i), 418.110(m)(7)(ii), and 418.110(m)(15) to be 45 minutes per event per hospice for a total of 8,702 events annually. The annual burden associated with the aforementioned information collection requirements is 6,527 hours.

Section 418.110(n) discusses the standard for restraint or seclusion staff training requirements. Specifically, §418.110(n)(1) states that all patient care staff working in the hospice inpatient facility must be trained and able to

demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment and providing care for a patient in restraint or seclusion. Section 418.110(n)(4) states that a hospice must document in the personnel records that each employee successfully completed the restraint and seclusion training and demonstrated competency. We estimate that it will take 96 hours to comply with these requirements. The estimated total annual burden associated with these requirements is 275,512 hours.

Section 418.110(o) states that hospices must report deaths associated with the use of restraint or seclusion. The hospice staff must document in the decedents clinical record the date and time the death was reported to CMS. We cannot accurately estimate the number of deaths that would occur annually as a result of restraint or seclusion. However, we believe the number is less than 10 per year. While this requirement is subject to the PRA, we believe the burden is exempt under 5 CFR §1320.3(c)(4), as it would affect less than 10 entities

Condition of participation: Hospices that provide hospice care to residents of a SNF/NF or ICF/MR (§418.112)

Section 418.112(c) discusses the requirement that a hospice and SNF/NF or ICF/MR must have a written agreement

that specifies the provision of hospice services in the facility. The agreement must be signed by authorized representatives of the hospices and the SNF/NF or ICF/MR prior to the provision of hospice care services. At a minimum, the written agreements must address the issues listed in **§**418.112(c)(1)-(8). The burden associated with this requirement is the time and effort necessary to develop, draft, sign, and maintain the written agreement. However, the use of this type of written agreement is a usual and customary business practice; the associated burden is exempt from the PRA under 5 CFR §1320.3(b)(2).

Section 418.112(d) discusses the standard for the hospice plan of care. A written plan of care must be established and maintained in consultation with SNF/NF or ICF/MR representatives. The burden associated with this requirement is discussed in detail under our discussion of §418.56(c).

Condition of participation: Personnel qualifications. (§418.114)

Section 418.114(d)(1) requires hospices to obtain criminal background checks on all hospice employees who have direct patient contact or access to patient records. Additionally, all hospice contracts must require that all contracted entities obtain criminal background checks on

contracted employees who have direct patient contact or access to patient records. The burden associated with this requirement is the time and effort necessary to conduct background checks and the time and effort necessary to develop, draft, and maintain contracts that require all contracted staff to obtain background checks. While this requirement is subject to the PRA, we believe the associated burden is exempt as stated in 5 CFR 1320.3(b)(2). While fulfilling these requirements, a hospice will not incur any burden above and beyond its usual and customary business practice.

Table XX: Estimated Annual Reporting and Recordkeeping Burden

Regulation Section(s)	OMB Control Number	Respondents	Responses	Total Annual Burden (hours)
§418.52(a)	0938-New	2,872	870,216	72,518
§418.52(b)	0938-New	2,872	43,080	43,080
§418.56(b-c)	0938-0302	2,874	2,874	9,930,912
§418.58	0938-New	2,872	2,872	402,080
§418.76(b)(4)	0938-New	2,872	2,872	239
§418.76(c)	0938-New	2,872	2,872	239
§418.76(d)	0938-New	2,872	2,872	5,744
§418.76(h)(2)	0938-New	2,872	14,360	1,197
§418.78(a)	0938-New	2,872	2,872	1,436

§418.78(c)	0938-New	2,872	2,872	8,616
§418.78(d)	0938-New	2,872	2,872	8,616
§418.78(e)	0938-New	2,872	2,872	1,723,200
§418.102(b-c)	0938-New	2,872	2,872	143,600
§418.110(m)(15)	0938-New	2,872	8,702	6,527
§418.110(n)(1-4)	0938-New	2,872	2,872	275,512
Total		2,874	967,952	12,623,516

We have submitted a copy of this final rule to OMB for its review of the information collection requirements contained within this document. These requirements are not effective until they are approved by OMB.

VI. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is

necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($110 million or more in any 1 year). This is not a major rule, since the overall economic impact for all proposed new Conditions of Participation is estimated to be $40.7 million in the first year.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. Individuals and States are not included in the definition of a small entity. For purposes of the RFA, most hospices (approximately 82% of Medicare certified facilities) are considered to be small entities, either by virtue of their nonprofit or government status or by having revenues of less than $12.5 million in any one year (for details, see the Small Business Administration's regulation that sets forth size standards for health care industries at 65 FR 69432). We estimate there are approximately 2,872 hospices with average admissions of approximately 303 patients per hospice (based on the number of patients in 2005 divided by the number of hospices in 2005). The National Hospice and Palliative Care Organization (Facts and Figures—2005 Findings) estimates that 82.4 percent of hospice patients

are Medicare beneficiaries, thus we have not considered other sources of revenue in this analysis.

We certify that this rule would not have a significant impact on a substantial number of small entities because the cost of this rule is less than 1 percent of total hospice Medicare revenue. According to the CMS 2005 national expenditure data, Medicare paid $8.2 billion to providers for hospice care in FY 2005. We estimate this rule will cost hospices approximately $40.7 million or approximately $32,223 per average hospice (operating its own inpatient unit and requiring the supervisory services of an MSW) in the first year. An average hospice that does not operate its own inpatient unit and does not need to hire an MSW, accounting for the vast majority of hospices, will expend $11,151 to comply with this final rule in the first year. While we understand that a few very small hospices (described below) may expend a larger percentage of their revenue to comply with this rule, we believe that this group of hospices is quite small.

We understand that there are different sizes of hospices and that the burden for hospices of different sizes will vary. Therefore, we have assessed the burden for hospices that are smaller than the statistically average hospice used for calculations in part B of this section, Anticipated effects on hospices. The smaller hospices have been broken up into two categories based on the number of routine home care days, the most common level of hospice

care provided. The categories are group 1 hospices providing 0 to 1,754 routine home care days, and group 2 hospices providing 1,755 to 4,373 routine home care days. Group 1 hospices, averaging 67 patients per year, would spend approximately $18,980 or $5,980, depending on the need to hire and MSW supervisor, to comply with these regulations. The average hospice in this group received $229,406 from Medicare for routine home care days under the 2005 hospice payment rates. Group 2 hospices, averaging 167 patients per year, would spend approximately $21,191 or $8,191, also depending on the need to hire an MSW supervisor, to comply with these regulations. The average hospice in this group received $571,945 from Medicare for routine home care days under the 2005 rates.

The time and cost burden for these providers is less than that of the average hospice used in part B of this section because a portion of the burden associated with these regulations is directly related to patient care and the staff necessary to provide care. Therefore, a consistently smaller patient census leads to reduced burden because the smaller hospices have less staff, complete less data collection and less patient rights orientation etc. These estimates of the annual burden for smaller hospices make only minor adjustments to the estimated quality assessment and performance improvement burden described in part B of this section in the area of patient level data collection. Additionally, these figures do not include the

time and cost burden estimates associated with a hospice inpatient facility because it is very uncommon for a hospice with a small annual patient census to operate its own inpatient facility. We estimate that the financial burden for group 1 hospices would be approximately 8.25 or 2.5 percent of the payment received for routine home care days, depending on whether or not the hospice needs to hire an MSW supervisor. For group 2 hospices, the financial burden would be 3.75 or 1.5 percent of the payment received for routine home care days, also depending on whether or not the hospice needs to hire an MSW supervisor. Since employing an MSW is considered the standard within the hospice industry, we believe that very few group 1 and 2 hospices will incur the additional expense of hiring an MSW above their present level of staffing (see B., Anticipated effects on hospices, Personnel qualifications for a more detailed discussion). These percentages do not include amounts paid by Medicare for continuous home care days, respite care days, and regular inpatient care days. The percentages also do not include amounts paid by Medicaid, private insurers, and individual patients, which account for approximately 18 percent of hospice revenue. Additionally, these percentages do not include additional income from fundraising, donations, foundations, etc. that hospices routinely use to finance operations and programs. Therefore, we believe that the actual cost incurred by a group 1 or a group 2 hospice accounts for a significantly smaller portion of hospice's

overall revenue, and does not have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We believe that this rule would not have a significant impact on the operations of a substantial number of small rural hospitals, since there are few hospice programs in those facilities. Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $127 million. This final rule does not contain mandates that will impose spending costs on State, local, or tribal governments in the aggregate, or by the private sector of $127 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct compliance costs on State or local governments, preempts State law, or otherwise has

Federalism implications. This rule has no Federalism implications.

B. Anticipated Effects on Hospices

As described in the preamble, this final rule contains both new provisions and provisions that are carried over from the existing hospice regulations. For purposes of this section, we have assessed the impact of all provisions that may present a burden to a hospice.

Within this section, we have made several assumptions and estimates in order to assess the time that it would take for a hospice to comply with the provisions and the associated costs of compliance. We have detailed these assumptions and estimates in the table below. We have also detailed many, but not all, of the standards within each CoP, and have noted whether or not there is an impact for each. However, the requirements contained in many provisions are already standard medical or business practices. These requirements would, therefore, not provide additional burden to hospice providers.

Our assumptions are based on the idea of an average hospice, culled from national averages. While we understand that there is no average hospice, the idea of an average hospice allows us to quantify the impact of this final rule on a hospice's resources. For purposes of this section only, we describe an average hospice as one that is:

Freestanding;

Not-for-profit;

26 day median length of stay (NHPCO Facts & Figures 2005);

303 annual admissions;

40 employees and volunteers;

27% of patients residing in a SNF/NF, ICF/MR or assisted living facility; and

Table 1: Assumptions and estimates used throughout the Impact Analysis section

# of Medicare hospices nationwide	2,872
# of hospice patients nationwide	869,201
# of patients per average hospice	303
Hourly rate of registered nurse	$35
Hourly rate of office employee	$14
Hourly rate of administrator	$49
Hourly rate of home health aide	$19
Hourly rate of MSW	$25
Hourly rate of pharmacist	$56
Hourly rate of clinical manager	$36
Hourly rate of QAPI coordinator	$35
Hourly rate of medical director	$114

Note: All salary estimates include benefits package worth 30% of the fringe base salary.

Patient Rights (§418.52)

The final rule expands on the informed consent section (§418.62) of the current rule, recognizing that hospice patients are entitled to certain rights that must be protected and preserved, and that all patients must be able to freely exercise those rights.

(a) Standard: Notice of Rights. A hospice is required to provide patients or their representatives with written and verbal notice of the patient's rights and responsibilities during the initial assessment visit. A hospice is also required to document that the notice of rights was provided by obtaining the patient's or representative's signature. A hospice must also inform and distribute written information to the patient regarding its policies on advance directives. We estimate that it will take eight hours on a one time basis for a hospice to develop a patient rights form, at a cost of $392, based on the assumption that an administrator will develop the form. We estimate that it will take approximately five minutes per patient to incorporate this information into the existing informed consent process. At the average hourly rate for a registered nurse, it will cost $2.92 per patient to fulfill the requirement.

8 hours x $49 an hour= $392

$35 hour/60 minutes = $0.58 minute x 5 minutes = $3

(b) Standard: Exercise of rights and respect for property and person. A hospice is required to investigate and

document all allegations of abuse, unexplained injuries, and misappropriations of patient property involving hospice employees and contractors. Hospice employees and contractors must report alleged patient rights violations to the hospice administrator, and must report verified violations to appropriate State and local bodies having jurisdiction. A hospice must also take action to correct problems once they are identified.

We expect that a hospice administrator will investigate alleged patient rights violations. We estimate that as many as 5% (15) of an average hospice's patients would require a one hour-long investigational session, for a total of 15 hours per hospice. The cost for the entire hospice industry would be $2,110,920 a year, while the cost for an average hospice would be $735 a year.

15 investigations per hospice x 1 hour per investigation = 15 hours per hospice

$49 hour x 15 hours per hospice = $735 per average hospice

15 hours per hospice x 2872 hospices = 43,080 hours nationwide

$735 per average hospice x 2872 hospices = $2,110,920

<u>(c) Standard: Rights of the patient.</u> There is no burden associated with this standard.

Table 2: Patient rights burden assessment.

Standard	Time per patient	Time per hospice	Total time	Cost per patient	Cost per average hospice	Total cost
Develop form (1st year)	N/A	8 hours	22,976 hours	N/A	$392	$1,125,824
Notice of rights (annual)	5 minutes	25.25 hours	72,433 hours	$3	$885	$2,538,130
Exercise of rights (annual)	N/A	15 hours	43,080 hours	N/A	$735	$2,110,920
Totals	**5 minutes**	**48.25•hours**	**138,489 hours**	**$3**	**$2,012**	**$4,649,379**

Comprehensive Patient Assessment (§418.54)

(a) Standard: Initial assessment and (b) Standard: Time frame for completion of the comprehensive assessment.

The existing rule (§418.58(c)) requires the hospice to assess the patient's needs and to state in detail the scope and frequency of services needed. The final rule goes beyond this by specifying the time for completing the assessment, the factors to be included in the assessment, and the time for updating the assessment. However, we do not believe this will add any additional burden, since this section of the proposed rule reflects the contemporary standard practice of hospice programs.

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

assessment must identify the physical, psychosocial, emotional, and spiritual needs related to the terminal illness and related conditions that must be addressed in order to promote a hospice patient's well-being, comfort and dignity throughout the dying process. The assessment will include factors such as the patient's physical and nutritional needs, pain status, and psychological state. The assessment will also address complications and risk factors, functional status, imminence of death, severity of symptoms, drug profile and bereavement. This differs from the current rule in that it describes what must be included in the assessment. The factors of the comprehensive assessment were identified by the hospice industry and reflect standard industry practice.

(d)Standard: Update of the comprehensive assessment. Updates of the patient's comprehensive assessment must be conducted at least every 15 days or as frequently as the condition of the patient requires. The current regulation allows the plan of care to determine the frequency of updates. However, due to the rapidly changing status of hospice patients, it is standard practice for a hospice to update a patient assessment at least every 15 days, and often more frequently. This 15-day requirement is also in line with the recertification periods, at which time a hospice must review the patient's clinical information to determine whether a patient continues to be terminally ill with a prognosis of 6 months or less if the illness runs its

usual course. This new standard simply codifies current industry practice and does not present a burden.

(e)Standard: Patient outcome measures. The comprehensive assessment must include consistent, pre-determined data elements that allow for the measurement of patient care outcomes. (Note: There is no data reporting element.)

We believe this standard will pose a burden on the hospice provider. However, the burden of collecting information related to these outcome measures is calculated as part of a hospice's quality assessment and performance improvement program.

Interdisciplinary Group, Care Planning and Coordination of Services (§418.56)

The final rule makes several changes to the existing rule to improve patient care and lessen burden.

(a) Standard: Approach to service and delivery. This standard describes the members of the IDG and its role in patient care planning and delivery. There is no burden associated with this standard.

(b) Standard: Plan of care and (c) Standard: Content of the plan of care. This section describes the general content areas of each patient's plan of care. The items that are required under the final rule are already included in the standard industry patient plan of care.

(d) Standard: Review of the plan of care. The existing rule states that a patient's plan of care must be reviewed at intervals specified in the initial plan of care. The

final rule requires that the plan of care be reviewed at least every 15 days. Several commenters noted that documenting an update to a patient's plan of care takes 1-2 hours of a nurse's time per update. We agree that updating a patient's plan of care requires a fair amount of nursing time. However, we do not believe that requiring a hospice to update a patient's plan of care on a regularly scheduled and as needed basis will present a burden because these are already standard practices within the hospice industry.

Quality Assessment and Performance Improvement (§418.58)

The quality assessment and performance improvement (QAPI) requirement builds off of the existing quality assurance requirement. Indeed, quality assurance is already part of standard hospice practice. This rule requires a data-driven approach to assessing and improving quality in all aspects of hospice care, from clinical services to staffing to contracts, that enables hospices to develop a clear understanding of their strengths and weaknesses in a wide variety of areas. However, at this time we do not prescribe the precise areas that each hospice must examine, nor do we prescribe the precise mechanisms for these examinations. Rather, we provide a basic outline of what QAPI is and how we expect it to function in the hospice environment. Each hospice is free to decide how to implement the QAPI requirement in a manner that reflects its own unique needs and goals.

In response to public comments stating that we

underestimated the impact of the QAPI CoP on the average hospice, we have significantly revised our impact assessment methodology. Rather than describing the impact in proportion to the impact that this same CoP had on hospitals, we have described the impact in three general phases that we believe an average hospice will go through. These phases are based off of our experience in implementing the QAPI requirements of the proposed rule in the Rural Hospice Demonstration project required by section 409 of the MMA, and from discussions with hospice industry representatives who are active in implementing QAPI programs nationwide. The description of these phases, and the hour and dollar estimates that accompany them were not available at the time that the proposed hospice rule was published. We believe that this new information more accurately reflects the hospice environment.

While we have outlined these phases below, we stress that a hospice is not required to approach QAPI in this manner. We are not requiring a hospice to collect data for a specific domain; use specific quality measures, policies and procedures, or forms; submit data to an outside body; or conduct a specified number of performance improvement projects. A hospice may choose to implement a data-driven, comprehensive QAPI program that meets the requirements of this rule in any way that meets its individual needs. These phases described below simply provide a framework for assessing the potential impact of the QAPI requirement upon

an average hospice.

In phase one, we believe that a hospice will:

Identify quality domains and measurements that reflect it organizational complexity; involve all hospice services; affect palliative outcomes, patient safety, and quality of care; focus on high risk, high volume, or problem-prone areas; and track adverse patient events;

Develop policies and procedures to ensure that data is consistently collected, documented, retrieved, and analyzed in an accurate manner; and

Educate hospice employees and contractors about the QAPI requirement, philosophy, policies, and procedures.

In phase two, we believe that a hospice will:

Enter data into patient clinical records during patient assessments and IDG meetings;

Aggregate data by collecting the same pieces of data from patient clinical records and other sources (for example, human resource records, pharmacy records, etc.);

Analyze the data that is aggregated through charts, graphs, and various other methods to identify patterns, anomalies, areas of concern, etc. that may be useful in targeting areas for improvement; and

Develop, implement, and evaluate major and minor performance improvement projects based on a thorough analysis of the data collected.

In phase three, we believe that a hospice will:

Identify new domains and measures that may replace or be in addition to the domains and measures already being monitored by the hospice;

Develop and/or revise policies and procedures to accommodate the new domains and measures; and

Educate hospice employees and contractors on the new domains and measures, as well as the policies and procedures for them.

In addition to these three phases, a hospice will likely allocate resources to an individual responsible for the general overall coordination of its QAPI program. For simplicity, we refer to this individual as the QAPI coordinator; however, a hospice is not required to use this title.

Based on these three phases, we have anticipated the impact of the QAPI requirement on a hospice's resources. In phase one, we anticipate that a hospice will use 12 hours to identify quality domains and measures. These hours will be distributed among the three members of the hospice's QAPI committee. While we do not require a hospice to have a QAPI committee, we believe that most hospices will choose to do so. The hospice model is based on the idea of an interdisciplinary group of people working together, and we believe that hospices will choose to use this group decision-making model in the QAPI process as well. We believe that the QAPI committee will include the QAPI coordinator, the hospice administrator, and a clinical

manager. We estimate that the QAPI committee will meet four times quarterly for 1 hour each meeting to identify appropriate quality domains and measures. The total cost for an average hospice to identify the domains and measures, then, is $480.

4 meetings x 1 hour per meeting x $35/hour for QAPI coordinator = $140

4 meetings x 1 hour per meeting x $49/hour for administrator = $196

4 meetings x 1 hour per meeting x $36/hour for clinical manager = $144

While we anticipate that a hospice will use resources to develop policies and procedures and educate staff, we believe that these activities are part of standard business practice and do not pose an additional burden to a hospice. For example, a hospice already conducts a regular in-service training program for its employees in accordance with the in-service training requirement at existing §418.64. A hospice can incorporate QAPI training into this existing in-service training program with no associated increase in burden.

In phase two, we anticipate that a hospice will use 91 hours to enter data (at the time of each assessment, 40.4 hours + at the time of each IDG meeting, 50.5 hours), 48 hours to aggregate data, and 12 hours to analyze data. Although thoroughly assessing a patient is already standard

practice, we believe that collecting quality measure data during the patient assessment will be a new practice for many hospices. We estimate that a hospice will spend 40.4 hours a year to collect patient-level quality data during patient assessments, and that a registered nurse is the most likely person to perform this data collection.

4 minutes per patient assessment to collect quality data x 2 assessments per patient x 303 patients = 40.4 hours x $35/hr for a registered nurse = $1,414

The QAPI CoP requires a hospice to use the quality data collected during the patient assessment during the IDG meeting to monitor the effectiveness of interventions in helping the patient and family achieve desired outcomes. While a hospice IDG already makes decisions based on the information contained in the patient's clinical record, they may not be systematically documenting this analysis and its results. We believe that documenting the results of the data analysis (for example, any changes to the plan of care based on the specific quality measure data) during the IDG meeting will require additional time for each patient. We estimate that this activity will require 50.5 hours for an average hospice, based on an assumed five minutes per patient to document quality measure analysis. We believe that the registered nurse assigned to coordinate the patient's plan of care is the individual most likely to document this information.

5 minutes per patient to document during IDG meeting x 2 IDG meetings per patient x 303 patients = 50.5 hours x $35/hour for a registered nurse = $1,768

In addition to using quality measure data on a patient level, a hospice must gather the patient-level data and other data. Once gathered, a hospice must organize the data in a meaningful way. We estimate that, in order to ensure that the volume of gathered data is manageable, a hospice will gather its data once a month. A hospice may choose to gather data on a more or less frequent basis to suit its needs and circumstances. Some hospices may choose to gather all patient-level data, while others may choose to gather data from a sample of all patient-level data. Likewise, some hospices may choose to gather data from a wide variety of administrative files, while others may choose to select only a few administrative data sources. There are many combinations that a hospice may choose to use when it comes to gathering data, and no single approach is considered preferable to another. Given this variability, it is difficult to estimate how long an average hospice may spend gathering and organizing data. For purposes of this analysis only, we assume that an average hospice will use four hours per month to gather data, for a total of 48 hours a year. We believe that an office employee will perform the data aggregation and organization.

4 hours a month to gather and organize data x 12 months = 48 hours x $14/hr for an office employee = $672

Following data gathering and organization, a hospice must analyze the data to identify trends, patterns, anomalies, areas of strength and concern, etc. We believe that this data analysis will be done by the QAPI committee described previously. In order to identify trends and patterns, the committee would need to examine several months of data at the same time. Therefore, we assume that the committee will meet once every quarter to examine the data and make decisions based off of it. We assume that these meetings will be one hour each, for a total cost of $480.

4 meetings x 1 hour per meeting x $35/hour for QAPI coordinator = $140

4 meetings x 1 hour per meeting x $49/hour for administrator = $196

4 meetings x 1 hour per meeting x $36/hour for clinical manager = $144

Performance improvement projects follow all of the data entry, gathering, organization, and analysis. A hospice must conduct projects to improve its performance in areas where a weakness is identified. Performance improvement projects must reflect the hospice's scope, complexity, and past performance. They must also be data-driven, and affect palliative outcomes, patient safety, and quality of care. Although this final rule more clearly describes a performance improvement project, its basis, and its purpose, are fundamentally the same as the current requirement at §418.66, "Quality assurance." That requirement states that,

"A hospice must….correct identified problems and … revise hospice policies if necessary…. [and] [m]ake suggestions for improving patient care." Since a hospice already makes an organized effort to improve patient care in all of its facets, and since providing safe and effective care at all times for all patients is the essential charge of all health care providers, including hospices, we believe that conducting both major and minor performance improvement projects is already a standard of practice within the hospice industry. Therefore there is no additional burden associated with this provision.

Phase three of the QAPI process builds upon the QAPI program that a hospice already has in place. We estimate that a hospice will use three hours a year to identify new domains and quality measures, and we believe that the QAPI committee will perform this task. Just as in phase one, we believe that the tasks of developing and/or updating the hospice's policies and procedures and educating the hospice's staff and contractors are standard practice within the hospice industry.

1 meeting x 1 hour per meeting x $35/hour for QAPI coordinator = $35

1 meeting x 1 hour per meeting x $49/hour for administrator = $49

1 meeting x 1 hour per meeting x $36/hour for clinical manager = $36

In order to ensure the adequate functioning of a hospice's QAPI program, a hospice must designate an individual to be responsible for its QAPI program. We estimate that a QAPI coordinator will spend 1.5 hours per week overseeing the QAPI program, performing various functions as needed, for a total of 78 hours per year. 1.5 hours/week x 52 weeks = 78 hours x $35/hour = $2,730

Table 3: Quality assessment and performance improvement burden assessment.

Standard	Time per hospice	Total time	Cost per hospice	Total cost
Identify domains and measures(1st year)	12 hours	34,464 hours	$480	$1,378,560
Enter data •(1st year and annual)	91 hours	261,352 hours	$3,182	$9,138,704
Aggregate data•(1st year and annual)	48 hours	137,856 hours	$672	$1,929,984
Data analysis (1st year and annual)	12 hours	34,464 hours	$480	$1,378,560
QAPI coordinator•(1st year and annual)	78 hours	224,016 hours	$2,730	$7,840,560
Update domains and measures	3 hours	8,616 hours	$120	$344,640

(annual)				
Total 1st year	**241 hours**	**692,152* hours**	**$7,544**	**$21,666,368***
Total annually	**232 hours**	**666,304* hours**	**$7,184**	**$20,632,448***

* Note: The overall national estimates are based on the assumption that every hospice will begin to develop and implement a QAPI program upon the effective date of this final rule. Anecdotal evidence suggests that many hospices began developing and implementing QAPI programs upon publication of the proposed hospice rule, and therefore will not be impacted to the same extent as we have estimated above. Thus, we expect that the actual impact of this final requirement will be less than estimated in this section.

Infection Control (§418.60)

There is no specific existing requirement for infection control other than what is briefly mentioned in the existing §418.100(i), "Standard: Isolation areas." However, we believe that hospice clinicians such as nurses, physicians, and therapists are already using infection control practice as part of the current requirement that hospice clinicians provide services to patients in accordance with accepted standards of practice. It is an accepted standard of practice to use infection control methods when caring for patients. This final regulation reinforces those positive infection control practices and addresses the serious nature of infectious and communicable diseases. Infection control and standard precautions are long-standing clinical practices that are standard throughout the medical industry.

This final CoP requires a hospice to continue to take specific and appropriate actions to address the prevention and control of infections, including patient, staff, and caregiver education. We acknowledge that this is a new focus; however, we do not believe this will add any regulatory burden, since this section of the final rule

reflects contemporary standard practice in hospice programs.

Core Services (§418.64)

The final rule allows core services to be provided under contract in certain extraordinary or other non-routine circumstances as described, allowing hospices more flexibility. One specific provision allows a hospice to contract for highly specialized nursing services, providing even more staffing flexibility. The option to contract out for highly specialized nursing services allows a hospice to provide such highly specialized services at a lower cost than if it directly employed an individual(s) to perform such services. A hospice that chooses to contract for core services or highly specialized nursing services must have a contract with the entity providing the contracted services. Negotiating, documenting and signing a business contract is standard business practice and does not impose a burden.

(d) Standard: Counseling services. The final rule also requires a hospice to offer bereavement services to appropriate residents of a SNF/NF or ICF/MR. Residents of a facility often act as a patient's family, providing care, support, and companionship throughout the terminal illness. In such cases, we believe that it is appropriate for a hospice to offer bereavement services to the affected residents in the same manner that bereavement services are offered to a patient's family. Since offering and subsequently providing bereavement services to a patient's family is standard practice, we do not believe that

extending such services to those who act as a patient’s family in a SNF/NF or ICF/MR imposes an additional burden upon a hospice relative to the burden of providing bereavement services to a patient’s family.

Waiver of requirement – Physical therapy, occupational therapy, speech-language pathology, and dietary counseling (§418.74)

This waiver, currently implemented through a memorandum from CMS's Center for Medicaid and State Operations, will reduce the compliance burden on hospices located in non-urbanized areas. If the hospice program demonstrates that recruitment efforts were unsuccessful, it may request certain waivers with respect to PT, OT, speech-language pathology, and dietary counseling. There have been no applications for this waiver in the past 5 years; therefore we believe that the burden is negligible.

Hospice aide and homemaker services (§418.76)

Hospice aide and homemaker services are an integral part of hospice care, yet they receive little attention in the current regulation. These services are briefly addressed in §418.94 with a standard regarding the supervision of home health aide services and a standard regarding written patient care instructions. These two standards appear in the final regulation, with some minor alterations. The final regulation also adds several new requirements.

<u>(b) Standard: Content and duration of hospice aide classroom and supervised practical training; (c) Standard: Competency evaluation; (d) Standard: In-service training.</u>

These three standards describe the ways in which a hospice aide can meet the qualification requirements. All of these standards require the hospice to maintain documentation that each hospice aide meets these qualifications. The burden associated with these standards is the time to complete the required documentation. We estimate that it will take five minutes to document the information and that an office employee will complete this task. In addition, we have calculated the burden based on an employee turnover rate of 30% (2002 NHPCO National Data Set Summary Report), meaning that we expect that the average hospice would replace 30% of its hospice aides in a given year, or roughly one hospice aide a year based on the employment of 5 hospice aides. Based on the above-mentioned estimates and assumptions, we estimate that will cost an average hospice $1.17 to document that its hospice aides meet the qualification requirements, for a total cost of $3,360 nationwide.

$14 an hour for an office employee to document compliance/60 minutes = $0.23 minute x 5 minutes per aide to document compliance = $1.17 x 1 document per year = $1.17 per hospice

$1.17 per hospice x 2,872 hospices = $3,360

5 min to document x 2872 hospices = 14,360/60min = 239 hours

<u>(g) Standard: Hospice aide assignments and duties.</u> The hospice aide is required to report changes in the patient's needs to a registered nurse, and complete appropriate records in compliance with the hospice's policies and procedures. This new requirement reflects the standard

industry practice of maintaining communication between all healthcare providers and maintaining a complete patient record.

(h) Standard: Supervision of hospice aides. This standard retains the current rule's requirement that a registered nurse visit the patient's home to assess hospice aide services every 14 days. This standard also requires that a registered nurse visit the patient's home annually or more frequently when there are care/performance issues, when the aide is providing services in the home. We believe that thoroughly supervising employees is standard practice and does not increase burden.

(j) Standard: Homemaker qualifications. The final regulation requires homemakers to complete a hospice orientation program addressing the needs and concerns of patients and families coping with a terminal illness. We believe that this standard does not impose any additional regulatory burden because hospices train all of their employees, including homemakers, to deal with the realities of hospice care.

(k) Standard: Homemaker supervision and duties. A member of the IDG is required to develop written instructions for the homemaker. We have also added a requirement that a member of the IDG must coordinate and supervise the homemaker services. We believe that providing patient care instructions, coordinating care, and supervising homemakers are usual and customary practice;

therefore, this requirement would not impose any additional regulatory burden.

Table 4: Hospice aide and homemaker services burden assessment.

Standard	Time per aide	Time per hospice	Total time	Cost per aide	Cost per average hospice	Total cost
Documentation(based on 1 new hospice aide per year)	5 minutes	5 minutes	239 hours	$1.17	$1.17	$3,360
Totals	**5 minutes**	**5 minutes**	**239 hours**	**$1.17**	**$1.17**	**$3,360**

Organization and Administration of Services (§418.100)

The revised requirements for the organization and administration of services are essentially the same as those in the previous conditions of participation. We added a requirement to clarify the relationship between the hospice governing body and the hospice administrator. This clarification presents no burden for a hospice.

(f) Standard: Hospice multiple locations. We also added a requirement that a hospice must apply to CMS to receive authorization for the opening of a multiple location. This practice is currently mandated through a June 1997 memorandum from CMS' Center for Medicaid and State Operations. Requesting approval from CMS to provide services to Medicare and Medicaid patients from a particular location is standard practice in the industry and does not present a burden for a hospice.

(g) Standard: Training. Finally, we added two employee training requirements. First, we added a requirement that a hospice must provide an initial orientation for each

employee that addresses the employee's specific job duties. Second, we added a specification for the maintenance of in-service training records to help a hospice document its compliance with the provision of in-service training requirement. These additions reflect standard practice in the industry and present no additional burden.

Medical Director (§418.102)

This rule includes a new requirement that a hospice must designate a physician to assume the role and responsibilities of the medical director when the medical director is not available. All hospices routinely meet the medical needs of their patients 24 hours a day, including the need for physician services. As such, they must already have a physician available at all times. A single physician cannot fulfill this 24-hour a day hospice physician role; therefore hospices already have more than one physician available. We believe that identifying the alternative physician as the physician designee, ready and able to fulfill the medical director role in the medical director's absence, does not pose a burden to a hospice.

(a) Standard: Medical director contract. We added a provision permitting the medical director to work under a contractual arrangement, reducing the program and hiring burden on the hospice. If a hospice chooses to secure medical director services through a contract, this rule requires the contract to specify the physician who will serve as the medical director. Identifying a single

individual to serve as the hospice medical director is standard practice in the hospice industry and does not present a burden.

(b) Standard: Initial certification of terminal illness and (c) Standard: Recertification of the terminal illness. This rule codifies the current standards of practice to which medical directors adhere for certifying and recertifying a patient's terminally ill status.

(d) Standard: Medical director responsibility. This rule re-codifies the requirement that the medical director or designee has responsibility for the medical component of the hospice's patient care program. It is standard practice for the hospice medical director to lead, and thus bear responsibility for, the medical component of the hospice's patient care services. Therefore, this re-codified provision does not impose a burden upon a hospice.

Clinical Records (§418.104)

This rule adds specificity in regard to content, authentication, retrievability, retention, and transfer of records. It requires a hospice to include all relevant patient care information in each patient's clinical record in order to facilitate communication and coordination among all disciplines involved in a patient's care. It also requires a hospice to ensure that clinical record entries are legible, clear, complete, and authenticated in accordance with its own policies. Furthermore, this rule requires a hospice to protect and retain the information

contained in the clinical record in accordance with the Department's rules regarding personal health information at 45 CFR parts 160 and 164. All of these requirements reflect standard hospice practices and do not pose a burden.

(e) Standard: Discharge or transfer of care. This rule requires a hospice to prepare and send a comprehensive discharge summary for all patients that are discharged alive. The discharge summary must include a summary of the patient's stay, the patient's current plan of care, the most recent physician orders, and any other documentation to aid in post-discharge care of the patient. These are standard elements for discharge summaries in the health care industry, including the hospice industry. This rule also requires a hospice to send a copy of the patient's clinical record to the provider assuming care of the patient, if the provider assuming care requests a copy of the clinical record. A comprehensive discharge summary should remove any reason for the provider assuming care to request a copy of the patient's clinical record. Therefore, we do not believe that this requirement will pose a burden to a hospice. We believe that these discharge requirements reflect standard industry practice and add no burden.

Drugs, Medical Supplies and Durable Medical Equipment (§418.106)

(a) Standard: Managing drugs and biologicals. We added a requirement that a hospice must ensure that its IDG(s) confers with an individual with education and

training in drug management to ensure that drugs and biologicals meet each patient's needs. A hospice may meet this requirement in a variety of ways that is, by hiring or contracting with a pharmacist(s), by contracting with a pharmacy benefit management company, by hiring or contracting with a physician or other clinician with the necessary education and training in drug management (for example, a physician who is board certified in palliative care once board certification is available in October 2008), or by ensuring the appropriate education and training of one or more existing hospice employees.

For purposes of our analysis only, we are estimating the impact of this provision based on the assumption that an average hospice will choose to use a pharmacist to meet this requirement. We have made this assumption based on two factors. First, pharmacists are relatively easier to access in most parts of the country as compared to clinicians who have specialized drug management education and training. Second, pharmacist services can be easily accessed by phone and electronic communications through a local pharmacy or a pharmacy benefit management company. Hospices are in no way required to use a pharmacist to fulfill this role. We estimate that an average hospice already spends $123,842 annually to provide drugs and biologicals for its patients ($15.72 per patient day (dollar figure is not adjusted for inflation) for drugs and biologicals based on 2001 Millman USA report titled "The Costs of Hospice Care: An Actuarial

Evaluation of the Medicare Hospice Benefit" and consistent with the 2002 NHPCO National Data Set). Based on discussions with the leading hospice pharmacy benefit management company, for approximately this same price ($12-18 per patient day), a hospice may contract with a pharmacy benefit management company to provide all drugs and biologicals for its patients. In addition, the pharmacy benefit management company allows a hospice IDG to speak with a pharmacist on a 24-hour basis to gather information, input, and advice from the pharmacist regarding an individual patient's drug and biological profile. Contracting with a pharmacy benefit management company and utilizing its pharmacists satisfies the new requirement without increasing a hospice's expenditures beyond what it is currently spending to provide drugs and biologicals alone. Since hospices currently have the option of contracting with a pharmacy benefit management company to comply with this requirement without increasing overall pharmacy costs, we do not believe that this new requirement poses a burden to a hospice. As of January 2008 approximately 1600 hospices currently use the services of pharmacy benefit management companies.

If a hospice decides not to use a pharmacy benefit management company, it may also choose to employ or contract with a pharmacist(s) for pharmacist advisement services. A hospice that chooses to use the services of a pharmacist (or other individual with specialized education and training in

drug management) in lieu of a pharmacy benefit management company retains the responsibility and flexibility of managing the purchase of drugs and biologicals. We estimate that it requires 30 minutes for an individual such as a pharmacist to initially review a patient's drug and biologicals profile and advise the IDG during the time of the patient's comprehensive assessment and development of the plan of care. Additionally, we estimate that it requires 15 minutes of a individual's time to review updates to the patient's drug profile and advise the IDG about updates to the patient's plan of care. Based on a 26 day median length of stay, patients would likely receive two updates to their plans of care. Using these estimates, a hospice would expend $56 per patient to secure pharmacist advisement services. An average hospice would expend $16,968 annually to secure pharmacist advisement services for all of its patients. We have not estimated the cost associated with a hospice using an individual from another clinical discipline who has specialized education and training in drug management because we are unsure of what disciplines would be used in this role, depending upon the needs of each hospice.

30 minute initial advisement per patient at $28 + 15 minute update advisement per patient at $14 + 15 minute update advisement per patient at $14 = $56 per patient for all pharmacists advisement services

$56 per patient x 303 patients = $16,968

(b) Standard: Ordering of drugs, (c) Standard: Dispensing of drugs and biologicals and (d) Standard: Administration of drugs and biologicals. We added requirements governing the ordering, dispensing, and administration of drugs and biologicals. Having written policies and procedures in place to manage drugs and biologicals, and educating patients and families about these policies and procedures is standard practice in the hospice industry. Therefore, these requirements pose no burden to a hospice.

(e) Standard: Labeling, disposing and storing of drugs and biologicals. This standard requires a hospice to ensure safe labeling of all drugs and biologicals in accordance with current standards of practice. This standard also requires a hospice-operated inpatient facility to investigate discrepancies involving controlled drugs and to document an account of the investigation. Of the 2,533 deficiencies issued by State surveyors in 1,161 surveys in 2006, two were potentially related to controlled drug discrepancies. The 1,161 surveys in 2006 represent approximately 30 percent of all hospices. Therefore, we can expect that if all hospices were surveyed, six deficiencies would be issued that are potentially related controlled drug discrepancies. We do not expect a significant increase in discrepancies, and estimate that six investigations would be conducted and documented throughout the hospice industry.

The rule requires the hospice's pharmacist and

administrator to conduct controlled drug investigations. We estimate that a thorough investigation, including an examination of the records of incoming and outgoing drugs and biologicals, and report would require one hour per incident. The entire industry would thus spend six hours annually at a cost of $624 to fulfill this requirement. Maintaining inventory records incoming and outgoing drugs and biologicals is a usual and customary business practice and is not a burden.

$55 hour + $49 hour = $104 hour x 1 hour investigation = $104 per investigation

$104 per investigation x 6 investigations = $624 industry wide

In addition, we added a requirement regarding documentation of patient and family drug education. A hospice must document in the patient's clinical record that it provided a copy of its controlled drug policy to the patient and family at the time when a controlled drug is first ordered. A hospice must also document that it discussed the controlled drug policy with the patient and family. Documenting the provision of the material and the education session requires approximately five minutes, and will likely be completed by a registered nurse. Fulfilling the requirement would cost $2.25 per patient based upon the average hourly rate for a registered nurse.

$27 hour/60 minutes = $0.45 minute x 5 minutes = $2.25

$2.25 per patient x 303 patients = $682

$2.25 per patient x 303 patients x 2872 hospices = $1,957,986

(f) Standard: use and maintenance of equipment and supplies. We added a requirement that a hospice must ensure that manufacturer recommendations for routine and preventive maintenance of equipment are followed. If manufacturer recommendations do not exist, a hospice must ensure that maintenance policies are developed. A hospice must also ensure that the patient and family receive instruction regarding the use of equipment and supplies, and that the patient and family can safely demonstrate the use of the equipment and supplies. Hospices already require their equipment and supply vendors to properly maintain the equipment supplied to hospice patients. Therefore, we believe that this maintenance requirement does not impose a burden. Additionally, hospices already assure that patients and families can operate the supplied equipment. When a patient and family safely and effectively use equipment, the hospice does not need to continually send it staff to the patient's home for equipment problems. Since this routine education already occurs, benefiting both the patient and the hospice, this requirement does not impose a burden.

The vast majority of hospices provide durable medical equipment and supplies under contract with one or more vendors. For this reason, we added a requirement that a hospice may only contract with a durable medical equipment supplier that meets the Medicare DMEPOS Supplier Standards

at 42 CFR 424.57. We do not believe that this requirement will compromise a hospice's ability to secure a contract or significantly increase the cost of that contract because most vendors choose to meet the Medicare Supplier Standards in order to furnish equipment and supplies to Medicare beneficiaries. Therefore, there is sufficient competition among vendors to provide high quality services at a reasonable cost to hospices seeking contracts.

Table 5: Drugs, medical supplies and durable medical equipment burden assessment.

Standard	Time per patient	Time per average hospice	Total industry time	Cost per patient	Cost per average hospice	Total industry cost
Drug Policy Education	5 minutes	25.25 hours	72,518 hours	$2.25	$681.75	$1,957,986
Drug Discrepancy Investigation	N/A	N/A	6 hours	N/A	N/A	$624
Totals	**5 minutes**	**25.25 hours**	**72,524 hours**	**$2.25**	**$681.75**	**$1,958,610**

Short Term Inpatient Care (§418.108)

(b) Standard: Inpatient care for respite purposes. This rule allows a hospice to contract for respite care with a facility that does not have a registered nurse on-duty providing direct patient care 24-hours a day. This provision will make it easier for hospices to contract with long term care facilities.

(c) Standard: Inpatient care provided under arrangements. This rule provides additional guidance with respect to the substance of the written agreement between a hospice and an inpatient facility, which we believe is a

usual and customary business practice. Therefore, this provision therefore does not increase regulatory burden.

(d) Standard: Inpatient care limitation and (e) Standard: Exemption from limitation. This rule also maintains the 20 percent limitation on inpatient days and the exemption to this limitation. These requirements are statutory and have been in place since the inception of the Medicare hospice benefit. They reflect the goal of the hospice movement and benefit to keep patients in their home, where most patients prefer to stay. Therefore, they are standard practice.

Hospices That Provide Inpatient Care Directly (§418.110)

(b) Standard: Twenty-four hour nursing services. This rule includes the 24-hour nursing requirement from the existing rule. In short, a hospice that provides general inpatient care directly must have a registered nurse who provides direct patient care on each shift. This requirement has been in place since the inception of the Medicare hospice Conditions of Participation. As such, it is standard practice and does not pose a burden.

(c) Standard: Physical environment through (l) Standard: Meal service and menu planning. This rule requires a hospice to maintain a safe physical environment in its inpatient facility. A hospice must:

Have and rehearse a disaster preparedness plan;

Manage all aspects of the building (that is, waste, water supply, and ventilation);

Comply with applicable fire safety requirements;

Have a home-like atmosphere with sufficient space and amenities;

Have an adequate infection control program;

Have clean linens and properly handle soiled ones; and

Serve meals to meet patient needs.

These requirements are standard practice in hospice-operated inpatient facilities and pose no additional burden.

(m) Standard: Restraint or seclusion, (n) Standard: Restraint or seclusion staff training requirements and (o) Standard: Death reporting requirements.

This rule adds considerable detail in regard to seclusion and restraint. This section is adapted from the language of the Patient's Rights Condition of Participation for hospitals published as a Final Rule in the Federal Register in December 2006, and codified at 42 CFR 482.13. While we anticipate that hospices with their own inpatient facilities will be impacted by this rule, we do not have the benefit of several key pieces of information. For example, we do not have reliable data on the prevalence of restraint and seclusion use, data on the volume of staff in inpatient hospices, or data on the varying levels and qualifications of hospice staff who may be involved in restraint and seclusion use. Factors such as size, services rendered, staffing, and patient populations vary as well. We are hesitant to make impact estimates in this final rule that may not account for these and other unforeseen variations.

Thus, we reserve the right to provide estimates when feasible. Below we discuss the anticipated effects on providers of the standards related to restraints and seclusion.

(m) Standard: Restraint or seclusion. Standard 418.110(m) sets out the patient's rights in the event he or she is restrained or secluded, and limits when and by whom restraint or seclusion can be implemented. We recognize that there will be some impact associated with performing patient assessment and monitoring to ensure that seclusion and restraint are only used when necessary and are implemented in a safe and effective manner. However, patient assessment and monitoring are standard components of patient care, and this requirement does not pose a burden to a hospice.

Section 418.110(m)(6) requires that the medical director or physician designee must be consulted as soon as possible if the attending physician did not order the restraint or seclusion. Although this may minimally increase burden to hospices, we believe it is a best practice for patient safety.

We have added elements at §418.110(m)(14) that monitoring must occur face-to-face by trained staff or by using both video and audio equipment, when there is simultaneous use of restraint and seclusion. We have added elements at §418.110(m)(15) regarding the documentation that must be included in the patient's medical record when the

patient is restrained or secluded, including the 1-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior, the patient's behavior and intervention used, alternatives or other less restrictive interventions attempted (as applicable), the patient's condition or symptom(s) that warranted restraint or seclusion use, and the patient's response to the use of the restraint or seclusion intervention, including the need for continued use of restraint or seclusion. We do not believe additional burdens are imposed by this requirement since it is a routine and customary practice to document the circumstances surrounding such an event for comprehensiveness of patient care.

In response to the December 19, 1997 proposed rule that we published concerning the use of seclusion and restraint in hospitals, the National Association of Psychiatric Health Systems (NAPHS) supplied data from fifty members for the time and cost of complying with the CMS requirements that a physician evaluate a patient face-to-face within 1 hour of the initiation of restraint or seclusion. The NAPHS stated their respondents reported it took an estimated 30 minutes to 1 hour to document all the specific elements required by CMS after a restraint or seclusion episode. This included several elements unique to the rule such as physician notification if the restraint was ordered by someone other than the patient's attending physician.

We believe that the time associated with documenting seclusion or restraint episode in a hospice is similar to that in a hospital. Thus, our burden estimate is based on a median timeframe (that is, 45 minutes) that we believe it takes to complete the required documentation in the patient's clinical record. However, since we are unable to estimate the prevalence of restraint and seclusion, we can not apply this estimate to assess the associated burden across hospices.

(n) Standard: Restraint or seclusion staff training requirements. Standard 418.110(n) identifies the training requirements for all staff involved in the use of seclusion and restraint in the hospice inpatient facility. While we have tried to minimize the burden which will be placed on hospices in order to meet this requirement, we believe it is important for the provision of safe and effective restraint or seclusion use. We require that before staff apply restraints, implement seclusion, perform associated monitoring and assessment of the restrained or secluded patient, or provide care for a restrained or secluded patient, the staff must be trained and able to demonstrate competency in the performance of these actions. The staff training requirements address the following broad areas: training intervals, training contents, trainer requirements, and trainer documentation.

To reduce burden and create a reasonable requirement while assuring patient safety, we have mandated that only

those staff who are involved in the application of restraint or seclusion or performing associated monitoring and assessment of, or providing care for restrained or secluded patients have this training. While we expect physicians to be trained in the proper use of restraint or seclusion, we do not expect that they will be trained with the other hospice staff. Thus, we have not included physicians in the burden associated with these requirements. Instead, we require the remaining hospice staff who have direct contact with patients must be trained in restraint or seclusion use.

In this final rule, we have specified broad topics to be covered in training, and have not required that staff be trained by an outside organization. We believe that in-house training may be more economical than sending staff off-site for instruction. However, hospices have the option of sending either selected or all staff to outside training if they believe that this is warranted.

Thus, we have based our burden estimate on having the actual number of trainers attend the training from an outside organization one time. We believe that most hospices would, in turn, have these trained individuals function as program developers and trainers of the appropriate hospice staff. We believe in most instances this professional will be a registered nurse.

Train-the-trainer programs are the way many hospices provide staff instruction. The four day instructor certification program given by the Crisis Prevention

Institute (CPI, INC.) costs $1,200 dollars in tuition plus travel, lodging, and participant salary (HYPERLINK "http://www.crisisprevention.com" www.crisisprevention.com).

We estimate, on average, that roundtrip travel for each nurse will cost approximately $400 to cover the need for either local or distant travel, lodging for each nurse will costs approximately $120 per night X 3 nights, and the meals and incidental expenses (M&IE) will be approximately $50 per day depending upon the location within the designated state. Thus, we anticipate the cost to train one nurse would be $3,280. If all 906 hospices (estimate based on March 2006 Hospice Facts & Statistics report from the Hospice Association of America that 31.54 percent of hospices have their own inpatient facilities) with inpatient facilities were to send one nurse to such training, the total cost for the 906 hospices would be $2,971,680.

$1,200 for instructor certification program + $400 airfare + $360 for 3 days lodging + $200 for 4 days M&IE + $1120 for nurse salary at $35 per hour X 8 hours per day X 4 days = $3,280 per nurse per hospice inpatient facility.

$3,280 per nurse per hospice x 906 hospices = $2,971,680

We believe that hospices will add seclusion and restraint training onto their existing in-service training programs. The train-the-trainer program described above will provide hospices with the necessary personnel and

materials to implement a staff-wide seclusion and restraint training program. We estimate that developing this staff-wide training program will require 40 hours of the trainer's time on a one-time basis for all affected hospices, at a cost of $1,400 per hospice inpatient facility.

We require that each individual who will potentially be involved in restraint and seclusion of a patient have training in the proper techniques. According to the NAPHS, initial training in de-escalation techniques, restraint and seclusion policies and procedures, and restraint and seclusion techniques range from 7 to 16 hours of staff and instructor time.

Using data from a March 2006 Hospice Association of America report, there were 116,148 total hospice employees and volunteers in 2005. Of these employees and volunteers, 32,412 employees and volunteers were nurses and physicians. Thus the average hospice operating its own inpatient facility has 11 nurse and physician employees and volunteers. We realize that some hospices will have more or less employees and volunteers to train. Based on one nurse trainer conducting an 8 hour training course for 11 hospice inpatient employees and volunteers, we estimate that this requirement will cost $3,360.

8 trainer hours at $35/hr= $280

88 trainee hours at $35/hr = $3080

$280 trainer cost + $3080 trainee costs = $3,360

We require that each individual will receive annual updates to the training and that the annual training will also be documented. Again, according to NAPHS, annual updates are about 4 hours of staff and instructor time per each employee who has direct patient contact. Again, an average size hospice has 11 employees who have direct patient contact that must to be trained in de-escalation techniques. Therefore, we estimate that it will cost $1,680 annually to update each person's training.

4 trainer hours at $35/hr = $140

44 trainee hours at $35/hr = $1540

$140 trainer costs + $1540 trainee costs =$1,680

Additionally, we required recordkeeping for documenting in each trained individual's personnel record that he or she has successfully completed training. We estimate that it will take the trainer 5 minutes per trainee to document each participant's completion of the training. As described above, we estimate that 11 hospice employees and volunteers will be trained.

5 minutes per trainee x 11 trainees = 55 minutes annually

55 minutes x $35/hr = $32 annually

55 minutes per hospice x 906 hospices = 830.5 hours industry wide

830.5 hours industry wide x $35/hr = $29,067.5 industry wide

Finally, we require that each hospice revise its training program annually as needed. We estimate this task, completed by the trainer, to take approximately 4 hours annually per hospice.

4 hours x $35/hr = $140 per hospice

$140 per hospice x 906 hospices = $126,840 industry wide

(o) Standard: Death reporting requirements. This requirement applies to all deaths associated with the use of restraint or seclusion throughout the hospice inpatient facility. A hospice must report to CMS each death that occurs while a patient is in restraint or seclusion at the hospice inpatient facility, each death that occurs within 24 hours after the patient has been removed from restraint or seclusion, and the hospice must report each death known to the hospice that occurs within 1 week after restraint or seclusion where it is reasonable to assume that the use of restraint seclusion contributed directly or indirectly to a patient's death.

Each death referenced in this section must be reported to CMS by telephone no later than the close of business the next business day following knowledge of the patient's death. We have no data from which to base an estimate on the number of deaths in hospice that may be related to the use of seclusion and restraint. However, based on a lack of family complaints to State agencies or CMS we believe such deaths to be a rare occurrence. Although our goal is to ensure the safe and appropriate use of seclusion and

restraint and reduce associated deaths, we are aware that the actual number of reported deaths from seclusion and restraint may increase due to these reporting requirements.

Thus, we anticipate there will be burden associated with this requirement due to the increased number of deaths that will be reported by the hospice industry. Given the lack of historical data, we assume the number of reports certainly should average less than one per hospice inpatient facility per year. Thus, we believe the impact associated with this provision (that is, making a telephone call and filling in a written report) to be negligible.

Table 6: Hospices that provide inpatient care directly burden assessment (one time).

Standard	Time per •average hospice	Total time	Cost per average hospice	Total # of hospice inpatient facilities	Total cost
4 day trainer training	32 hours	16,896 hours	$3,280	906	$2,971,680
Staff training program development	40 hours	21,120 hours	$1,400	906	$1,268,400
Staff training	96 hours	50,688 hours	$3,360	906	$3,044,160
Staff training records	55 minutes	830.5 hours	$32	906	$29,068
Totals 1st year	**169 hours**	**89,535 hours**	**$8,072**	**906**	**$7,313,308**

Table 7: Hospices that provide inpatient care directly burden assessment (annual).

Standard	Time per average hospice	Total time	Total # of hospice inpatient facilities	Cost per average hospice	Total cost
Staff training update	48 hours	43,488 hours	906	$1,680	$1,522,080
Staff training records	55 minutes	830.5 hours	906	$32	$29,068
Staff training program update	4 hours	3,624 hours	906	$140	$126,840
Totals annually	**53 hours**	**47,943 hours**	**906**	**$1,852**	**$1,677,988**

Hospices That Provide Hospice Care to Residents of a SNF/NF or ICF/MR (§418.112)

(c) Standard: Written agreement. This rule establishes the minimum content of the written agreement that a hospice provider must have with a SNF/NF or ICF/MR if the hospice is caring for a resident of the facility. Establishing a contract with another provider to coordinate patient care is standard practice and does not pose a burden to a hospice that chooses to care for patients in these settings.

(d) Standard: Hospice plan of care. This rule also includes several requirements for a patient's plan of care that are in addition to the plan of care requirements in §418.56(b), (c), and (d). If a hospice patient is a resident of a SNF/NF or ICF/MR, the hospice plan of care for the patient must reflect the participation of the hospice, the facility, the patient, and the family to the extent possible. In addition, the hospice plan of care must identify which provider (the hospice or the facility) is responsible for each activity identified in the plan of

care. Any changes in the hospice plan of care must be discussed by the hospice with the patient or representative, and facility representatives. The hospice must approve all changes to the hospice plan of care before the changes are implemented.

(e) Standard: Coordination of services. In addition to the plan of care requirements, we added a coordination of services standard. This new standard requires a hospice to designate an IDG member to coordinate a patient's care with facility representatives, and communicate with facility representatives and other health care providers. The standard also requires the hospice IDG to communicate with all physicians involved in the care of a particular patient. These communication and coordination requirements are essential to providing safe, quality patient care.

Any additional effort by hospice personnel to meet these requirements will, we believe, be offset by the reduced costs associated with the provision of more effective and efficient patient care. For example, by communicating and coordinating with a facility, a hospice can avoid situations where duplicative or contradictory orders are issued by the hospice physician and the facility physician. If duplicative orders are avoided, the hospice may be able to eliminate the duplicative service, thereby decreasing hospice expenditures while maintaining quality patient care. If contradictory orders are avoided, a hospice can avoid furnishing care that is rendered

ineffective by the opposing care furnished by the facility. This, too, would decrease hospice expenditures, while at the same time improving the patient's well being.

Furthermore, the standard requires a hospice to provide a facility with specified information about the patient's care. With the exception of the election and advanced directives forms, certification forms, and physician orders, all of the specified information is routinely provided to a patient's caregiver(s). Since the facility is the caregiver, providing this information presents no burden to a hospice. We estimate that providing the facility with the election and advanced directives forms, certification forms, and physician orders for each patient would cost $2.33 per patient, based on 10 minutes of an office employee's time to fax the required documents to the facility. According to a March 2006 report from the Hospice Association of America ("Hospice Facts & Statistics"), 27.19 percent of hospice patients nationwide resided in a SNF or other long term care facility. Therefore, we estimate that hospices will provide forms to SNFs/NFs and ICFs/MR for 236,336 hospice patients residing in those facilities. We also estimate that the average hospice will provide care to 82 patients residing in a SNF/NF or ICF/MR (236,336 patients nationwide / 2,872 hospices).

82 patients in a facility x 10 minutes per patient to provide forms / 60 minutes = 13.7 hours per hospice

13.7hours x office employee at $14/hr = $192

10 minutes per patient x 236,336 patients nationwide / 60 minutes = 39,389 hours industry wide

39,389 hours x $14/hr = $551,446

$551,446/236,336 patients = $2.33 per patient

(f) Standard: Orientation and training of staff.

Finally, this rule requires a hospice to assure the orientation of SNF/NF and ICF/MR staff caring for hospice patients. Staff orientation must address the following topics: hospice philosophy; hospice policies regarding patient comfort methods, pain control, and symptom management; principles about death and dying; individual responses to death; patient rights; appropriate forms; and record keeping requirements. As many commenters noted, not every hospice will conduct the orientation itself because several hospices may serve residents of a single facility. Rather, many hospices will rely on the orientation already provided by another hospice. We do not know exactly how many hospices serve patients residing in a SNF/NF or ICF/MR, or how many of those facilities are served by multiple hospices. Therefore, we cannot estimate the number of hospices that will conduct orientation sessions for SNF/NF and ICF/MR staff. We believe that any burden associated with orienting SNF/NF and ICF/MR will be minimal because hospices already orient patients and families/caregivers about many of the topics covered in this standard (that is, hospice philosophy and principles about death and dying). Since the SNF/NF or ICF/MR staff act as the patient's care

giver, orienting them would be very similar to orienting the patient's family/caregiver.

Table 9: Hospices that provide hospice care to residents of a SNF/NF or ICF/MR burden assessment.

Standard	Time per patient	Time per •average hospice	Total time	Cost per patient	Cost per average hospice	Total cost
Providing forms to facility	10 minutes	13,7hours	39,389 hours	$2.33	$192	$551,446
Totals	**10 minutes**	**13.7hours**	**39,389 hours**	**$2.33**	**$192**	**$551,446**

Personnel Qualifications (§418.114)

(b) Standard: Personnel qualifications for certain disciplines and (c) Standard: Personnel qualifications when no State licensing, certification or registration requirements exist. The final rule establishes personnel qualifications for a variety of positions within a hospice. In particular, this rule establishes the personnel qualifications for hospice social workers. A social worker in a hospice must meet one of the following qualifications:

- Have a Master of Social Work (MSW) degree from a school of social work accredited by the Council on Social Work Education and one year of experience in a health care setting;
- Have a baccalaureate degree in social work (BSW) from a school of social work accredited by the Council on Social Work Education and one year of experience in a health care setting; or
- Have a baccalaureate degree in psychology,

sociology, or other field related to social work and at least one year of social work experience in a health care setting.

If a hospice chooses to employ a social worker with a baccalaureate degree in social work, psychology, sociology, or other field related to social work, the services of the baccalaureate social worker (BSW) must be provided under the supervision of a social worker with an MSW from a school of social work accredited by the Council on Social Work Education and one year of experience in a health care setting. The MSW supervisor role is that of an active advisor, consulting with the BSW on assessing the needs of patients and families, developing and updating the social work portion of the plan of care, and delivering care to patients and families. This supervision may occur in person, over the telephone, through electronic communication, or any combination thereof.

Social workers with a baccalaureate degree from a school of social work accredited by the Council on Social Work Education and who are employed by the hospice before the effective date of this final rule are exempted from the MSW supervision requirement. Therefore, if a hospice currently employs a BSW, it is not required to hire an MSW to supervise the BSW. If a hospice hires a new social worker with a baccalaureate degree and one year of experience in a health care setting, then the new baccalaureate social worker must be supervised by an MSW who

has one year of experience in a health care setting.

The impact associated with this social work qualification requirement is the expense of employing an MSW to supervise a BSW. By virtue of the personnel qualifications for social workers in hospice that have been in effect since 1983, all hospices are already required to have, at minimum, a social worker with a baccalaureate degree in social work from a school of social work accredited by the Council on Social Work Education. Therefore, all hospices should qualify for the exemption for MSW supervision described above.

We are aware that many hospices already employ at least one MSW to provide direct patient care. In fact, when tracking the number of social workers serving hospice patients, the Hospice Association of America only reports the number of MSWs (6,177 in 2005) working in the hospice industry, rather than the number of BSWs, precisely because an MSW is the standard level of care within hospice. Thus, we believe that the number of hospices currently solely relying on BSWs is relatively low. We do not know the precise number of hospices without an MSW. For purposes of this estimate only, we assume that 33 percent of hospices (944) rely solely on BSWs to provide social work services to patients. Of the 944 hospices without an MSW, we estimate that 25 percent will hire a social worker after the effective date of this rule (based on a 25% social worker turnover rate described in the "Hospice Salary & Benefits

Report 2006-2007" issued by the Hospital & Healthcare Compensation Service and the "2002 NHPCO National Data Set Summary Report"). Therefore, an estimated 236 hospices a year would be required to employ an MSW on a part-time basis to supervise the services of a BSW.

Based on information from the "Hospice Facts & Statistics 2006" report, the "Assuring the Sufficiency of Frontline Workforce: A National Study of Licensed Social Workers" report, and the "Licensed Social Workers in the United States, 2004" report, we estimate that the annual compensation for a full-time, supervisory, MSW working in the hospice industry is $52,811 ($25/hr). Furthermore, we estimate that a hospice would employ an MSW for 10 hours a week to supervise the care and services provided by a BSW. As such, we estimate that an affected hospice would spend $13,000 annually to employ a part-time supervisory MSW to meet the requirements of this rule.

10 hours per week for MSW at $25/hour x 52 weeks = $13,000

$13,000 x 236 hospices = $3,068,000

10 hours per week x 52 weeks = 520 hours annually

520 hours x 236 hospices = 122,720 hours industry wide

(d) Standard: Criminal background checks. Additionally, this final rule requires a background check for each employee providing direct patient contact or accessing patient records. In 2006, 40 states required criminal background checks for hospice employees. In these states, approximately 92,920 hospice employees already received a

criminal background check, thus greatly reducing the overall potential burden. We estimate that hospices that have not previously performed background checks, accounting for approximately 23,228 hospice employees, will each obtain 40 criminal background checks initially. Each background check request form will take 6 minutes to prepare and send, for a total of 4 hours per hospice the first year. For each year thereafter, we estimate that hospices in states that do not require background checks will complete background checks on approximately 10 new employees per year, for a total of 1 hour per affected hospice per year, and 582 hours nationally per year.

116,148 employees in 2005 according to National Association for Home Care 2005 Hospice Facts and Statistics / 50 states = 2323 average number of employees per state x 40 states already requiring background checks = 92,920 already required to have background checks

116,148 total employees – 92,920 already required to have background checks = 23,228 employees not already required to have background checks

116,148 employees/2,872 hospices in 2005 = 40 employees per average hospice

40 employees x 6 minutes per check = 4 hours per hospice

23,228 employees x 6 minutes per check = 2,323 hours nationwide

2,872 hospices nationwide/50 States=57.4 average number of hospices per State x 10 States not currently requiring

background checks = 574 affected hospices.

574 affected hospice x 10 new employees requiring background check per year x 6 minutes per check/60 minutes = 96 hours

We researched a wide variety of agencies that perform criminal background checks and determined that the average cost for an individual background check is $17.00 plus $1 for 6 minutes of clerical time per background check to process the paper work. We understand that some agencies or states may charge more or less that this fee to conduct a background check. In addition, some hospices may choose to conduct more extensive background checks that may cost more.

We are not requiring that hospices conduct a specific type of background check (that is, State or Federal) or obtain such a check from a specific source (that is, State police or FBI). The flexibility of the requirement will allow hospices to identify the most cost efficient method of meeting the requirement.

$18 per check x 40 employees requiring checks = $720

$18 per check x 23,228 employees not already requiring checks = $418,104

$18 per check x 10 new employees requiring checks = $180.00 per hospice

$180 per hospice x 574 affected hospices = $103,320

Table 9: Personnel qualifications burden assessment.

Standard	Time per average hospice	Total industry time	Total # of affected hospices	Total cost per average hospice	Total industry cost
MSW supervisor	520 hours	122,720 hours	236	$13,000	$3,068,000
Criminal background check	1st year- 4 hours•annually - 1 hour	1st year- 2,323 hours•annually - 96 hours	574	1st year- $720•annually- $180	1st year- $418,104annually-$103,320
Totals	**1st year- 524**	**1st year-**	**N/A**	**1st year-**	**1st year-**

	hours•Annually - 521 hours	**125,043 hours•Annually -122,816 hours**		**$13,720•Annually- $13,180**	**$3,486,104•Annually- $3,171,320**

Compliance with Federal, State, and local laws and regulations related to the health and safety of patients (§418.116)

This final condition of participation requires that the hospice operate and furnish services in compliance with applicable with Federal, State, and local laws and regulations related to the health and safety of patients. We do not believe this will add any regulatory burden, since this section of the final rule reflects current requirements and contemporary standard practice in hospice.

Table 10: Total burden assessment for all requirements in the first year CoP.

	Total time per patient	Total time per average hospice	Total industry time	Total cost per patient	Total cost per average hospice	Total industry cost
Patient rights	5 minutes	48.25 hours	138,489 hours	$3	$2,012	$4,649,379
QAPI	N/A	241 hours	692,152 hours	N/A	$7,544	$21,666,368
Hospice aide	N/A	5 minutes	239 hours	N/A	$1.17	$3,360
Drugs and DME	5 minutes	25.25 hours	72,524 hours	$2.25	$681.75	$1,958,610
Inpatient care directly	N/A	169 hours	89,535 hours	N/A	$8,072	$7,313,308
SNF/NF or ICF/MR	10 minutes	13.7 hours	39,389 hours	$2.33	$192	$551,446
Personnel qualifications	N/A	524 hours	125,043 hours	N/A	$13,720	$3,486,104
Totals	**20 minutes**	**1,021.3 hours**	**1,157,371 hours**	**$7.58**	***$32,222.92**	**$40,754,007**

* Includes cost of operating an inpatient facility and hiring a MSW supervisor. Most hospices will not incur these expenses. Therefore, this rule will cost most hospices $11,151 in the first year.

We believe that the burden associated with this rule is reasonable and necessary to ensure the health and safety of all hospice patients. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and budget.

2. Effects on other providers:

Effects on other providers: We do not expect this regulation to affect any other provider.

List of Subjects in 42 CFR Part 418

Health Facilities, Hospice Care, Medicare, Incorporation by reference, Reporting and record keeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV as set forth below:

PART 418--HOSPICE CARE

1. The authority citation for part 418 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Provision and Definitions

2. Section 418.2 is revised to read as follows:

§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.

3. Section 418.3 is amended by:

a. Revising the definitions of “Bereavement counseling, “Employee,” “Hospice,” “Physician,” “Representative,” and “Terminally ill”; and

b. Adding the definitions of “Clinical note,” “Comprehensive assessment,” “Dietary counseling,” “Hospice care,” “Initial assessment,” “Licensed professional” “Multiple location,” “Palliative care,” “Physician designee,” “Restraint,” and “Seclusion.”

The revisions and additions read as follows:

§418.3 Definitions.

For the purposes of this part—

* * * * *

Bereavement counseling means emotional, psychosocial, and spiritual support and services provided before and after the death of the patient to assist with issues related to grief, loss, and adjustment.

* * * * *

Clinical note means a notation of a contact with the patient and/or the family that is written and dated by any

person providing services and that describes signs and symptoms, treatments and medications administered, including the patient's reaction and/or response, and any changes in physical, emotional, psychosocial or spiritual condition during a given period of time.

Comprehensive assessment means a thorough evaluation of the patient’s physical, psychosocial, emotional and spiritual status related to the terminal illness and related conditions. This includes a thorough evaluation of the caregiver’s and family’s willingness and capability to care for the patient.

Dietary counseling means education and interventions provided to the patient and family regarding appropriate nutritional intake as the patient’s condition progresses. Dietary counseling is provided by qualified individuals, which may include a registered nurse, dietitian or nutritionist, when identified in the patient’s plan of care.

Employee means a person who: (1) works for the hospice and for whom the hospice is required to issue a W-2 form on his or her behalf; or (2) if the hospice is a subdivision of an agency or organization, an employee of the agency or organization who is assigned to the hospice; or (3) 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 group 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.

Initial assessment means an evaluation of the patient's physical, psychosocial and emotional status related to the terminal illness and related conditions to determine the patient's immediate care and support needs.

Licensed professional means a person licensed to provide patient care services by the State in which services are delivered.

Multiple location means a Medicare-approved location from which the hospice provides the same full range of hospice care and services that is required of the hospice issued the certification number. A multiple location must meet all of the conditions of participation applicable to hospices.

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.

Physician means an individual who meets the qualifications and conditions as defined in section 1861(r) of the Act and implemented at §410.20 of this chapter.

Physician designee means a doctor of medicine or osteopathy designated by the hospice who assumes the same responsibilities and obligations as the medical director when the medical director is not available.

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-- (1) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely, not including devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve

the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort); or

(2) A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.

Seclusion means the involuntary confinement of a patient alone in a room or an area from which the patient is physically prevented from leaving.

Terminally ill means that the individual has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course.

4. Subparts C and D are revised and Subpart E is removed and reserved to read as follows:

Subpart C--Conditions of Participation: Patient Care

418.52 Condition of participation: Patient's rights.

418.54 Condition of participation: Initial and comprehensive assessment of the patient.

418.56 Condition of participation: Interdisciplinary group, care planning, and coordination of services.

418.58 Condition of participation: Quality assessment and performance improvement.

418.60 Condition of participation: Infection control.

418.62 Condition of participation: Licensed professional services.

CORE SERVICES

418.64 Condition of participation: Core services.

418.66 Condition of participation: Nursing services waiver of requirement that substantially all nursing services be routinely provided directly by a hospice.

NON-CORE SERVICES

418.70 Condition of participation: Furnishing of non-core services.

418.72 Condition of participation: Physical therapy, occupational therapy, and speech-language pathology.

418.74 Waiver of requirement-Physical therapy, occupational therapy, speech-language pathology and dietary counseling.

418.76 Condition of participation: Hospice aide and homemaker services.

418.78 Condition of participation: Volunteers.

Subpart D--Conditions of Participation: Organizational Environment

418.100 Condition of participation: Organization and administration of services.
418.102 Condition of participation: Medical director.
418.104 Conditions of participation: Clinical records.
418.106 Condition of participation: Drugs and biologicals, medical supplies, and durable medical equipment.
418.108 Condition of participation: Short-term inpatient care.
418.110 Condition of participation: Hospices that provide inpatient care directly.
418.112 Condition of participation: Hospices that provide hospice care to residents of a SNF/NF or ICF/MR.
418.114 Condition of participation: Personnel qualifications.
418.116 Condition of participation: Compliance with Federal, State, and local laws and regulations related to the health and safety of patients.
Subpart E [Removed and Reserved]

Subpart C--Conditions of Participation: Patient Care

§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 and responsibilities.

(1) During the initial assessment visit in advance of furnishing care the hospice must provide the patient or representative with verbal (meaning spoken) and written notice of the patient's rights and responsibilities in a language and manner that the patient understands.

(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 obtain the patient’s or representative’s signature confirming that he or she has received a copy of the notice of rights and responsibilities.

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

(iii) To voice grievances regarding treatment or care that is (or fails to be) furnished and the lack of respect

for property by anyone who is furnishing services on behalf of the hospice; and

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

(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 by anyone furnishing services on behalf of the hospice, are reported immediately by hospice employees and contracted staff to the hospice administrator;

(ii) Immediately investigate all alleged violations involving anyone furnishing services on behalf of the hospice and immediately take action to prevent further potential violations while the alleged violation is being

verified. Investigations and/or documentation of all alleged violations must be conducted in accordance with established procedures;

(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) Ensure that verified violations are reported to State and local bodies having jurisdiction (including to the State survey and certification agency) within 5 working days of becoming aware of the violation.

(c) Standard: Rights of the patient. The patient has a right to the following:

(1) Receive effective pain management and symptom control from the hospice for conditions related to the terminal illness;

(2) Be involved in developing his or her hospice plan of care;

(3) Refuse care or treatment;

(4) Choose his or her attending physician;

(5) Have a confidential clinical record. Access to or release of patient information and clinical records is permitted in accordance with 45 CFR parts 160 and 164.

(6) Be free from mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property;

(7) Receive information about the services covered under the hospice benefit;

(8) Receive information about the scope of services that the hospice will provide and specific limitations on those services.

§418.54 Condition of participation: Initial and 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 physical, psychosocial, emotional, and spiritual care. This assessment includes all areas of hospice care related to the palliation and management of the terminal illness and related conditions.

(a) Standard: Initial assessment. The hospice registered nurse must complete an initial assessment within 48 hours after the election of hospice care in accordance with §418.24 is complete (unless the physician, patient, or representative requests that the initial assessment be completed in less than 48 hours.)

(b) Standard: Time frame for completion of the

comprehensive assessment. The hospice interdisciplinary group, in consultation with the individual's attending physician (if any), must complete the comprehensive assessment no later than 5 calendar days after the election of hospice care in accordance with §418.24.

(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 must take into consideration the following factors:

(1) The nature and condition causing admission (including the presence or lack of objective data and subjective complaints).

(2) Complications and risk factors that affect care planning.

(3) Functional status, including the patient's ability to understand and participate in his or her own care.

(4) Imminence of death.

(5) Severity of symptoms.

(6) Drug profile. A review of all of the patient's prescription and over-the-counter drugs, herbal remedies and

other alternative treatments that could affect drug therapy. This includes, but is not limited to, identification of the following:

(i) Effectiveness of drug therapy.

(ii) Drug side effects.

(iii) Actual or potential drug interactions.

(iv) Duplicate drug therapy.

(v) Drug therapy currently associated with laboratory monitoring.

(7) 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 plan of care and considered in the bereavement plan of care.

(8) 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 (in collaboration with the individual’s attending physician, if any) 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 as frequently as the condition of the patient requires, but no less frequently than every 15 days.

(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.

§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 as such needs relate 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, psychosocial, 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 registered nurse 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 an employee or under contract with the hospice).

(ii) A registered nurse.

(iii) A social worker.

(iv) A pastoral or other counselor.

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

(b) Standard: Plan of care. All hospice care and services furnished to patients and their families must follow an individualized written plan of care established by the hospice interdisciplinary group in collaboration with the attending physician (if any), the patient or representative, and the primary caregiver in accordance with the patient's needs if any of them so desire. The hospice must ensure that each patient and the primary care giver(s) receive education and training provided by the hospice as appropriate to their responsibilities for the care and services identified in the plan of care.

(c) Standard: Content of the plan of care. The hospice must develop an individualized written plan of care for each patient. The plan of care must reflect patient and family goals and interventions based on the problems identified in the initial, comprehensive, and updated comprehensive assessments. The plan of care must include all services necessary for the palliation and management of the terminal illness and related conditions, including the

following:

(1) Interventions to manage 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 outcomes anticipated from implementing and coordinating the plan of care.

(4) Drugs and treatment necessary to meet the needs of the patient.

(5) Medical supplies and appliances necessary to meet the needs of the patient.

(6) The interdisciplinary group's documentation of the patient’s or representative’s level of understanding, involvement, and agreement with the plan of care, in accordance with the hospice’s own policies, in the clinical record.

(d) Standard: Review of the plan of care. The hospice interdisciplinary group (in collaboration with the individual’s attending physician, if any) must review, revise and document the individualized plan as frequently as the patient’s condition requires, but no less frequently than every 15 calendar days. A revised plan of care must include information from the patient's updated comprehensive assessment and must note the patient’s progress toward

outcomes and goals 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--

(1) Ensure that the interdisciplinary group maintains responsibility for directing, coordinating, and supervising the care and services provided.

(2) Ensure that the 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.

(4) Provide for and ensure the ongoing sharing of information between all disciplines providing care and services in all settings, whether the care and services are provided directly or under arrangement.

(5) Provide for an ongoing sharing of information with other non-hospice healthcare providers furnishing services unrelated to the terminal illness and related conditions.

§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; 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 related to improved palliative outcomes and hospice 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 use 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 do the following:

(i) Monitor the effectiveness and safety of services and quality of care.

(ii) Identify opportunities and priorities for improvement.

(3) The frequency and detail of the data collection must be approved 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.

(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 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. Beginning **[OFR--INSERT 240 days AFTER THE PUBLICATION DATE OF THIS FINAL RULE]** hospices must develop, implement, and evaluate performance improvement projects.

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

(2) The hospice must document what performance 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, and is evaluated annually.

(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.

(3) That one or more individual(s) who are responsible for operating the quality assessment and performance improvement program are designated.

§418.60 Condition of participation: Infection control.

The hospice must maintain and document an effective infection control program that protects patients, families, visitors, and hospice personnel by preventing and controlling infections 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 the following:

(i) A method of identifying infectious and communicable disease problems; and

(ii) A plan for implementing the appropriate actions that are expected to result in improvement and disease prevention.

(c) Standard: Education. The hospice must provide infection control education to employees, contracted providers, patients, and family members and other

caregivers.

§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 hospice care, in accordance with current professional standards and practice, including participating in ongoing interdisciplinary comprehensive assessments, developing and evaluating the plan of care, and contributing to patient and family counseling and education; and

(c) Licensed professionals must participate in the hospice's quality assessment and performance improvement program and hospice sponsored in-service training.

CORE SERVICES

§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 paragraph (a) of this section. A hospice may use contracted staff, if necessary, to supplement hospice employees in order to meet the needs of patients under extraordinary or other non-routine circumstances. A hospice may also enter into a written arrangement with another Medicare certified hospice program for the provision of core services to supplement hospice employee/staff to meet the needs of patients. Circumstances under which a hospice may enter into a written arrangement for the provision of core services include: unanticipated periods of high patient loads, staffing shortages due to illness or other short-term temporary situations that interrupt patient care; and temporary travel of a patient 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 and conditions related to the terminal illness.

(1) All physician employees and those under contract, must function under the supervision of the hospice medical

director.

(2) All physician employees and those under contract shall meet this requirement by either providing the services directly or through coordinating patient care with the attending physician.

(3) If the attending physician is unavailable, the medical director, contracted physician, and/or hospice physician employee is responsible for meeting the medical needs of the patient.

(b) Standard: Nursing services. (1) The hospice must provide nursing care and services by or under the supervision of a registered nurse. Nursing services must ensure that the nursing needs of the patient are met as identified in the patient's initial assessment, comprehensive assessment, and updated assessments.

(2) If State law permits registered nurses to see, treat, and write orders for patients, then registered nurses may provide services to beneficiaries receiving hospice care.

(3) Highly specialized nursing services that are provided so infrequently that the provision of such services by direct hospice employees would be impracticable and prohibitively expensive, may be provided under contract.

(c) Standard: Medical social services. Medical social

services must be provided by a qualified social worker, under the direction of a physician. Social work services must be based on the patient's psychosocial assessment and the patient's and family's needs and acceptance of these services.

(d) Standard: Counseling services. Counseling services must be available to the patient and family to assist the patient and family in minimizing the stress and problems that arise from the terminal illness, related conditions, and the dying process. 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 or education in grief or loss counseling.

(ii) Make bereavement services available to the family and other individuals in the bereavement plan of care up to 1 year following the death of the patient. Bereavement counseling also extends to residents of a SNF/NF or ICF/MR 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 offered and the frequency of service delivery. A special coverage provision for bereavement counseling is specified in §418.204(c).

(2) Dietary counseling. Dietary 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) Make all reasonable efforts to facilitate visits by local clergy, pastoral counselors, or other individuals who can support the patient's spiritual needs to the best of its ability.

(iv) Advise the patient and family of this service.

§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 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 non-urbanized 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 the following:

(i) Proof that the organization was established to provide hospice services on or before January 1, 1983.

(ii) Evidence that hospice-type services were furnished to patients on or before January 1, 1983.

(iii) 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.

(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) 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 waiver have not changed since the initial waiver was granted.

NON-CORE SERVICES

§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.

§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.

§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 the following:

(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.

(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) 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 conditions under which it

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

§418.76 Condition of participation: Hospice aide and homemaker services.

All hospice 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: Hospice aide qualifications. (1) A qualified hospice aide is a person who has successfully completed one of the following:

(i) A training program and competency evaluation as specified in paragraphs (b) and (c) of this section respectively.

(ii) A competency evaluation program that meets the requirements of paragraph (c) of this section.

(iii) A nurse aide training and competency evaluation program approved by the State as meeting the requirements of §483.151 through §483.154 of this chapter, and is currently listed in good standing on the State nurse aide registry.

(iv) A State licensure program that meets the requirements of paragraphs (b) and (c) of this section.

(2) A hospice aide is not considered to have completed

a program, as specified in paragraph (a)(1) of this section, 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 program, as specified in paragraph (a)(1) of this section, before providing services.

(b) Standard: Content and duration of hospice aide classroom and supervised practical training. (1) Hospice aide training must include classroom and supervised practical 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 a 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 l6 hours of supervised practical training as part of the 75 hours.

(3) A hospice aide training program must address each of the following subject areas:

(i) Communication skills, including the ability to read, write, and verbally report clinical information to patients, care givers, and other hospice staff.

(ii) Observation, reporting, and documentation of patient status and the care or service furnished.

(iii) Reading and recording temperature, pulse, and respiration.

(iv) Basic infection control procedures.

(v) Basic elements of body functioning and changes in body function that must be reported to an aide’s supervisor.

(vi) Maintenance of a clean, safe, and healthy environment.

(vii) Recognizing emergencies and the knowledge of emergency procedures and their application.

(viii) The physical, emotional, and developmental needs of and ways to work with the populations served by the hospice, including the need for respect for the patient, his or her privacy, and his or her property.

(ix) Appropriate and safe techniques in performing personal hygiene and grooming tasks, including items on the following basic checklist:

(A) Bed bath.

(B) Sponge, tub, and shower bath.

(C) Hair shampoo (sink, tub, and bed).

(D) Nail and skin care.

(E) Oral hygiene.

(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 hospice 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 hospice aide services on behalf of a hospice only after that individual has successfully completed a competency evaluation program as described in this section.

(1) The competency evaluation must address each of the subjects listed in paragraph (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 hospice aide with a patient.

(2) A hospice aide competency evaluation program may be offered by any organization, except as described 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 hospice 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. A hospice aide is not considered to have successfully completed a competency evaluation if the aide has an "unsatisfactory" rating in more than one of the required areas.

(5) The hospice must maintain documentation that demonstrates the requirements of this standard are being met.

(d) Standard: In-service training. A hospice aide must receive at least l2 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, 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 and supervised practical training. Classroom and supervised practical training must be performed by a registered nurse who possesses a minimum of 2 years nursing experience, at least 1 year of which must be in home care, or by other individuals under the general supervision of a registered nurse.

(f) Standard: Eligible competency evaluation organizations. A hospice aide competency evaluation program as specified in paragraph (c) of this section may be offered by any organization except by a home health agency that, within the previous 2 years:

(1) Had been of compliance with the requirements of §484.36(a) and (b) of this chapter.

(2) Permitted an individual that does not meet the definition of a “qualified home health aide” as specified in §484.36(a) of this chapter to furnish home health aide services (with the exception of licensed health professionals and volunteers).

(3) Had been 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) Had been assessed a civil monetary penalty of $5,000 or more as an intermediate sanction.

(5) Had been 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.

(7) Had been 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.

(v) Been closed by CMS or the State, or had its patients transferred by the State.

(g) Standard: Hospice aide assignments and duties.

(l) Hospice aides are assigned to a specific patient by a registered nurse that is a member of the interdisciplinary group. Written patient care instructions for a hospice aide must be prepared by a registered nurse who is responsible for the supervision of a hospice aide as specified under paragraph (h) of this section.

(2) A hospice aide provides services that are:

(i) Ordered by the interdisciplinary group.

(ii) Included in the plan of care.

(iii) Permitted to be performed under State law by such hospice aide.

(iv) Consistent with the hospice aide training.

(3) The duties of a hospice aide include the following:

(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.

(iv) Assistance in administering medications that are ordinarily self-administered.

(4) Hospice aides must report changes in the patient’s medical, nursing, rehabilitative, and social needs to a

registered nurse, as the changes relate to the plan of care and quality assessment and improvement activities. Hospice aides must also complete appropriate records in compliance with the hospice's policies and procedures.

(h) Standard: Supervision of hospice aides. (l) A registered nurse must make an on-site visit to the patient's home:

(i) No less frequently than every 14 days to assess the quality of care and services provided by the hospice aide and to ensure that services ordered by the hospice interdisciplinary group meet the patient's needs. The hospice aide does not have to be present during this visit.

(ii) If an area of concern is noted by the supervising nurse, then the hospice must make an on-site visit to the location where the patient is receiving care in order to observe and assess the aide while he or she is performing care.

(iii) If an area of concern is verified by the hospice during the on-site visit, then the hospice must conduct, and the hospice aide must complete a competency evaluation in accordance with §418.76(c).

(2) A registered nurse must make an annual on-site visit to the location where a patient is receiving care in order to observe and assess each aide while he or she is

performing care.

(3) The supervising nurse 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 hospice aide by the registered nurse.

(ii) Creating successful interpersonal relationships with the patient and family.

(iii) Demonstrating competency with assigned tasks.

(iv) Complying with infection control policies and procedures.

(v) Reporting changes in the patient's condition.

(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 this chapter, on behalf of a hospice agency.

(1) Before the individual may furnish personal care services, the individual must be found competent by the State (if regulated by the State) to furnish those services. The individual only needs to demonstrate competency in the services the individual is required to furnish.

(2) Services under the Medicaid personal care benefit may be used to the extent that the hospice would routinely use the services of a hospice patient's family in implementing a patient's plan of care.

(3) The hospice must coordinate its hospice aide and homemaker services with the Medicaid personal care benefit to ensure the patient receives the hospice aide and homemaker services he or she needs.

(j) Standard: Homemaker qualifications. A qualified homemaker is—

(1) An individual who meets the standards in §418.202(g) and has successfully completed hospice orientation addressing the needs and concerns of patients and families coping with a terminal illness; or

(2) A hospice aide as described in §418.76.

(k) Standard: Homemaker supervision and duties.

(1) Homemaker services must be coordinated and supervised 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.

§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 the following:

(1) The identification of each position that is occupied by a volunteer.

(2) The work time spent by volunteers occupying those positions.

(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.

(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.

Subpart D--Conditions of participation: Organizational Environment

§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 the terminal illness and related conditions.

(a) Standard: Serving the hospice patient and family.

The hospice must provide hospice care that-

(1) Optimizes comfort and dignity; and

(2) Is consistent with patient and family needs and goals, with patient needs and goals as priority.

(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 appointed by and reporting to the governing body 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 with accepted standards of practice:

(i) Nursing services.

(ii) Medical social services.

(iii) Physician services.

(iv) Counseling services, including spiritual counseling, dietary counseling, and bereavement counseling.

(v) Hospice aide, volunteer, and homemaker services.

(vi) Physical therapy, occupational therapy, and speech-language pathology 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 oversight 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 qualified personnel; and

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

(f) Standard: Hospice multiple locations.

If a hospice operates multiple locations, it must meet the following requirements:

(1) Medicare approval.

(i) All hospice multiple locations must be approved by Medicare before providing hospice care and services to Medicare patients.

(ii) The multiple location must be part of the hospice and must share administration, supervision, and services with the hospice issued the certification number.

(iii) The lines of authority and professional and administrative control must be clearly delineated in the hospice's organizational structure and in practice, and must be traced to the location that issued the certification number.

(iv) The determination that a multiple location does or does not meet the definition of a multiple 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, in

accordance with the requirements of this subpart and subparts A and C of this section.

(g) Standard: Training.

(1) A hospice must provide orientation about the hospice philosophy to all employees and contracted staff who have patient and family contact.

(2) A hospice must provide an initial orientation for each employee that addresses the employee's specific job duties.

(3) 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.

§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 an employee, or is under contract with the hospice. When the medical director is not available, a physician designated by the hospice assumes the

same responsibilities and obligations as the medical director.

(a) Standard: Medical director contract. (1) A hospice may contract with either of the following—

(i) A self-employed physician; or

(ii) A physician employed by a professional entity or physicians group. When contracting for medical director services, the contract must specify the physician who assumes the medical director responsibilities and obligations.

(b) 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 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; and

(5) Information about the medical management of any of the patient's conditions unrelated to the terminal illness.

(c) 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 the patient's clinical information.

(d) Standard: Medical director responsibility. The medical director or physician designee has responsibility for the medical component of the hospice's patient care program.

§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 correct clinical information that is available to the patient's attending physician and hospice staff. The clinical record may be maintained electronically.

(a) Standard: Content. Each patient's record must include the following:

(1) The initial plan of care, updated plans of care, initial assessment, comprehensive assessment, updated comprehensive assessments, and clinical notes.

(2) Signed copies of the notice of patient rights in accordance with §418.52 and election statement in accordance with §418.24.

(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 §418.25 and described in §418.102(b) and §418.102(c) respectively, if appropriate.

(6) Any advance directives as described in §418.52(a)(2).

(7) Physician orders.

(b) Standard: Authentication. All entries must be legible, clear, complete, and appropriately authenticated and dated in accordance with hospice policy and currently accepted standards of practice.

(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 as set out at 45 CFR parts 160 and 164.

(d) Standard: Retention of records. Patient clinical records must be retained for 6 years after the death or discharge of the patient, unless State law stipulates a longer period of time. If the hospice discontinues operation, hospice policies must provide for retention and storage of clinical records. The hospice must inform its

State agency and its CMS Regional office where such clinical records will be stored and how they may be accessed.

(e) Standard: Discharge or transfer of care. (1) If the care of a patient is transferred to another Medicare/Medicaid-certified facility, the hospice must forward to the receiving facility, a copy of-

(i) The hospice discharge summary; and

(ii) The patient’s clinical record, if requested.

(2) If a patient revokes the election of hospice care, or is discharged from hospice in accordance with §418.26, the hospice must forward to the patient’s attending physician, a copy of-

(i) The hospice discharge summary; and

(ii) The patient’s clinical record, if requested.

(3) The hospice discharge summary as required in paragraph (e)(1) and (e) (2) of this section 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 or that is requested by the attending physician or receiving facility.

(f) 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.

§418.106 Condition of participation: Drugs and biologicals, medical supplies, and durable medical equipment.

Medical supplies and appliances, as described in §410.36 of this chapter; durable medical equipment, as described in §410.38 of this chapter; and drugs and biologicals related to the palliation and management of the terminal illness and related conditions, as identified in the hospice plan of care, must be provided by the hospice while the patient is under hospice care.

(a) Standard: Managing drugs and biologicals.

(1) The hospice must ensure that the interdisciplinary group confers with an individual with education and training in drug management as defined in hospice policies and procedures and State law, who is an employee of or under contract with the hospice to ensure that drugs and biologicals meet each patient’s needs.

(2) A hospice that provides inpatient care directly in its own facility must provide pharmacy services under the direction of a qualified licensed pharmacist who is an employee of or under contract with the hospice. The provided pharmacist services must include evaluation of a patient’s

response to medication therapy, identification of potential adverse drug reactions, and recommended appropriate corrective action.

(b) Standard: Ordering of drugs.

(1) Only 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, may order drugs for the patient.

(2) If the drug order is verbal or given by or through electronic transmission—

(i) It must be given only to a licensed nurse, nurse practitioner (where appropriate), pharmacist, or physician; and

(ii) The individual receiving the order must record and sign it immediately and have the prescribing person sign it in accordance with State and Federal regulations.—

(c) Standard: Dispensing of drugs and biologicals. The hospice must--

(1) Obtain drugs and biologicals from community or institutional pharmacists or stock drugs and biologicals itself.

(2) The hospice that provides inpatient care directly in its own facility must:

(i) Have a written policy in place that promotes dispensing accuracy; and

(ii) Maintain current and accurate records of the receipt and disposition of all controlled drugs.

(d) Standard: Administration of drugs and biologicals.

(1) 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 to the patient in his or her home.

(2) Patients receiving care in a hospice that provides inpatient care directly in its own facility may only be administered medications by the following individuals:

(i) A licensed nurse, physician, or other health care professional in accordance with their scope of practice and State law;

(ii) An employee who has completed a State-approved training program in medication administration; and

(iii) The patient, upon approval by the interdisciplinary group.

(e) Standard: Labeling, disposing, and storing of drugs and biologicals.

(1) Labeling. Drugs and biologicals must be labeled in accordance with currently accepted professional practice and must include appropriate usage and cautionary instructions, as well as an expiration date (if applicable).

(2) Disposing. (i) Safe use and disposal of controlled

drugs in the patient’s home. The hospice must have written policies and procedures for the management and disposal of controlled drugs in the patient’s home. At the time when controlled drugs are first ordered the hospice must:

(A) Provide a copy of the hospice written policies and procedures on the management and disposal of controlled drugs to the patient or patient representative and family;

(B) Discuss the hospice policies and procedures for managing the safe use and disposal of controlled drugs with the patient or representative and the family in a language and manner that they understand to ensure that these parties are educated regarding the safe use and disposal of controlled drugs; and

(C) Document in the patient’s clinical record that the written policies and procedures for managing controlled drugs was provided and discussed.

(ii) Disposal of controlled drugs in hospices that provide inpatient care directly. The hospice that provides inpatient care directly in its own facility must dispose of controlled drugs in compliance with the hospice policy and in accordance with State and Federal requirements. The hospice must maintain current and accurate records of the receipt and disposition of all controlled drugs.

(3) Storing. The hospice that provides inpatient care

directly in its own facility must comply with the following additional requirements-

(i) All drugs and biologicals must be stored in secure areas. All controlled 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 drugs as noted in paragraph (d)(2) of this section may have access to the locked compartments; and

(ii) Discrepancies in the acquisition, storage, dispensing, administration, disposal, or return of controlled drugs must be investigated immediately by the pharmacist and hospice administrator and where required reported to the appropriate State authority. A written account of the investigation must be made available to State and Federal officials if required by law or regulation.

(f) Standard: Use and maintenance of equipment and supplies.

(1) The hospice must ensure that manufacturer recommendations for performing routine and preventive maintenance on durable medical equipment are followed. The equipment must be safe and work as intended for use in the patient's environment. Where a manufacturer recommendation

for a piece of equipment does not exist, the hospice must ensure that repair and routine maintenance policies are developed. The hospice may use persons under contract to ensure the maintenance and repair of durable medical equipment.

(2) The hospice must ensure that the patient, where appropriate, as well as the family and/or other caregiver(s), receive instruction in the safe use of durable medical equipment and supplies. The hospice may use persons under contract to ensure patient and family instruction. 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.

(3) Hospices may only contract for durable medical equipment services with a durable medical equipment supplier that meets the Medicare DMEPOS Supplier Quality and Accreditation Standards at 42 CFR §424.57.

§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-certified hospice that meets the conditions of participation for providing inpatient care directly as specified in §418.110.

(2) A Medicare-certified hospital or a skilled nursing facility that also meets the standards specified in §418.110(b) and (e) regarding 24-hour nursing services and patient areas.

(b) Standard: Inpatient care for respite purposes.

(1) Inpatient care for respite purposes must be provided by one of the following:

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

(ii) A Medicare or Medicaid-certified nursing facility that also meets the standards specified in §418.110(f).

(2) The facility providing respite care 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: 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 written agreement, coordinated by the hospice, and 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;

(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 and events regarding care that occurred at the facility; that a copy of the discharge summary be provided to the hospice at the time of discharge; and that a copy of the inpatient clinical record is available to the hospice at the time of discharge;

(4) That the inpatient facility has identified an individual within the facility who is responsible for the implementation of the provisions of the agreement;

(5) That the hospice retains responsibility for ensuring that the training of personnel who will be providing the patient’s care in the inpatient facility has been provided and that a description of the training and the

names of those giving the training is documented; and

(6) A method for verifying that the requirements in paragraphs(c)(1) through (c)(5) of this section are met.

(d) Standard: Inpatient care limitation. The total number of inpatient days used by Medicare beneficiaries who elected hospice coverage in a 12-month 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.

§418.110 Condition of participation: Hospices that provide inpatient care directly.

A hospice that provides inpatient care directly in its own facility 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. (1)

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.

(2) If at least one patient in the hospice facility is receiving general inpatient care, then each shift must include a registered nurse who provides direct patient care.

(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.

(ii) 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 controlling the reliability and quality of--

(i) The routine storage and prompt 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 (NFPA). 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 hospices.

(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 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) 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

(iv) 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 C.F.R. 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.

(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 and their family members;

(v) 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

(vi) Be equipped with an easily-activated, functioning device accessible to the patient, that is used for calling for assistance.

(4) For a facility occupied by a Medicare-participating hospice on **[OFR insert effective date of final rule]**, CMS may waive the space and occupancy requirements of paragraphs (f)(2)(iv) and (f)(2)(v) of this section 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 and 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: Restraint or seclusion. All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.

(1) Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient, a staff member, or others from harm.

(2) The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others

from harm.

(3) The use of restraint or seclusion must be--

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

(ii) Implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospice policy in accordance with State law.

(4) The use of restraint or seclusion must be in accordance with the order of a physician authorized to order restraint or seclusion by hospice policy in accordance with State law.

(5) Orders for the use of restraint or seclusion must never be written as a standing order or on an as needed basis (PRN).

(6) The medical director or physician designee must be consulted as soon as possible if the attending physician did not order the restraint or seclusion.

(7) Unless superseded by State law that is more restrictive--

(i) Each order for restraint or seclusion used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others may only be renewed in accordance with the following limits for up to a total of 24 hours:

(A) 4 hours for adults 18 years of age or older;

(B) 2 hours for children and adolescents 9 to 17 years of age; or

(C) 1-hour for children under 9 years of age; and

After 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician authorized to order restraint or seclusion by hospice policy in accordance with State law must see and assess the patient.

(ii) Each order for restraint used to ensure the physical safety of the non-violent or non-self-destructive patient may be renewed as authorized by hospice policy.

(8) Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order.

(9) The condition of the patient who is restrained or secluded must be monitored by a physician or trained staff that have completed the training criteria specified in paragraph (n) of this section at an interval determined by hospice policy.

(10) Physician, including attending physician, training requirements must be specified in hospice policy. At a minimum, physicians and attending physicians authorized to

order restraint or seclusion by hospice policy in accordance with State law must have a working knowledge of hospice policy regarding the use of restraint or seclusion.

(11) When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen face-to-face within 1 hour after the initiation of the intervention --

(i) By a--

(A) Physician; or

(B) Registered nurse who has been trained in accordance with the requirements specified in paragraph (n) of this section.

(ii) To evaluate--

(A) The patient’s immediate situation;

(B) The patient’s reaction to the intervention;

(C) The patient’s medical and behavioral condition; and

(D) The need to continue or terminate the restraint or seclusion.

(12) States are free to have requirements by statute or regulation that are more restrictive than those contained in paragraph (m)(11)(i) of this section.

(13) If the face-to-face evaluation specified in §418.110(m)(11) is conducted by a trained registered nurse, the trained registered nurse must consult the medical director or physician designee as soon as possible after the completion of the 1-hour face-to-face evaluation.

(14) All requirements specified under this paragraph are applicable to the simultaneous use of restraint and seclusion. Simultaneous restraint and seclusion use is only permitted if the patient is continually monitored--

(i) Face-to-face by an assigned, trained staff member; or

(ii) By trained staff using both video and audio equipment. This monitoring must be in close proximity to the patient.

(15) When restraint or seclusion is used, there must be documentation in the patient’s clinical record of the following:

(i) The 1-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior;

(ii) A description of the patient’s behavior and the intervention used;

(iii) Alternatives or other less restrictive interventions attempted (as applicable);

(iv) The patient’s condition or symptom(s) that warranted the use of the restraint or seclusion; and the patient’s response to the intervention(s) used, including the rationale for continued use of the intervention.

(n) Standard: Restraint or seclusion staff training requirements. The patient has the right to safe implementation of restraint or seclusion by trained staff.

(1) Training intervals. All patient care staff working in the hospice inpatient facility must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion--

(i) Before performing any of the actions specified in this paragraph;

(ii) As part of orientation; and

(iii) Subsequently on a periodic basis consistent with hospice policy.

(2) Training content. The hospice must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:

(i) Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger

circumstances that require the use of a restraint or seclusion.

(ii) The use of nonphysical intervention skills.

(iii) Choosing the least restrictive intervention based on an individualized assessment of the patient’s medical, or behavioral status or condition.

(iv) The safe application and use of all types of restraint or seclusion used in the hospice, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia).

(v) Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary.

(vi) Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospice policy associated with the 1-hour face-to-face evaluation.

(vii) The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification.

(3) Trainer requirements. Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors.

(4) Training documentation. The hospice must document in the staff personnel records that the training and demonstration of competency were successfully completed.

(o) Standard: Death reporting requirements. Hospices must report deaths associated with the use of seclusion or restraint.

(1) The hospice must report the following information to CMS:

(i) Each unexpected death that occurs while a patient is in restraint or seclusion.

(ii) Each unexpected death that occurs within 24 hours after the patient has been removed from restraint or seclusion.

(iii) Each death known to the hospice that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death. "Reasonable to assume" in this context includes, but is not limited to, deaths related to restrictions of

movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation.

(2) Each death referenced in this paragraph must be reported to CMS by telephone no later than the close of business the next business day following knowledge of the patient’s death.

(3) Staff must document in the patient's clinical record the date and time the death was reported to CMS.

§418.112 Condition of participation: Hospices that provide hospice care to residents of a SNF/NF or ICF/MR.

In addition to meeting the conditions of participation at §418.10 through §418.116, a hospice that provides hospice care to residents of a SNF/NF or ICF/MR 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 ICF/MR are subject to the Medicare hospice eligibility criteria set out at §418.20 through §418.30.

(b) Standard: Professional management. The hospice must assume responsibility for professional management of the resident’s hospice services provided, in accordance with the hospice plan of care and the hospice conditions of participation, and make any arrangements necessary for

hospice-related inpatient care in a participating Medicare/Medicaid facility according to §418.100 and §418.108.

(c) Standard: Written agreement. The hospice and SNF/NF or ICF/MR must have a written agreement that specifies the provision of hospice services in the facility. The agreement must be signed by authorized representatives of the hospice and the SNF/NF or ICF/MR before the provision of hospice services. The written agreement must include at least the following:

(1) The manner in which the SNF/NF or ICF/MR and the hospice are to communicate with each other and document such communications to ensure that the needs of patients are addressed and met 24 hours a day.

(2) A provision that the SNF/NF or ICF/MR immediately notifies the hospice if—

(i) A significant change in a 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 need to transfer a patient from the SNF/NF or ICF/MR, and the hospice makes arrangements for, and remains responsible for, any necessary continuous care or inpatient care necessary related to the terminal illness and related

conditions; or

(iv) A patient dies.

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

(4) An agreement that it is the SNF/NF or ICF/MR responsibility to continue to furnish 24 hour room and board care, meeting the personal care and nursing needs that would have been provided by the primary caregiver at home at the same level of care provided before hospice care was elected.

(5) An agreement that it is the hospice’s responsibility to provide services at the same level and to the same extent as those services would be provided if the SNF/NF or ICF/MR resident were in his or her own home.

(6) A delineation of the hospice’s responsibilities, which include, but are not limited to the following: providing medical direction and management of the patient; nursing; counseling (including spiritual, dietary and bereavement); social work; provision of medical supplies, durable medical equipment and drugs necessary for the palliation of pain and symptoms associated with the terminal illness and related conditions; and all other hospice services that are necessary for the care of the resident’s

terminal illness and related conditions.

(7) A provision that the hospice may use the SNF/NF or ICF/MR nursing personnel where permitted by State law and as specified by the SNF/NF or ICF/MR to assist in the administration of prescribed therapies included in the plan of care only to the extent that the hospice would routinely use the services of a hospice patient’s family in implementing the plan of care.

(8) A provision stating that the hospice must report all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property by anyone unrelated to the hospice to the SNF/NF or ICF/MR administrator within 24 hours of the hospice becoming aware of the alleged violation.

(9) A delineation of the responsibilities of the hospice and the SNF/NF or ICF/MR to provide bereavement services to SNF/NF or ICF/MR staff.

(d) Standard: Hospice plan of care. In accordance with §418.56, a written hospice plan of care must be established and maintained in consultation with SNF/NF or ICF/MR representatives. All hospice care provided must be in accordance with this hospice plan of care.

(1) The hospice 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 hospice plan of care.

(2) The hospice plan of care reflects the participation of the hospice, the SNF/NF or ICF/MR, and the patient and family to the extent possible.

(3) Any changes in the hospice plan of care must be discussed with the patient or representative, and SNF/NF or ICF/MR representatives, and must be approved by the hospice before implementation.

(e) Standard: Coordination of services. The hospice must:

(1) Designate a member of each interdisciplinary group that is responsible for a patient who is a resident of a SNF/NF or ICF/MR. The designated interdisciplinary group member is responsible for:

(i) Providing overall coordination of the hospice care of the SNF/NF or ICF/MR resident with SNF/NF or ICF/MR representatives; and

(ii) Communicating with SNF/NF or ICF/MR representatives and other health care providers participating in the provision of care for the terminal illness and related conditions and other conditions to

ensure quality of care for the patient and family.

(2) Ensure that the hospice IDG communicates with the SNF/NF or ICF/MR medical director, the patient's attending physician, and other physicians participating in the provision of care to the patient as needed to coordinate the hospice care of the hospice patient with the medical care provided by other physicians.

(3) Provide the SNF/NF or ICF/MR with the following information:

(i) The most recent hospice plan of care specific to each patient;

(ii) Hospice election form and any advance directives specific to each patient;

(iii) Physician certification and recertification of the terminal illness specific to each patient;

(iv) Names and contact information for hospice personnel involved in hospice care of each patient;

(v) Instructions on how to access the hospice's 24-hour on-call system;

(vi) Hospice medication information specific to each patient; and

(vii) Hospice physician and attending physician (if any) orders specific to each patient.

(f) Standard: Orientation and training of staff.

Hospice staff must assure orientation of SNF/NF or ICF/MR 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.

§418.114 Condition of participation: Personnel qualifications.

(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) in accordance with applicable Federal, State and local laws, 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 certain disciplines.

The following qualifications must be met:

(1) Physician. 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) Hospice aide. Hospice aides must meet the

qualifications required by section 1891(a)(3) of the Act and implemented at §418.76.

(3) Social worker. A person who—

(i) (A) Has a Master of Social Work (MSW) degree from a school of social work accredited by the Council on Social Work Education; or

(B) Has a baccalaureate degree in social work from an institution accredited by the Council on Social Work Education; or a baccalaureate degree in psychology, sociology, or other field related to social work and is supervised by an MSW as described in paragraph (b)(3)(i)(A) of this section; and

(ii) Has 1 year of social work experience in a health care setting; or

(iii) Has a baccalaureate degree from a school of social work accredited by the Council on Social Work Education, is employed by the hospice before **[OFR insert effective date of final rule]**, and is not required to be supervised by an MSW.

(4) Speech language pathologist. A person who meets either of the following requirements:

(i) The education and experience requirements for a Certificate of Clinical Competence in speech-language

pathology granted by the American Speech-Language-Hearing Association.

(ii) The educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

(5) Occupational therapist. A person who—

(i)(A) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing, unless licensure does not apply;

(B) Graduated after successful completion of an occupational therapist education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA), or successor organizations of ACOTE; and

(C) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(ii) On or before December 31, 2009—

(A) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing; or

(B) When licensure or other regulation does not apply—

(1) Graduated after successful completion of an occupational therapist education program accredited by the accreditation Council for Occupational therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or successor organizations of ACOTE; and

(2) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc., (NBCOT).

(iii) On or before January 1, 2008—

(A) Graduated after successful completion of an occupational therapy program accredited jointly by the committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association; or

(B) Is eligible for the National Registration Examination of the American Occupational Therapy Association or the National Board for Certification in Occupational Therapy.

(iv) On or before December 31, 1977—

(A) Had 2 years of appropriate experience as an occupational therapist; and

(B) Had achieved a satisfactory grade on an occupational therapist proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(v) If educated outside the United States—

(A) Must meet both of the following:

(1) Graduated after successful completion of an occupational therapist education program accredited as substantially equivalent to occupational therapist assistant entry level education in the United States by one of the following:

(i) The Accreditation Council for Occupational Therapy Education (ACOTE).

(ii) Successor organizations of ACOTE.

(iii) The World Federation of Occupational Therapists.

(iv) A credentialing body approved by the American Occupational Therapy Association.

(v) Successfully completed the entry level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(2) On or before December 31, 2009, is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing.

(6) Occupational therapy assistant. A person who—

(i) Meets all of the following:

(A) Is licensed or otherwise regulated, if applicable, as an occupational therapy assistant by the State in which practicing, unless licensure does apply.

(B) Graduated after successful completion of an occupational therapy assistant education program accredited by the Accreditation Council for Occupational Therapy Education, (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or its successor organizations.

(C) Is eligible to take or successfully completed the entry-level certification examination for occupational therapy assistants developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(ii) On or before December 31, 2009—

(A) Is licensed or otherwise regulated as an occupational therapy assistant, if applicable, by the State in which practicing; or any qualifications defined by the State in which practicing, unless licensure does not apply; or

(B) Must meet both of the following:

(1) Completed certification requirements to practice as an occupational therapy assistant established by a

credentialing organization approved by the American Occupational Therapy Association.

(2) After January 1, 2010, meets the requirements in paragraph (b)(6)(i) of this section.

(iii) After December 31, 1977 and on or before December 31, 2007—

(A) Completed certification requirements to practice as an occupational therapy assistant established by a credentialing organization approved by the American Occupational Therapy Association; or

(B) Completed the requirements to practice as an occupational therapy assistant applicable in the State in which practicing.

(iv) On or before December 31, 1977—

(A) Had 2 years of appropriate experience as an occupational therapy assistant; and

(B) Had achieved a satisfactory grade on an occupational therapy assistant proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(v) If educated outside the United States, on or after January 1, 2008—

(A) Graduated after successful completion of an occupational therapy assistant education program that is

accredited as substantially equivalent to occupational therapist assistant entry level education in the United States by—

(1) The Accreditation Council for Occupational Therapy Education (ACOTE).

(2) Its successor organizations.

(3) The World Federation of Occupational Therapists.

(4) By a credentialing body approved by the American Occupational Therapy
Association; and

(5) Successfully completed the entry level certification examination for occupational therapy assistants developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(7) Physical therapist. A person who is licensed, if applicable, by the State in which practicing, unless licensure does not apply and meets one of the following requirements:

(i) Graduated after successful completion of one of a physical therapist education program approved by one of the following:

(A) The Commission on Accreditation in Physical Therapy Education (CAPTE).

(B) Successor organizations of CAPTE.

(C) An education program outside the United States determined to be substantially equivalent to physical therapist entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or an organization identified in 8 CFR 212.15(e) as it relates to physical therapists.

(D) Passed an examination for physical therapists approved by the State in which physical therapy services are provided.

(ii) On or before December 31, 2009—

(A) Graduated after successful completion of a physical therapy curriculum approved by the Commission on Accreditation in Physical Therapy Education (CAPTE); or

(B) Meets both of the following:

(1) Graduated after successful completion of an education program determined to be substantially equivalent to physical therapist entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or identified in 8 CFR 212.15(e) as it relates to physical therapists.

(2) Passed an examination for physical therapists approved by the State in which physical therapy services are provided.

(iii) Before January 1, 2008—

(A) Graduated from a physical therapy curriculum approved by one of the following:

(1) The American Physical Therapy Association.

(2) The Committee on Allied Health Education and Accreditation of the American Medical Association.

(3) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association.

(iv) On or before December 31, 1977 was licensed or qualified as a physical therapist and meets both of the following:

(A) Has 2 years of appropriate experience as a physical therapist.

(B) Has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(v) Before 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; and

(C) Graduated from a physical therapy curriculum in a 4-year college or university approved by a State department of education.

(vi) Before January 1, 1966 was licensed or registered, and before January 1, 1970, had 15 years of fulltime 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.

(vii) If trained outside the United States before January 1, 2008, meets the following requirements:

(A) Was graduated since 1928 from a physical therapy curriculum approved in the country in which the 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.

(8) Physical therapist assistant. A person who is licensed, registered or certified as a physical therapist assistant, if applicable, by the State in which practicing, unless licensure does not apply and meets one of the following requirements:

(i) Graduated from a physical therapist assistant curriculum approved by the Commission on Accreditation in Physical Therapy Education of the American Physical Therapy Association; or if educated outside the United States or

trained in the United States military, graduated from an education program determined to be substantially equivalent to physical therapist assistant entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or identified at 8 CFR 212.15(e); and

(ii) Passed a national examination for physical therapist assistants.

(A) On or before December 31, 2009, meets one of the following:

(1) Is licensed, or otherwise regulated in the State in which practicing.

(2) In States where licensure or other regulations do not apply, graduated before December 31, 2009, from a 2-year college-level program approved by the American Physical Therapy Association and after January 1, 2010, meets the requirements of paragraph (b)(8) of this section.

(3) Before January 1, 2008, where licensure or other regulation does not apply, graduated from a 2-year college level program approved by the American Physical Therapy Association.

(4) On or before December 31, 1977, was licensed or qualified as a physical therapist assistant and has achieved a satisfactory grade on a proficiency examination conducted,

approved, or sponsored by the U.S. Public Health Service.

(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) Registered nurse. A graduate of a school of professional nursing.

(2) Licensed practical nurse. A person who has completed a practical nursing program.

(d) Standard: Criminal background checks. (1) The hospice must obtain a criminal background check on all hospice employees who have direct patient contact or access to patient records. Hospice contracts must require that all contracted entities obtain criminal background checks on contracted employees who have direct patient contact or access to patient records.

(2) Criminal background checks must be obtained in accordance with State requirements. In the absence of State requirements, criminal background checks must be obtained within three months of the date of employment for all states that the individual has lived or worked in the past 3 years.

§418.116 Condition of participation: Compliance with Federal, State, and local laws and regulations related to the 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: Multiple locations. Every hospice must comply with the requirements of §420.206 of this chapter regarding disclosure of ownership and control information. All hospice multiple locations must be approved by Medicare and licensed in accordance with State licensure laws, if applicable, before providing Medicare reimbursed services.

(b) 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.

Subpart E [Removed and Reserved]

§418.200 [Amended]

5. Section 418.200 is amended by revising the reference "§418.58" to read "§418.56".

§418.202 [Amended]

6. 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".

CMS-3844-F

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare--Hospital Insurance; and Program No. 93.774, Medicare--Supplementary Medical Insurance Program)

Dated: _____

Kerry Weems,

Acting Administrator,

Centers for Medicare & Medicaid Services.

Approved:

Michael O. Leavitt,

Secretary.

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